

Literatura ACTA MEDICINAE 3/2022 Biologická a cílená léčba

- 3 **Baricitinib**
doc. MUDr. Lukáš Zlatohlávek, Ph.D. III. interní klinika 1. LF UK a VFN, Praha
PharmDr. Jan Miroslav Hartinger, Ph.D. Oddělení klinické farmakologie a farmacie, Farmakologický ústav 1. LF UK a VFN, Praha
- 3 **Levodopa-entakapon-karbidopa intestinální gel (LECIG) v léčbě Parkinsonovy nemoci**
MUDr. Martin Nevrly Neurologická klinika, FN a LF Univerzity Palackého, Olomouc
- 3 **SGLT2 inhibitory u nedíabetických onemocnění ledvin**
MUDr. Jan Vachek | prof. MUDr. Vladimír Tesař, DrSc., MBA Klinika nefrologie 1. LF UK a VFN, Praha
- 3 **Novinky v léčbě atypického hemolytico-uremického syndromu**
prof. MUDr. Romana Ryšavá, CSc. Klinika nefrologie, 1. LF UK a VFN, Praha
- 4 **Biologická léčba migrény – současnost a budoucnost**
MUDr. Petra Migálová Centrum pro diagnostiku a léčbu bolestí hlavy, Neurologická klinika FN Ostrava
- 4 **Současné možnosti biologické léčby astmatu v České republice**
doc. MUDr. Norbert Pauk, Ph.D. Klinika pneumologie 3. LF UK a FN Bulovka, pracoviště Národního centra pro těžké astma, Praha
- 4 **Dlouhodobé výsledky léčby baricitinibem v českém národním registru ATTRA**
prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha
Mgr. Lucie Nekvindová Institut biostatistiky a analýz, s. r. o., 1. LF UK, Praha
MVDr. Renata Rouhová Institut biostatistiky a analýz, Brno
- 4 **Mladý muž s koxartrózou a bolestmi zad – kazuistika**
MUDr. Monika Gregová, Ph.D. Revmatologický ústav, Klinika revmatologie 1. LF UK, Praha
- 5 **Přístupy k léčbě bolesti u pacientů s revmatoidní artritidou**
prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha
- 5 **Role interleukinu 6 v rozvoji anemie u revmatoidní artritidy**
prof. MUDr. Ladislav Šenolt, Ph.D. Revmatologický ústav, Praha
- 5 **Konec dobrý, všechno dobré? Kazuistiky pacientů se spondyloartritidami**
prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha
- 6 **Biologická léčba systémového lupus erythematoses**
MUDr. Martina Skácelová, Ph.D. | prof. MUDr. Pavel Horák, CSc. | MUDr. Jakub Videman
III. interní klinika – nefrologická, revmatologická a endokrinologická, FN a LF UP, Olomouc
- 6 **Subkutánní infliximab v léčbě zánětlivých revmatických onemocnění**
prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha
- 6 **Pět let zkušeností s Benepali v reálné klinické praxi**
prof. MUDr. Jiří Vencovský, DrSc. Revmatologický ústav, Praha
- 7 **Těžká forma chronické ložiskové psoriázy u 21letého pacienta úspěšně léčená secukinumabem – kazuistika**
MUDr. Jan Šternberský, Ph.D. | MUDr. Martin Tichý, Ph.D. Klinika chorob kožních a pohlavních FN a LF UP, Olomouc
- 7 **Guselkumab v terapii velmi těžké formy psoriázy – kazuistika**
MUDr. Jan Šternberský, Ph.D. Klinika chorob kožních a pohlavních FN a LF UP, Olomouc
- 7 **Generalizovaná psoriáza u polymorbidní pacientky v terapii guselkumabem – kazuistika**
MUDr. Martina Blažková Kožní oddělení, Nemocnice Jihlava
- 7 **Těžká forma psoriázy úspěšně léčená guselkumabem – kazuistika**
MUDr. Monika Hudymačová Dermatovenerologické oddělení Slezské nemocnice v Opavě, p. o.
- 7 **Biologická léčba mnohočetného myelomu v roce 2021**
prof. MUDr. Ivan Špička, CSc. I. interní klinika, klinika hematoonkologie, LF UK a VFN, Praha
- 8 **Venetoklax v léčbě akutní myeloidní leukemie**
MUDr. Zdeněk Koříštek, Ph.D. Klinika hematoonkologie, Fakultní nemocnice Ostrava

- 8 22. pražské hematologické dny – zpráva ze sympozia společnosti Pfizer: Management léčby přípravkem Mylotarg u pacientů s akutní myeloidní leukemií
- 8 Pokročilý endometriální karcinom a inovativní léčba
prof. MUDr. Jindřich Fínek, Ph.D. MHA Onkologická a radioterapeutická klinika FN a LF UK, Plzeň
- 8 Terapie časného HER2 pozitivního karcinomu prsu
doc. MUDr. Iveta Kolářová, Ph.D. Klinika onkologie a radioterapie, Fakultní nemocnice Hradec Králové
doc. MUDr. Jaroslav Vaňásek, CSc. Onkologické centrum Multiscan Pardubice
- 9 Metastatický triple negativní karcinom prsu – deprese začíná ustupovat
prof. MUDr. Petra Tesařová, CSc. Onkologická klinika 1. LF UK a Všeobecné fakultní nemocnice, Praha
- 9 Imunoterapie v první linii léčby nemalobuněčného karcinomu plic
MUDr. Leona Koubková Pneumologická klinika 2. LF UK a FN v Motole, Praha
- 10 Léčba karcinomu ledviny v roce 2022
doc. MUDr. Tomáš Büchler, Ph.D. Onkologická klinika 1. LF UK a Fakultní Thomayerovy nemocnice, Praha
- 10 Biosimilární bevacizumab v léčivém přípravku Oyavas 25 mg/ml koncentrát pro infuzní roztok
doc. MUDr. Jiří Slíva, Ph.D. Ústav farmakologie, 3. LF UK, Praha

Baricitinib

doc. MUDr. Lukáš Zlatohlávek, Ph.D. III. interní klinika 1. LF UK a VFN, Praha

PharmDr. Jan Miroslav Hartinger, Ph.D. Oddělení klinické farmakologie a farmacie, Farmakologický ústav 1. LF UK a VFN, Praha

- 1 Yamaoka, K. – Saharinen, P. – Pesu, M., et al.: The Janus kinases (Jaks). *Genome Biol.*, 2004, 5, s. 253.
- 2 Jorgensen, S. C. J. – Tse, C. L. Y. – Burry, L., et al.: Baricitinib: a review of pharmacology, safety, and emerging clinical experience in COVID-19. *Pharmacotherapy*, 2020, 40, s. 843–856.
- 3 Watowich, S. S.: The erythropoietin receptor. *J Investig Med*, 2011, 59, s. 1067–1072.
- 4 Yamaoka, K.: Janus kinase inhibitors for rheumatoid arthritis. *Curr Opin Clin Biol*, 2016, 32, s. 29–33.
- 5 Taylor, P. C. – Takeuchi, T. – Burmester, G. R., et al.: Safety of baricitinib for the treatment of rheumatoid arthritis over a median of 4.6 and up to 9.3 years of treatment: final results from long-term extension study and integrated database. *Ann Rheum Dis*, 2022, 81, s. 335–343.
- 6 Kalil, A. C. – Patterson, T. F. – Mehta, A. K., et al.: Baricitinib plus remdesivir for hospitalized adults with covid-19. *N Engl J Med*, 2021, 384, s. 795–807.
- 7 Loo, J. – Spittle, D. A. – Newnham, M.: COVID-19, immunothrombosis and venous thromboembolism: biological mechanisms. *Thorax*, 2021, 76, s. 412–420.
- 8 Marconi, V. C. – Ramanan, A. V. – de Bono, S., et al.: Efficacy and safety of baricitinib for the treatment of hospitalised adults with COVID-19 (COV-BARRIER): a randomised, double-blind, parallel-group, placebo-controlled phase 3 trial. *Lancet Respir Med*, 2021, 9, s. 1407–1418.
- 9 Plátna SPC uváděných přípravků. SÚKL.
- 10 Cantini, F. – Niccoli, L. – Nannini, C., et al.: Beneficial impact of baricitinib in COVID-19 moderate pneumonia; multicentre study. *J Infect*, 2020, 81, s. 647–679.
- 11 Rodriguez-Garcia, J. L. – Sanchez-Nievas, G. – Arevalo-Serrano, J., et al.: Baricitinib improves respiratory function in patients treated with corticosteroids for SARS-CoV-2 pneumonia: an observational cohort study. *Rheumatology*, 2021, 60, s. 399–407.
- 12 Pérez-Alba, E. – Nuzzolo-Shihadeh, L. – Aguirre-García, G. M., et al.: Baricitinib plus dexamethasone compared to dexamethasone for the treatment of severe COVID-19 pneumonia: A retrospective analysis. *J Microbiol Immunol Infect*, 2021, 54, s. 787–793.
- 13 Kmiotowicz, Z.: Covid-19: WHO recommends baricitinib and sotrovimab to treat patients. *BMJ*, 2022, 376, s. o97.
- 14 WHO Working Group on the Clinical Characterisation and Management of COVID-19 infection: A minimal common outcome measure set for COVID-19 clinical research. *Lancet Infect Dis*, 2020, 20, s. e192–e197.

Levodopa-entakapon-karbidopa intestinální gel (LECIG) v léčbě Parkinsonovy nemoci

MUDr. Martin Nevrly Neurologická klinika, FN a LF Univerzity Palackého, Olomouc

- 1 Antonini, A. – Poewe, W. – Chaudhuri, K. R., et al.: GLORIA study co-investigators. Levodopa-carbidopa intestinal gel in advanced Parkinson's: Final results of the GLORIA registry. *Parkinsonism Relat Disord*, 2017, 45, s. 13–20.
- 2 Fernandez, H. H. – Standaert, D. G. – Hauser, R. A., et al.: Levodopa-carbidopa intestinal gel in advanced Parkinson's disease: final 12-month, open-label results. *Mov Disord*, 2015, 30, s. 500–509.
- 3 Lang, A. E. – Rodriguez, R. L. – Boyd, J. T., et al.: Integrated safety of levodopa-carbidopa intestinal gel from prospective clinical trials. *Mov Disord*, 2016, 31, s. 538–546.
- 4 LeWitt, P. A.: Levodopa therapy for Parkinson's disease: Pharmacokinetics and pharmacodynamics. *Mov Disord*, 2015, 30, s. 64–72.
- 5 Liao, X. – Wu, N. – Liu, D., et al.: Levodopa/carbidopa/entacapone for the treatment of early Parkinson's disease: a meta-analysis. *Neuro Sci*, 2020, 41, s. 2045–2054.
- 6 Nyholm, D. – Johansson, A. – Lennernäs, H., et al.: Levodopa infusion combined with entacapone or tolcapone in Parkinson's disease: a pilot trial. *Eur J Neurol*, 2012, 19, s. 820–826.
- 7 Nyholm, D. – Nilsson Remahl, A. I. – Dizdar, N., et al.: Duodenal levodopa infusion monotherapy vs oral polypharmacy in advanced Parkinson's disease. *Neurology*, 2005, 64, s. 216–223.
- 8 Olanow, C. W. – Kieburtz, K. – Odin, P., et al.: LCG Horizon Study Group: Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study. *Lancet Neurol*, 2014, 13, s. 141–149.
- 9 Öthman, M. – Widman, E. – Nygren, I., et al.: Initial experience of the levodopa-entacapone-carbidopa intestinal gel in clinical practice. *J Pers Med*, 2021, 11, s. 254.
- 10 Senek, M. – Nielsen, E. I. – Nyholm, D.: Levodopa-entacapone-carbidopa intestinal gel in Parkinson's disease: A randomized crossover study. *Mov Disord*, 2017, 32, s. 283–286.
- 11 Senek, M. – Nyholm, D. – Nielsen, E. I.: Population pharmacokinetics of levodopa gel infusion in Parkinson's disease: effects of entacapone infusion and genetic polymorphism. *Sci Rep*, 2020, 10, s. 18057.

SGLT2 inhibitory u nedíabetických onemocnění ledvin

MUDr. Jan Vachek | prof. MUDr. Vladimír Tesař, DrSc., MBA Klinika nefrologie 1. LF UK a VFN, Praha

- 1 Heerspink, H. J. L. – Stefansson, B. V. – Correa-Rotter, R., et al.: Dapagliflozin in patients with chronic kidney disease. *N Engl J Med*, 2020, 383, s. 1436–1446.
- 2 Wiviott, S. D. – Raz, I. – Bonaca, M. P., et al.: Dapagliflozin and cardiovascular outcomes in type 2 diabetes. *N Engl J Med*, 2019, 380, s. 347–357.
- 3 Perkovic, V. – Jardine, M. J. – Neal, B., et al.: Canaglifllozin and renal outcomes in type 2 diabetes and nephropathy. *N Engl J Med*, 2019, 380, s. 2295–2306.
- 4 Neuen, B. L. – Jardine, M. J. – Perkovic, V.: Sodium-glucose cotransporter 2 inhibition: which patient with chronic kidney disease should be treated in the future. *Nephrol Dial Transplant*, 2020, suppl. 1, s. i48–i55.
- 5 Heerspink, H. J. L. – Jongs, N. – Chertow, G. M., et al.: Effect of dapagliflozin on the rate of decline in kidney function in patients with chronic kidney disease with and without type 2 diabetes: a pre-specified analysis from the DAPA-CKD trial. *Lancet Diabetes Endocrinol*, 2021, 9, s. 743–754.
- 6 Wheeler, D. – Toto, R. D. – Stefansson, B. V., et al.: A pre-specified analysis of the DAPA-CKD trial demonstrates the effects of dapagliflozin on major adverse kidney events in patients with IgA nephropathy. *Kidney Int*, 2021, 100, s. 215–224.
- 7 Parving, H.-H. – Lehnert, H. – Brochner-Mortensen, J., et al.: The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. *N Engl J Med*, 2001, 345, s. 870–878.
- 8 Heerspink, H. J. L. – Parving, H.-H. – Andress, D. L., et al.: Atrasentan and renal events in patients with type 2 diabetes and chronic kidney disease (SONAR): a double-blind, randomised, placebo-controlled trial. *Lancet*, 2019, 393, s. 1937–1947.
- 9 Bakris, G. L. – Agarwal, R. – Anker, S. D., et al.: Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. *N Engl J Med*, 2020, 383, s. 2219–2229.
- 10 No authors listed. Randomised placebo-controlled trial of effect of ramipril on decline in glomerular filtration rate and risk of terminal renal failure in proteinuric, non-diabetic nephropathy. The GISEN Group (Gruppo Italiano di Studi Epidemiologici in Nefrologia). *Lancet*, 1997, 349, s. 1857–1863.
- 11 Fried, L. F. – Emanuele, N. – Zhang, J. H., et al.: Combined angiotensin inhibition for the treatment of diabetic nephropathy. *N Engl J Med*, 2013, 369, s. 1892–1903.
- 12 Parving, H. H. – Brenner, B. M. – McMurray, J. J., et al.: Cardiorenal endpoints in a trial of aliskiren for type 2 diabetes. *N Engl J Med*, 2012, 367, s. 2204–2213.
- 13 Herrington, W. G. – Preiss, D. – Haynes, R., et al.: The potential for improving cardio-renal outcomes by sodium-glucose co-transporter-2 inhibition in people with chronic kidney disease: a rationale for the EMPA-KIDNEY. *Clin Kidney J*, 2018, 11, s. 749–761.
- 14 KDIGO Diabetes Work Group: KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney Int*, 2020, 98, s. 51–515.
- 15 Rauen, T. – Eitner, F. – Fitzner, C., et al.: Intensive supportive care plus immunosuppression in IgA nephropathy. *N Engl J Med*, 2015, 373, s. 2225–2236.
- 16 Barratt, J. – Floege, J.: SGLT-2 inhibition in IgA nephropathy: the new standard of care? *Kidney Int*, 2021, 50085–2538(21)00385–9, doi: 10.1016/j.kint.2021.04.002.
- 17 McDonagh, T. A. – Metra, M. – Adamo, M., et al.: 2021 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure: Developed by the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure of the European Society of Cardiology (ESC) With the Special Contribution of the Heart Failure Association (HFA) of the ESC. *Eur Heart J*, 2021, 42, s. 3599–3726, dostupné z: <https://doi.org/10.1093/euroheartj/ehab368>, vyhledáno 23. 3. 2022.

Novinky v léčbě atypického hemolyticko-uremického syndromu

prof. MUDr. Romana Ryšavá, CSc. Klinika nefrologie, 1. LF UK a VFN, Praha

- 1 Fakhouri, F. – Zuber, J. – Frémeaux-Bacchi, V., et al.: Haemolytic uraemic syndrome. *Lancet*, 2017, 390, s. 681–696.
- 2 Goodship, T. H. J. – Cook, T. H. – Fakhouri, F., et al.: Atypical hemolytic uremic syndrome and C3 glomerulopathy: conclusions from a, Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int*, 2017, 91, s. 539–551.
- 3 Loirat, Ch. – Fakhouri, F. – Ariceta, G., et al.: An international consensus approach to the management of atypical hemolytic uremic syndrome in children. *Pediatr Nephrol*, 2016, 31, s. 15–39.
- 4 Caprioli, J. – Noris, M. – Brioshi, S., et al.: Genetics of HUS: the impact of MCP, CFH, and IF mutations on clinical presentation, response to treatment, and outcome. *Blood*, 2006, 108, s. 1267–1279.
- 5 Fremeaux-Bacchi, V. – Fakhouri, F. – Garnier, A., et al.: Genetics and outcome of atypical hemolytic uremic syndrome: a nationwide French series comparing children and adults. *Clin J Am Soc Nephrol*, 2013, 8, s. 554–562.
- 6 Keating, G. M.: Eculizumab: a review of its use in atypical haemolytic uremic syndrome. *Drugs*, 2013, 73, s. 2053–2066.
- 7 Legendre, C. M. – Licht, C. – Muus, P., et al.: Terminal complement inhibitor eculizumab in atypical hemolytic-uremic syndrome. *N Engl J Med*, 2013, 368, s. 2169–2181.
- 8 Loirat, Ch. – Fremeaux-Bacchi, V.: Hemolytic uremic syndrome recurrence after renal transplantation. *Pediatr Transplant*, 2008, 12, s. 619–629.
- 9 Licht, Ch. – Greenbaum, L. A. – Muus, P., et al.: Efficacy and safety of eculizumab in atypical hemolytic uremic syndrome from 2-year extensions of phase 2 studies. *Kidney Int*, 2015, 87, s. 1061–1073.
- 10 Wijnsma, K. L. – Duineveld, C. – Wetzel, J. F. M., et al.: Eculizumab in hemolytic uremic syndrome: strategies to ward restrictive use. *Pediatr Nephrol*, 2019, 34, s. 2261–2277.
- 11 Walle, J. V. – Delmas, Y. – Ardissino, G., et al.: Improved renal recovery in patients with atypical hemolytic uremic syndrome following rapid initiation of eculizumab treatment. *J Nephrol*, 2017, 30, s. 127–134.
- 12 Ardissino, G. – Testa, S. – Possenti, I., et al.: Discontinuation of eculizumab maintenance treatment for atypical hemolytic uremic syndrome: a report of 10 cases. *Am J Kidney Dis*, 2014, 64, s. 633–637.

- 13 Fakhouri, F. – Fila, M. – Provost, F., et al.: Pathogenic variants in complement genes and risk of atypical hemolytic syndrome relapse after eculizumab discontinuation. *Clin J Am Soc Nephrol*, 2017, 12, s. 50–59.
- 14 Macia, M. – de Alvaro Moreno, F. – Dutt, T., et al.: Current evidence on the discontinuation of eculizumab in patients with atypical haemolytic uraemic syndrome. *Clin Kidney J*, 2017, 10, s. 310–319.
- 15 Olson, S. R. – Lu, E. – Sulpizio, E., et al.: When to stop eculizumab in complement-mediated thrombotic microangiopathies. *Am J Nephrol*, 2018, 48, s. 96–107.
- 16 Caverio, T. – Rabasco, C. – López, A., et al.: Eculizumab in secondary atypical haemolytic uraemic syndrome. *Nephrol Dial Transplant*, 2017, 32, s. 466–474.
- 17 Caravaca-Fontan, F. – Praga, M.: Complement inhibitors are useful in secondary hemolytic uraemic syndromes. *Kidney Int*, 2019, 96, s. 826–835.
- 18 Rondeau, E. – Scully, M. – Ariceta, G., et al.: The long-acting C5 inhibitor, ravulizumab, is effective and safe in adult patients with atypical hemolytic uraemic syndrome naïve to complement inhibitor treatment. *Kidney Int*, 2020, 97, s. 1287–1296.
- 19 Fakhouri, F. – Hourmant, M. – Campistol, J. M., et al.: Terminal complement inhibitor eculizumab in adult patients with atypical hemolytic uraemic syndrome: a single-arm, open-label trial. *Am J Kidney Dis*, 2016, 68, s. 84–93.
- 20 Ariceta, G. – Dixon, B. P. – Kim, S. H., et al.: The long-acting C5 inhibitor, ravulizumab, is effective and safe in pediatric patients with atypical hemolytic uraemic syndrome naïve to complement inhibitor treatment. *Kidney Int*, 2021, 100, s. 225–237.
- 21 Syed, Y. Y.: Ravulizumab: A review in atypical haemolytic uraemic syndrome. *Drugs*, 2021, 81, s. 587–594.

Biologická léčba migrény – současnost a budoucnost

MUDr. Petra Migáčová Centrum pro diagnostiku a léčbu bolestí hlavy, Neurologická klinika FN Ostrava

- 1 Steiner, T. J. – Stovner, L. J. – Vos, T.: GBT 2015: migraine is the third cause of disability in under 50s. *J Headache Pain*, 2016, 17, s. 104.
- 2 Doležil, D.: Poster IHc, Dublin, 2019.
- 3 Kotas, R.: *Bolesti hlavy v klinické praxi*. Praha, Maxdorf, 2015.
- 4 Goadsby, P. J. – Edvinsson, L. – Ekman, R.: Vasoactive peptide release in the extra cerebral circulation of humans during migraine headache. *Ann Neurol*, 1990, 28, s. 183–187.
- 5 Edvinsson, L.: The CGRP pathway in migraine as a viable target for therapies. *Headache*, 2018, 58, suppl. 1, s. 33–47.
- 6 Hargreaves, R. – Olesen, J.: Calcitonin gene-related peptide modulators – the history and renaissance of new migraine drug class. *Headache*, 2019, 59, s. 951–970.
- 7 Tumová, I.: Predstavujú CGRP monoklonálne protilátky pokrok v profilaxi migrény? *Prakt Lekár*, 2020, 10, s. 7–12.
- 8 Tepper, D.: Headache tool box. *J Headache Pain*, 2020, s. 1037–1039.
- 9 Bigal, M. E., et al.: Calcitonin gene-related peptide (CGRP) and migraine current understanding and state of development. *Headache*, 2013, 53, s. 1230–1244.
- 10 Raddant, A. C. – Russo, A. F.: Calcitonin gene-related peptide in migraine: intersection of peripheral inflammation and central modulation. *Expert Rev Mol Med*, 2011, 13, s. e36.
- 11 Pellesi, L. – Guerzoni, S. – Pini, L. A.: Spotlight on anti-CGRP monoclonal antibodies in migraine: the clinical evidence to date. *Clin Pharmacol Drug Dev*, 2017, 6, s. 534–547.

Současné možnosti biologické léčby astmatu v České republice

doc. MUDr. Norbert Pauk, Ph.D. Klinika pneumologie 3. LF UK a FN Bulovka, pracoviště Národního centra pro těžké astma, Praha

1 GINA (Global Initiative for Asthma). Global Strategy for Asthma Management and Prevention, 2021. Dostupné z: <http://www.ginasthma.org>.

Dlouhodobé výsledky léčby baricitinibem v českém národním registru ATTRA

prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha

Mgr. Lucie Nekvindová Institut biostatistiky a analýz, s. r. o., 1. LF UK, Praha

MVDr. Renata Rouhová Institut biostatistiky a analýz, Brno

- 1 Smolen, J., et al.: Proposal for a new nomenclature of disease modifying antirheumatic drugs. *Ann Rheum Dis*, 2014, 73, s. 3–5.
- 2 Furst, D., et al.: Updated consensus statement on biological agents for the treatment of rheumatic diseases. *Ann Rheum Dis*, 2013, 72, s. ii2–ii34.
- 3 Walker, J. G. – Smith, M. D.: The Jak-STAT pathway in rheumatoid arthritis. *J Rheumatol*, 2005, 32, s. 1650–1653.
- 4 Angelini, J. – Tallota, R. – Roncato, R., et al.: JAK-Inhibitors for the treatment of rheumatoid arthritis: A focus on the present and an outlook on the future. *Biomolecules*, 2020, 10, s. 1002.
- 5 Smolen, J. S. – Aletaha, D. – Bijlsma, J. W., et al.: Treating rheumatoid arthritis to target: Recommendation of an international task force. *Ann Rheum Dis*, 2010, 69, s. 631–637.
- 6 Smolen, J. – Landewe, R. B. M. – Bijlsma, J. W. K., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs, 2019 update. *Ann Rheum Dis*, 2020, 79, s. 685–699.
- 7 Singh, J. A. – Saag, K. G. – Bridges, S. L., et al.: 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*, 2016, 68, s. 1–26.
- 8 Šenolt, L. – Mann, H. – Závada, J. – Pavelka, K. – Vencovský, J.: Doporučení České revmatologické společnosti pro farmakoterapii revmatoidní artritidy 2017. *Česká revmatologie*, 2017, 1, s. 8–24.
- 9 Smolen, J., et al.: Consensus statement on blocking the effects of interleukin 6 and in particular by interleukin 6 receptor inhibition in rheumatoid arthritis and other inflammatory conditions. *Ann Rheum Dis*, 2013, 72, s. 482–492.
- 10 Nash, P. – Kerschbaumer, A. – Dörner, T., et al.: Points to consider for the treatment of immune-mediated inflammatory diseases with Janus kinase inhibitors: a consensus statement. *Ann Rheum Dis*, 2021, 80, s. 71–87.
- 11 Pavelka, K. – Kříšková, Z. – Dušek, L.: Národní registr biologické a cílené léčby revmatických onemocnění ATTRA – 20leté zkušenosti. *Česká revmatologie*, 2020, 28, s. 120–130.
- 12 Lauper, K. – Mongin, D. – Bergstra, S. A., et al.: Heterogeneity in the pattern of use of JAK-inhibitors between countries participating in an international collaboration of registers of rheumatoid arthritis (the JAK-pot Study) patients. *Arthritis Rheumatol*, 2019, 71, suppl.
- 13 Fleischmann, R. – Schiff, M. – van der Heijde, D., et al.: Baricitinib, methotrexate, or combination in patients with rheumatoid arthritis and no or limited prior disease-modifying antirheumatic drug treatment. *Arthritis Rheum*, 2017, 69, s. 506–517.
- 14 Genovese, M. C. – Kremer, J. – Zamani, O., et al.: Baricitinib in patients with refractory rheumatoid arthritis. *N Engl J Med*, 2016, 374, s. 1243–1252.
- 15 Dougados, M. – van der Heijde, D. – Chen, Y. C., et al.: Baricitinib in patients with inadequate response or intolerance to conventional synthetic DMARDs: results from the RA-BUILD study. *Ann Rheum Dis*, 2017, 76, s. 88–95.
- 16 Smolen, J. S. – Kremer, J. M. – Gaich, C. L., et al.: Patient-reported outcomes from a randomised phase III study of baricitinib in patients with rheumatoid arthritis and an inadequate response to biological agents (RA-BEACON). *Ann Rheum Dis*, 2017, 76, s. 694–700.
- 17 Takahashi, N. – Asai, S. – Kobayakawa, T., et al.: Predictors for clinical effectiveness of baricitinib in rheumatoid arthritis patients in routine clinical practice: data from a Japanese multicenter registry. *Sci Rep*, 2020, 10, s. 21907, doi: 10.1038/s41598-020-7925-8.
- 18 Pavelka, K. – Kříšková, Z. – Nekvindová, L.: Terapie revmatoidní artritidy etanerceptem je učinnější u pacientů se střední než vysokou aktivitou nemoci. *Acta Medicinae*, 2021, 10, s. 18–23.
- 19 Pavelka, K. – Kříšková, Z. – Nekvindová, L.: Baricitinib v léčbě revmatoidní artritidy v běžné klinické praxi – výsledky z Českého národního registru ATTRA. *Česká Revmatologie*, 2021, 29, s. 133–143.
- 20 Miyazaki, Y., et al.: Efficacy and safety of tofacitinib versus baricitinib in patients with RA in real clinical practice. *Ann Rheum Dis*, 2021, 80, s. 1130–1136.

Mladý muž s koxartrózou a bolestmi zad – kazuistika

MUDr. Monika Gregová, Ph.D. Revmatologický ústav, Klinika revmatologie 1. LF UK, Praha

- 1 Zeidler, H., et al.: A historical perspective of spondyloarthritis. *Curr Opin Rheumatol*, 2011, 23, s. 327–333.
- 2 Rudwaleit, M., et al.: The development of Assessment of SpondyloArthritis International Society classification criteria for axial spondyloarthritis (part II): validation and final selection. *Ann Rheum Dis*, 2009, 68, s. 777–783.
- 3 Robinson, P. C., et al.: Axial spondyloarthritis: concept, construct, classification and implications for therapy. *Nat Rev Rheumatol*, 2020, 17, s. 109–118.
- 4 Van Praet, L., et al.: Microscopic gut inflammation in axial spondyloarthritis: a multiparametric predictive model. *Ann Rheum Dis*, 2013, 72, s. 414–417.
- 5 Stolwijk, C., et al.: The epidemiology of extra-articular manifestations in ankylosing spondylitis: a population-based matched cohort study. *Ann Rheum Dis*, 2015, 74, s. 1373.
- 6 Perez, A., et al.: Differential features between primary ankylosing spondylitis and spondylitis associated with psoriasis and inflammatory bowel disease. *J Rheumatol*, 2011, 38, s. 1656–1660.
- 7 Kim, D. Y., et al.: Progressive pulmonary fibrocystic changes of both upper lungs in a patient with ankylosing spondylitis. *Tuberc Respir Dis*, 2015, 78, s. 459.
- 8 Berdal, G., et al.: Restrictive pulmonary function is more prevalent in patients with ankylosing spondylitis than in matched population controls and is associated with impaired spinal mobility: a comparative study. *Arthritis Res Ther*, 2012, 14, s. R19.
- 9 Vander, B. C., et al.: Hip involvement in ankylosing spondylitis: epidemiology and risk factors associated with hip replacement surgery. *Rheumatology*, 2010, 49, s. 73–81.
- 10 Baraliakos, A., et al.: Hip involvement in ankylosing spondylitis: what is the verdict? *Rheumatology*, 2010, 49, s. 3–4.
- 11 López-Medina, et al.: Prevalence and distribution of peripheral musculoskeletal manifestations in spondyloarthritis including psoriatic arthritis: results of worldwide, cross-sectional ASAS-PerSpA study. *RMD Open*, 2021, 7, s. e001450.
- 12 Schett, G., et al.: Tumor necrosis factor blockers and structural remodeling in ankylosing spondylitis: what is reality and what is fiction? *Ann Rheum Dis*, 2007, 66, s. 709–721.
- 13 D’Agostino, M. A.: Ultrasound imaging in spondyloarthropathies. *Curr Opin Rheumatol*, 2012, 24, s. 375–379.
- 14 Carron, P., et al.: Anti-TNF-induced remission in very early peripheral spondyloarthritis: the CRESPA study. *Ann Rheum Dis*, 2017, 76, s. 1389–1395.
- 15 Ward, M. M., et al.: 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*, 2019, 71, s. 1599–1613.
- 16 Wink, F., et al.: High prevalence of hip involvement and decrease in inflammatory ultrasound lesions during tumor necrosis factor-a blocking therapy in ankylosing spondylitis. *Rheumatology*, 2019, 58, s. 1040–1046.

- 18 Huang, Z.-X., et al.: Magnetic resonance imaging in ankylosing spondylitis: reduction of active sacroiliitis and hip arthritis during treatment with an adalimumab biosimilar. *Clin Rheumatol*, 2021, 40, s. 2099–2101.
- 19 Rocha, F. A. C., et al.: Tumor necrosis factor inhibitors prevent structural damage in hips in ankylosing spondylitis – time to reconsider treatment guidelines? A case series and review of literature. *Clin Rheumatol*, 2021, 40, s. 1881–1887.
- 20 Nystad, T. W., et al.: Hip replacement surgery in patients with ankylosing spondylitis. *Ann Rheum Dis*, 2014, 73, s. 1194–1197.
- 21 López-Medina, C., et al.: Hip and shoulder involvement and their management in axial spondyloarthritis: a current review. *Curr Rheumatol Rep*, 2020, 22, s. 53.

Přístupy k léčbě bolesti u pacientů s revmatoidní artritidou

prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha

- 1 Radner, H. – Smolen, J. S. – Aletaha, D.: Remission in rheumatoid arthritis: benefit over low disease activity in patient-reported outcomes and costs. *Arthritis Res Ther*, 2014, 16, R56, <https://doi.org/10.1186/ar4491>.
- 2 Smolen, J. S. – Aletaha, D. – McInnes, I. B.: Rheumatoid arthritis. *Lancet*, 2016, 388, s. 2023–2038.
- 3 Salaffi, F. – Giacobazzi, G. – Di Carlo, M.: Chronic pain in inflammatory arthritis: mechanisms, metronome, and emerging targets—a focus on the JAK-STAT pathway. *Pain Research and Management*, 2018, článek ID 8564215, <https://doi.org/10.1155/2018/8564215>.
- 4 Durán, J. – Combe, B. – Niu, J., et al.: The effect on treatment response of fibromyalgic symptoms in early rheumatoid arthritis patients: results from the ESPOIR cohort. *Rheumatology*, 2015, 54, s. 2166–2170.
- 5 Olofsson, T. – Petersson, I. F. – Eriksson, J. K., et al.: ARTIS Study Group: Predictors of work disability after start of anti-TNF therapy in a national cohort of Swedish patients with rheumatoid arthritis: does early anti-TNF therapy bring patients back to work? *Ann Rheum Dis*, 2017, 76, s. 1245–1252.
- 6 Vergne-Salle, P. – Pouplin, S. – Trouvin, A. P., et al.: The burden of pain in rheumatoid arthritis: Impact of disease activity and psychological factors. *Eur J Pain*, 2020, 24, s. 1979–1989.
- 7 O’Shea, J. J. – Schwartz, D. M. – Villarino, A. V., et al.: JAK-STAT pathway impact on human disease and therapeutic intervention. *Ann Rev Med*, 2015, 66, s. 311–328.
- 8 Nash, P. – Kershbaumer, A. – Dorner, T., et al.: Points to consider for the treatment immune mediated inflammatory diseases with Janus kinase inhibitors: a consensus statement. *Ann Rheum Dis*, 2021, 80, s. 71–87.
- 9 Domingues, E. – Mauborgne, A. – Mallet, J. – Desclaux, M.: SOCS3-mediated blockade of JAK/STAT3 signaling pathway reveals its major contribution to spinal cord neuroinflammation and mechanical allodynia after peripheral nerve injury. *J Neuroscience*, 2010, 30, s. 5754–5766.
- 10 van Vollenhoven, R. – Takeuchi, T. – Pangan, A. L., et al.: Efficacy and safety of upadacitinib monotherapy in methotrexate naïve patients with moderately to severely active rheumatoid arthritis (SELECT-EARLY): A multicenter, multi-country, randomized, double-blind, active comparator – controlled trial. *Arthritis Rheumatol*, 2020, 72, s. 1607–1620.
- 11 Fleischmann, R. – Pangan, A. L. – Song, I. H., et al.: Upadacitinib versus placebo or adalimumab in patients with rheumatoid arthritis and an inadequate response to methotrexate: results of phase 3, double-blind, randomized controlled trial. *Arthritis Rheumatol*, 2019, 71, s. 1788–1800.
- 12 Smolen, J. S. – Pangan, A. L. – Emery, P., et al.: Upadacitinib as monotherapy in patients with active rheumatoid arthritis and inadequate response to methotrexate (SELECT-MONOTHERAPY): a randomised, placebo-controlled, double-blind phase 3 study. *Lancet*, 2019, 393, s. 2303–2311.
- 13 Burmester, G. R. – Kremer, J. M. – van den Bosch, F., et al.: Safety and efficacy of upadacitinib in patients with rheumatoid arthritis and inadequate response to conventional synthetic disease-modifying antirheumatic drugs (SELECT-NEXT): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*, 2018, 391, s. 2503–2512.
- 14 Genovese, M. C. – Fleischmann, R. – Combe, B., et al.: Safety and efficacy of upadacitinib in patients with active rheumatoid arthritis refractory to biologic disease-modifying antirheumatic drugs (SELECT-BEYOND): a double-blind, randomised controlled phase 3 trial. *Lancet*, 2018, 391, s. 2513–2524.
- 15 Geenen, R. – Overman, C. L. – Christensen, R., et al.: EULAR recommendations for the health professionals approach to pain management in inflammatory arthritis and osteoarthritis. *Ann Rheum Dis*, 2018, 77, s. 797–807.
- 16 Iannazzo, S. – Furneri, G. – Demma, F., et al.: The burden of rheumatic diseases: an analysis of an Italian Administrative Database. *Rheumatol Ther*, 2016, 3, s. 167–177.
- 17 Roubille, I. – Richer, V. – Starnino, T., et al.: The effect of anti-TNF, MTX and NSAID and glucocorticoids on cardiovascular events in RA, PsA and psoriasis, systematic review and meta-analysis. *Ann Rheum Dis*, 2015, 74, s. 480–489.
- 18 Curtis, J. R. – Xie, F. – Smith, C., et al.: Changing trends in opioid use among patients with rheumatoid arthritis in the United States. *Arthritis Rheumatol*, 2017, 69, s. 1733–1740.
- 19 Black, R. J. – Richards, B. – Lester, S., et al.: Factors associated with commencing and ceasing opioid therapy in patients with rheumatoid arthritis. *Semin Arthritis Rheum*, 2019, 49, s. 351–357.
- 20 Buttigereit, F. – Burmester, G. R. – Straub, R. H., et al.: Exogenous and endogenous glucocorticoids in rheumatic diseases. *Arthritis Rheum*, 2011, 63, s. 1–9.
- 21 Smolen, J. – Landewé, R. – Bijlsma, J., et al.: EULAR recommendations for the management of RA with systemic and biological disease modifying antirheumatic drugs, 2016 update. *Ann Rheum Dis*, 2017, 76, s. 960–977.
- 22 Combe, B. – Buttigereit, F. – Östör, A., et al.: Impact of concomitant glucocorticoids on the clinical efficacy and safety of upadacitinib in patients with rheumatoid arthritis: an ad hoc analysis of data from three phase 3 studies [abstract]. *Arthritis Rheumatol*, 2020, 72, suppl. 10.
- 23 Charles-Schoeman, C. – van der Heijde, D., et al.: Effect of glucocorticoids on the clinical and radiographic efficacy of tofacitinib in patients with rheumatoid arthritis: a posthoc analysis of data from 6 phase III studies. *J Rheumatol*, 2018, 45, s. 177–187.
- 24 Fleischmann, R., et al.: Poster THU0201 prezentovaný na EULAR 2020.

Role interleukinu 6 v rozvoji anemie u revmatoidní artritidy

prof. MUDr. Ladislav Šenolt, Ph.D. Revmatologický ústav, Praha

- 1 Šenolt, L.: Revmatoidní artrida. *Vnitr Lek*, 2018, 64, s. 98–106.
- 2 Figu, F. A. – Piga, M. – Azzolini, I., et al.: Rheumatoid arthritis: Extra-articular manifestations and comorbidities. *Autoimmun Rev*, 2021, 20, s. 102776.
- 3 Masson, C.: Rheumatoid anemia. *Joint Bone Spine*, 2011, 78, s. 131–137.
- 4 Weiss, G. – Goodnough, L. T.: Anemia of chronic disease. *N Engl J Med*, 2005, 352, s. 1011–1023.
- 5 Weiss, G. – Ganz, T. – Goodnough, L. T.: Anemia of inflammation. *Blood*, 2019, 133, s. 40–50.
- 6 Ganz, T. – Nemeth, E.: Iron sequestration and anemia of inflammation. *Semin Hematol*, 2009, 46, s. 387–393.
- 7 Raj, D. S.: Role of interleukin-6 in the anemia of chronic disease. *Semin Arthritis Rheum*, 2009, 38, s. 382–388.
- 8 Fleming, R. E. – Sly, W. S.: Hepcidin: a putative iron-regulatory hormone relevant to hereditary hemochromatosis and the anemia of chronic disease. *Proc Natl Acad Sci USA*, 2001, 98, s. 8160–8162.
- 9 Nairz, M. – Haschka, D. – Demetz, E., et al.: Iron at the interface of immunity and infection. *Front Pharmacol*, 2014, 5, s. 152.
- 10 Choy, E. H. – De Benedetti, F. – Takeuchi, T., et al.: Translating IL-6 biology into effective treatments. *Nat Rev Rheumatol*, 2020, 16, s. 335–345.
- 11 Madhok, R. – Crilly, A. – Watson, J., et al.: Serum interleukin 6 levels in rheumatoid arthritis: correlations with clinical and laboratory indices of disease activity. *Ann Rheum Dis*, 1993, 52, s. 232–234.
- 12 Nemeth, E. – Rivera, S. – Gabayan, V., et al.: IL-6 mediates hypoferremia of inflammation by inducing the synthesis of the iron regulatory hormone hepcidin. *J Clin Invest*, 2004, 113, s. 1271–1276.
- 13 Voulgaris, P. V. – Kolios, G. – Papadopoulos, G. K., et al.: Role of cytokines in the pathogenesis of anemia of chronic disease in rheumatoid arthritis. *Clin Immunol*, 1999, 92, s. 153–160.
- 14 Doyle, M. K. – Rahman, M. U. – Han, C., et al.: Treatment with infliximab plus methotrexate improves anemia in patients with rheumatoid arthritis independent of improvement in other clinical outcome measures – a pooled analysis from three large, multicenter, double-blind, randomized clinical trials. *Semin Arthritis Rheum*, 2008, 39, s. 123–131.
- 15 Aly, A. M. – Furst, D. E.: Update of sarilumab to treat rheumatoid arthritis based on randomized clinical trials: a systematic review. *Expert Rev Clin Immunol*, 2017, 13, s. 741–752.
- 16 Genovese, M. C. – Fleischmann, R. – Kivitz, A. J., et al.: Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a phase III study. *Arthritis Rheumatol*, 2015, 67, s. 1424–1437.
- 17 Burmester, G. R. – Lin, Y. – Patel, R., et al.: Efficacy and safety of sarilumab monotherapy versus adalimumab monotherapy for the treatment of patients with active rheumatoid arthritis (MONARCH): a randomised, double-blind, parallel-group phase III trial. *Ann Rheum Dis*, 2017, 76, s. 840–847.

Konec dobrý, všechno dobré? Kazuistiky pacientů se spondyloartritidami

prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha

- 1 van der Heijde, D. – Ramiro, S. – Landewé, R., et al.: 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*, 2017, 76, s. 978–991.
- 2 Rudwaleit, M. – van der Heijde, D. – Landewé, R.: Development of ASAS for axial spondyloarthritis, validation and final section. *Ann Rheum Dis*, 2009, 68, s. 777–783.
- 3 Rudwaleit, M. – van der Heijde, D. – Landewé, R., et al.: The Assessment of SpondyloArthritis International Society classification criteria for peripheral spondyloarthritis and for spondyloarthritis in general. *Ann Rheum Dis*, 2011, 70, s. 25–31.
- 4 Šenolt, L. – Závada, J. – Mann, H., et al.: Doporučení diagnostické a terapeutické postupy pro všeobecné lékaře. Novelize 2021. *Revmatologie*. Centrum doporučených postupů pro praktické lékaře. Praha, SVP, 2021.
- 5 Poddubnyj, D. – Listing, J. – Haibel, H., et al.: Functional relevance of radiographic spinal progression in axial spondyloarthritis: results from German Spondyloarthritis Inception Cohort. *Rheumatology*, 2018, 57, s. 703–711.
- 6 Smolen, J. – Schols, M. – Barun, J., et al.: Treating axial spondyloarthritis and peripheral spondyloarthritis especially psoriatic arthritis to target: 2017 update of recommendations by international task force. *Ann Rheum Dis*, 2018, 77, s. 3–17.
- 7 Pavelka, K., a Výbor české revmatologické společnosti: Doporučení České revmatologické společnosti pro farmakologickou léčbu axiálních spondyloartritid. *Česká revmatologie*, 2021, 1, s. 5–19.
- 8 Lie, E. – van der Heijde, D. – Uhlig, T., et al.: Effectiveness of switching between TNF inhibitors in ankylosing spondylitis: data from nor DMARD register. *Ann Rheum Dis*, 2011, 70, s. 157–163.
- 9 Harrisen, M. J., et al.: Rates of new-onset psoriasis in patients with rheumatoid arthritis receiving anti-tumor necrosis factor alpha therapy. Results from British Society of Rheumatology biologics registers. *Ann Rheum Dis*, 2009, 68, s. 209–215.
- 10 Emery, P., et al.: Long-term efficacy and safety in patients with rheumatoid arthritis continuing reference etanercept to SB4. *Ann Rheum Dis*, 2017, 76, s. 1986–1991.

Biologická léčba systémového lupus erythematoses

MUDr. Martina Skácelová, Ph.D. | prof. MUDr. Pavel Horák, CSc. | MUDr. Jakub Videman

III. interní klinika – nefrologická, revmatologická a endokrinologická, FN a LF UP, Olomouc

- 1 Fanouriakis, A. – Kostopoulou, M. – Alunno, A., et al.: 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis*, 2019, 78, s. 736–745.
- 2 Fanouriakis, A. – Kostopoulou, M. – Cheema, K., et al.: 2019 Update of the Joint European League Against Rheumatism and European Renal Association–European Dialysis and Transplant Association (EULAR/ERA–EDTA) recommendations for the management of lupus nephritis. *Ann Rheum Dis*, 2020, 79, s. 713–723.
- 3 Horák, P. – Tegzová, D. – Závada, J., et al.: Doporučení ČRS pro léčbu nemocných se SLE. *Čes Revmatol*, 2013, 21, s. 110–122.
- 4 Navarra, S. V. – Guzmán, R. M. – Gallacher, A. E., et al.: BLISS-52 Study Group. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomised, placebo-controlled, phase 3 trial. *Lancet*, 2011, 377, s. 721–731.
- 5 Furie, R. – Petri, M. – Zamani, O., et al.: A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. BLISS-76 Study Group. *Arthritis Rheum*, 2011, 63, s. 3918–3930.
- 6 Wallace, D. J. – Ginzler, E. M. – Merrill, J. T., et al.: Safety and efficacy of belimumab plus standard therapy for up to thirteen years in patients with systemic lupus erythematosus. *Arthritis Rheumatol*, 2019, 72, s. 1125–1134.
- 7 Iaccarino, L. – Andreoli, L. – Bocci, E. B., et al.: Clinical predictors of response and discontinuation of belimumab in patients with systemic lupus erythematosus in real life setting. Results of a large, multicentric, nationwide study. *J Autoimmun*, 2018, 86, s. 1–8.
- 8 van Vollenhoven, R. F. – Petri, M. A. – Cervera, R., et al.: Belimumab in the treatment of systemic lupus erythematosus: high disease activity predictors of response. *Ann Rheum Dis*, 2012, 71, s. 1343–1349.
- 9 Sciascia, S. – Radin, M. – Yazdany, J., et al.: Efficacy of belimumab on renal outcomes in patients with systemic lupus erythematosus: a systematic review. *Autoimmun Rev*, 2017, 16, s. 287–293.
- 10 Furie, R. – Rovin, B. H. – Houssiau, F., et al.: Two-year, randomized, controlled trial of belimumab in lupus nephritis. *N Engl J Med*, 2020, 383, s. 1117–1128.
- 11 Merrill, J. T. – Neuwelt, C. M. – Wallace, D. J., et al.: Efficacy and safety of rituximab in moderately-to-severely active systemic lupus erythematosus: the randomized, double-blind, phase II/III systemic lupus erythematosus evaluation of rituximab trial. *Arthritis Rheum*, 2010, 62, s. 222–233.
- 12 Rovin, B. H. – Furie, R. – Latinis, K., et al.: Efficacy and safety of rituximab in patients with active proliferative lupus nephritis: the Lupus Nephritis Assessment with Rituximab study. *Arthritis Rheum*, 2012, 64, s. 1215–1226.
- 13 Gomez Mendez, L. M. – Cascino, M. D. – Garg, J., et al.: Peripheral blood B cell depletion after rituximab and complete response in lupus nephritis. *Clin J Am Soc Nephrol*, 2018, 13, s. 1502–1509.
- 14 Merrill, J. T. – Furie, R. – Werth, V. P., et al.: Anifrolumab effects on rash and arthritis: impact of the type I interferon gene signature in the phase IIb MUSE study in patients with systemic lupus erythematosus. *Lupus Sci Med*, 2018, 5, s. e000284.
- 15 Furie, R. A. – Morand, E. F. – Bruce, I. N., et al.: Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. *The Lancet Rheumatology*, doi: [https://doi.org/10.1016/S2665-9913\(19\)30076-1](https://doi.org/10.1016/S2665-9913(19)30076-1).
- 16 Morand, E. F. – Furie, R. – Tanaka, Y., et al.: Trial of anifrolumab in active systemic lupus erythematosus. *N Engl J Med*, 2020, 382, s. 211–221.
- 17 Tummala, R. – Abreu, G. – Pineda, L., et al.: Safety profile of anifrolumab in patients with active SLE: an integrated analysis of phase II and III trials. *Lupus Sci Med*, 2021, 8, s. e000464.
- 18 van Vollenhoven, R. F. – Hahn, B. H. – Tsokos, G. C., et al.: Efficacy and safety of ustekinumab, an IL-12 and IL-23 inhibitor, in patients with active systemic lupus erythematosus: results of a multicentre, double-blind, phase 2, randomised, controlled study. *Lancet*, 2018, 392, s. 1330–1339.

Subkutánní infliximab v léčbě zánětlivých revmatických onemocnění

prof. MUDr. Karel Pavelka, DrSc. Revmatologický ústav, Praha

- 1 Smolen, J. – Aletaha, D. – Barton, A., et al.: Rheumatoid arthritis. *Nat Rev Dis Primers*, 2018, 4, s. 18002.
- 2 Maini, R. – St Clair, E. W. – Breedveld, F., et al.: Infliximab (chimeric anti-tumour necrosis factor alpha monoclonal antibody) versus placebo in rheumatoid arthritis patients receiving concomitant methotrexate: a randomised Phase III trial. ATTRACT Study Group. *Lancet*, 1999, 354, s. 1932–1939.
- 3 Goekkoop-Ruiterman, Y. P. – de Vries-Bouwstra, J. K. – Allaart, C. F., et al.: Clinical and radiographic outcomes of four different treatment strategies in patients with early rheumatoid arthritis (the BeSt study): a randomized, controlled trial. *Arthritis Rheum*, 2005, 52, s. 3381–3390.
- 4 European Medicines Agency Committee for Medicinal Products for Human Use (CHMP). Assessment report: Remsima (Infliximab) (2018). Dostupné z: https://www.ema.europa.eu/documents/assessment-report/remsimap-epar-public-assessment-report_en.pdf, vyhledáno 18. 2. 2022.
- 5 Yoo, D. H. – Hrycaj, P. – Miranda, P., et al.: A randomized, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. *Ann Rheum Dis*, 2013, 72, s. 1613–1620.
- 6 Park, W. – Hrycaj, P. – Jeka, S., et al.: A randomized, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. *Ann Rheum Dis*, 2013, 72, s. 1605–1612.
- 7 Jorgensen, K. K. – Olsen, I. C. – Goll, G. L., et al.: Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. *Lancet*, 2017, 389, s. 2304–2316.
- 8 European Commission Grants Marketing Authorisation Form World's First Subcutaneous Formulation Of Infliximab, Remsima cs, For An Additional Five Indications Including Use In Inflammatory Bowel Disease And Ankylosing Spondylitis. Celltrion Healthcare, Biosimilar development (2020). Dostupné z: <https://www.biosimilardervelopment.com/doc/european-commission-grants-marketing-authorisation-for-world-s-first-subcutaneous-0001>, vyhledáno 28. 2. 2022.
- 9 Westhovens, R. – Yoo, D. H. – Schreibers Reinish, W., et al.: Subcutaneous administration of a novel formulation of CT-P13 (infliximab biosimilar) is safe and achieves projected therapeutic drug levels: a Phase I study in healthy subjects. *Eur Gastroenterol J*, 2017, 5, suppl. 1, P0387.
- 10 Westhovens, R. – Wiland, P. – Zawadzki, M., et al.: Efficacy, pharmacokinetics and safety of subcutaneous versus intravenous CT-P13 in rheumatoid arthritis: a randomized Phase II/III trial. *Rheumatology*, 2021, 60, s. 2277–2287.
- 11 Westhovens, R. – Wiland, P. – Zawadzki, M., et al.: A novel formulation of CT-P13 for subcutaneous administration: 30 week results from a part 2 of Phase II/III randomised control trial in patients with rheumatoid arthritis. *Ann Rheum Dis*, 2019, 78, suppl. 2, s. 1158.2–1159.
- 12 Yoo, D. H. – Jaworski, J. – Matyska-Piekarska, E., et al.: A novel formulation of CT-P13 (infliximab biosimilar) for subcutaneous administration: 1 year results from a part Phase II/III randomized control trial in patients with active RA. *Ann Rheum Dis*, 2019, 78, suppl. 2, s. 733.1–733.
- 13 Mullerman, D. – Chu Miow Lin, D. – Docourau, E., et al.: Trough infliximab concentrations predict efficacy and sustained control of disease activity in rheumatoid arthritis. *Ther Drug Monit*, 2010, 32, s. 232–236.
- 14 Combe, B. – Allanore, Y. – Alten, R., et al.: Comparative efficacy of subcutaneous (CT-P13) and intravenous infliximab in adult patients with rheumatoid arthritis: a network meta-regression of individual patient data from two randomised trials. *Arthritis Res Ther*, 2021, 23, s. 1–11.
- 15 Westhovens, R. – Yoo, D. – Wiland, P., et al.: Utility of measuring the immunogenicity to CT-P13 for subcutaneous use in patients with active rheumatoid arthritis: 1-year results from a multicenter, randomized controlled pivotal trial [abstract]. *Arthritis Rheumatol*, 2020, 72, suppl. 10.
- 16 Yoo, D. H. – Ben-Horin, S. – Reinisch, W., et al.: Development of a subcutaneous formulation of CT-P13 (infliximab): maintenance subcutaneous administration may elicit lower immunogenicity compared to intravenous treatment [abstract]. *Arthritis Rheumatol*, 2018, 70, suppl. 10.
- 17 Yoo, D. – Westhovens, R. – Wiland, P., et al.: Impact of body mass index on clinical responses of novel subcutaneous infliximab (CT-P13 SC) in patients with active rheumatoid arthritis: 1-year results from a part 2 of phase II/III randomized controlled trial [abstract]. *Arthritis Rheumatol*, 2020, 72, suppl. 10.
- 18 Duk Ye, B. – Pescegova, M. – Alexeeva, O., et al.: Efficacy and safety of biosimilar CT-P13 compared with originator infliximab in patients with active Crohn's disease: an international, randomised, double-blind, Phase 3 non-inferiority study. *Lancet*, 2019, 393, s. 1699–1707.
- 19 Westhovens, R. – Yoo, D. H. – Jaworski, J., et al.: THU0191 Novel formulation of ct-p13 for subcutaneous administration in patients with rheumatoid arthritis: initial results from a phase II/III randomised controlled trial. *Ann Rheum Dis*, 2018, 77, s. 315.

Pět let zkušeností s Benepali v reálné klinické praxi

prof. MUDr. Jiří Vencovský, DrSc. Revmatologický ústav, Praha

- 1 Emery, P. – Vencovský, J. – Sylwestrzak, A., et al.: A phase III randomised, double-blind, parallel-group study comparing SB4 with etanercept reference product in patients with active rheumatoid arthritis despite methotrexate therapy. *Ann Rheum Dis*, 2017, 76, s. 51–57.
- 2 Emery, P. – Vencovský, J. – Sylwestrzak, A., et al.: 52-week results of the phase 3 randomised study comparing SB4 with reference etanercept in patients with active rheumatoid arthritis. *Rheumatology*, 2017, 56, s. 2093–2101.
- 3 Emery, P. – Vencovský, J. – Sylwestrzak, A., et al.: Long-term efficacy and safety in patients with rheumatoid arthritis continuing on SB4 or switching from reference etanercept to SB4. *Ann Rheum Dis*, 2017, 76, s. 1986–1991.
- 4 Šenolt, L. – Mann, H. – Závada, J. – Pavelka, K. – Vencovský, J.: Doporučení České revmatologické společnosti pro farmakoterapii revmatoidní artridy 2017. *Čes revmatol*, 2017, 25, s. 8–24.
- 5 Glintborg, B. – Loft, A. G. – Omerovic, E., et al.: To switch or not to switch: results of a nationwide guideline of mandatory switching from originator to biosimilar etanercept. One-year treatment outcomes in 2061 patients with inflammatory arthritis from the DANBIO registry. *Ann Rheum Dis*, 2019, 78, s. 192–200.
- 6 Codreanu, C. – Popescu, C. C. – Mogosan, C., et al.: Efficacy and safety of original and biosimilar etanercept (SB4) in active rheumatoid arthritis – a comparison in a real-world national cohort. *Biologicals*, 2019, 62, s. 27–32.
- 7 Selmi, C. – Krüger, K. – Cantagrel, A., et al.: BENEFIT: real-world effectiveness of SB4 after transition from reference etanercept in rheumatoid arthritis and axial spondyloarthritis. *Clin Exp Rheumatol*, 2021, 39, s. 365–371.
- 8 Holroyd, C. – Wallis, D. – Bennett, S., et al.: Switching from bio-originale etanercept to biosimilar etanercept SB4: patient acceptability and outcomes in the real world. *Ann Rheum Dis*, 2017, 76, suppl. 2, s. 1180.
- 9 Kiltz, U. – Pudelko, J. C. – Tsiami, S., et al.: Non-medical switching from reference to biosimilar etanercept – no evidence for nocebo effect: a retrospective analysis of real-life data. *Clin Exp Rheumatol*, 2021, 39, s. 1345–1351.

Těžká forma chronické ložiskové psoriázy u 21letého pacienta úspěšně léčená secukinumabem – kazuistika

MUDr. Jan Šternberský, Ph.D. | MUDr. Martin Tichý, Ph.D. Klinika chorob kožních a pohlavních FN a LF UP, Olomouc

- 1 Crowley, J.: Scalp psoriasis: an overview of the disease and available therapies. *J Drugs Dermatol*, 2010, 9, s. 912–918.
- 2 Kragballe, K.: Management of difficult to treat locations of psoriasis. Scalp, face, flexures, palm/soles and nails. *Curr Probl Dermatol*, 2009, 38, s. 160–171.
- 3 Hercogová, J.: Léčba psoriázy v dermatologické praxi. *Čes Dermatovenerol*, 2018, 8, s. 47–51.
- 4 Cetkovská, P. – Kojanová, K. – Arenberger, P., et al.: Přehled současných doporučených postupů pro systémovou „nebiologikou“ léčbu psoriázy. Doporučení výboru ČDS ČLS JEP pro praxi. *Čes Slov Derm*, 2017, 92, s. 1–52.
- 5 SPC, Cosentyx 150 mg injekční roztok v předplněném peru, poslední revize textu 20. 1. 2022.
- 6 Thaci, D. – Blauvelt, A. – Reich, K., et al.: Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate to severe plaque psoriasis: CLEAR, a randomized controlled trial. *J Am Acad Dermatol*, 2015, 73, s. 400–409.
- 7 Langley, R. G. – Elewski, B. E. – Lebwohl, M., et al.: Secukinumab in plaque psoriasis – results of two phase 3 trials. *N Engl J Med*, 2014, 371, s. 326–338.
- 8 Salavec, M.: Bezpečnost secukinumabu v terapii psoriázy. *Dermatol Praxi*, 2017, 11, s. 178–181.
- 9 Choi, J. – Koo, J. Y.: Quality of life issues in psoriasis. *J Am Acad Dermatol*, 2003, 49, suppl. 2, s. S57–S61.
- 10 Reich, K., et al.: Secukinumab shows high and sustained efficacy in nail psoriasis: 2.5-year results from the randomized placebo-controlled TRANSFIGURE study. *Br J Dermatol*, 2021, 184, s. 425–436.
- 11 Bagel, J., et al.: The effect of secukinumab on moderate-to-severe scalp psoriasis: Results of a 24-week, randomized, double-blind, placebo-controlled phase 3b study. *J Am Acad Dermatol*, 2017, 77, s. 667–674.
- 12 Gottlieb, A., et al.: Secukinumab shows significant efficacy in palmo-plantar psoriasis: Results from GESTURE, a randomized controlled trial. *J Am Acad Dermatol*, 2017, 76, s. 70–80.

Guselkumab v terapii velmi těžké formy psoriázy – kazuistika

MUDr. Jan Šternberský, Ph.D. Klinika chorob kožních a pohlavních FN a LF UP, Olomouc

- 1 Reich, K. – Armstrong, A. W. – Langley, R. G., et al.: Guselkumab versus secukinumab for the treatment of moderate-to-severe psoriasis (ECLIPSE): results from a phase 3, randomised controlled trial. *Lancet*, 2019, 394, s. 831–839.
- 2 Puig, L. – Tsai, T. F. – Bhutani, T., et al.: Safety in moderate-to-severe plaque psoriasis patients with latent tuberculosis treated with guselkumab and anti-tuberculosis treatments concomitantly: results from pooled phase 3 VOYAGE 1 & VOYAGE 2 trials. *J Eur Acad Dermatol Venereol*, 2020, 34, s. 1744–1749.

Generalizovaná psoriáza u polymorbidní pacientky v terapii guselkumabem – kazuistika

MUDr. Martina Blažková Kožní oddělení, Nemocnice Jihlava

- 1 Reich, K. – Gordon, K. B. – Strober, B. E., et al.: Five-year maintenance of clinical response and health-related quality of life improvements in patients with moderate-to-severe psoriasis treated with guselkumab: results from VOYAGE 1 and VOYAGE 2. *Br J Dermatol*, 2021, 185, s. 1146–1159.
- 2 Sandhu, V. K. – Ighani, A. – Fleming, P. – Lynde, C. W.: Biologic treatment in elderly patients with psoriasis: a systematic review. *J Cutan Med Surg*, 2020, 24, s. 174–186.

Těžká forma psoriázy úspěšně léčená guselkumabem – kazuistika

MUDr. Monika Hudymačová Dermatovenerologické oddělení Slezské nemocnice v Opavě, p. o.

- 1 Benáková, N., et al.: *Moderní farmakoterapie v dermatologii*. Maxdorf Jessenius, 2020, s. 197, 227.

Biologická léčba mnohočetného myelomu v roce 2021

prof. MUDr. Ivan Špička, CSc. I. interní klinika, klinika hematoonkologie, LF UK a VFN, Praha

- 1 San Miguel, J. F. – Schlag, R. – Khuageva, N. K., et al.: VISTA Trial Investigators: Bortezomib plus melphalan and prednisone for initial treatment of multiple myeloma. *N Engl J Med*, 2008, 359, s. 906–917.
- 2 Piechotta, V. – Jakob, T. – Langer, P., et al.: Multiple drug combinations of bortezomib, lenalidomide, and thalidomide for first-line treatment in adults with transplant-ineligible multiple myeloma: a network meta-analysis. *Cochrane Database Syst Rev*, 2019, 2019, CD013487.
- 3 Mateos, M. V. – Cavo, M. – Blade, J., et al.: Overall survival with daratumumab, bortezomib, melphalan, and prednisone in newly diagnosed multiple myeloma (ALCYONE): a randomised, open-label, phase 3 trial. *Lancet*, 2020, 395, s. 132–141.
- 4 Attal, M. – Richardson, P. G. – Rajkumar, S. V., et al.: Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): A randomised, multicentre, open-label, phase 3 study. *Lancet*, 2019, 394, s. 2096–2107.
- 5 Gandhi, U. H. – Cornell, R. F. – Lakshman, A., et al.: Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy. *Leukemia*, 2019, 33, s. 2266–2275.
- 6 Moreau, P. – Attal, M. – Hulin, C., et al.: Bortezomib, thalidomide, and dexamethasone with or without daratumumab before and after autologous stem-cell transplantation for newly diagnosed multiple myeloma (CASSIOPEIA): a randomised, open-label, phase 3 study. *Lancet*, 2019, 394, s. 29–38.
- 7 Voorhees, P. M. – Kaufman, J. L. – Laubach, J., et al.: Daratumumab, lenalidomide, bortezomib, and dexamethasone for transplant-eligible newly diagnosed multiple myeloma: the GRIFFIN trial. *Blood*, 2020, 136, s. 936–945.
- 8 Costa, L. J. – Chhabra, S. – Callander, N. S., et al.: Daratumumab, carfilzomib, lenalidomide and dexamethasone (Dara-KRD), autologous transplantation and MRD response-adapted consolidation and treatment cessation. Final primary endpoint analysis of the master trial. *ASH*, 12. 12. 2021, dostupné z: <https://ash.confex.com/ash/2021/webprogram/Paper145494.html>, vyhledáno 9. 2. 2022.
- 9 Goldschmidt, H. – Mai, E. K. – Nievergall, E., et al.: Addition of isatuximab to lenalidomide, bortezomib and dexamethasone as induction therapy for newly-diagnosed, transplant-eligible multiple myeloma patients: the phase III GMMG-HD7 trial. *ASH*, 12. 12. 2021, dostupné z: <https://ash.confex.com/ash/2021/webprogram/Paper145097.html>, vyhledáno 9. 2. 2022.
- 10 Madry, C. – Laabi, Y. – Callebaut, I., et al.: The characterization of murine BCMA gene defines it as a new member of the tumor necrosis factor receptor superfamily. *Int Immunopharmacol*, 1998, 10, s. 1693–1702.
- 11 Tai, Y. T. – Acharya, C. – An, G., et al.: APRIL and BCMA promote human multiple myeloma growth and immunosuppression in the bone marrow microenvironment. *Blood*, 2016, 127, s. 3225–3236.
- 12 Ghermezi, M. – Li, M. – Vardanyan, S., et al.: Serum B-cell maturation antigen: A novel biomarker to predict outcomes for multiple myeloma patients. *Haematologica*, 2017, 102, s. 785–795.
- 13 Gavriatopoulou, M. – Ntanasis-Stathopoulos, I. – Dimopoulos, M. A., et al.: Anti-BCMA antibodies in the future management of multiple myeloma. *Expert Rev Anticancer Ther*, 2019, 19, s. 319–326.
- 14 Dispignier, A. – Soof, C. M. – Rajkumar, S. V., et al.: Serum BCMA levels to predict outcomes for patients with MGUS and smoldering multiple myeloma (SMM). *J Clin Oncol*, 2019, 37, s. 8020.
- 15 Martino, M. – Pavlidianiti, A.: An update on B-cell maturation antigen-targeted therapies in multiple myeloma. *Expert Opin Biol Ther*, 2021, 21, s. 1025–1034.
- 16 Sheikh, S. – Lebel, E. – Trudel, S.: Belantamab mafodotin in the treatment of relapsed or refractory multiple myeloma. *Future Oncol*, 2020, 16, s. 2783–2798.
- 17 Trudel, S. – Lendvai, N. – Popat, R., et al.: Targeting B-cell maturation antigen with GSK2857916 antibody-drug conjugate in relapsed and refractory multiple myeloma (BMA117159): A dose escalation and expansion phase 1 trial. *Lancet Oncol*, 2018, 19, s. 1641–1653.
- 18 Lonial, S. – Lee, H. C. – Badros, A., et al.: Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM-2): A two-arm, randomised, open-label, phase 2 study. *Lancet Oncol*, 2020, 21, s. 207–221.
- 19 Lonial, S. – Lee, H. C. – Badros, A., et al.: Pivotal DREAMM-2 study: Single-agent belantamab mafodotin (GSK2857916) in patients with relapsed/refractory multiple myeloma (RRMM) refractory to proteasome inhibitors (PIs), immunomodulatory agents, and refractory and/or intolerant to anti-CD38 monoclonal antibodies (mAbs). *J Clin Oncol*, 2020, 38, s. 8536.
- 20 Nooka, A. K. – Stockerl-Goldstein, K. – Quach, H., et al.: DREAMM-6: Safety and tolerability of belantamab mafodotin in combination with bortezomib/dexamethasone in relapsed/refractory multiple myeloma (RRMM). *J Clin Oncol*, 2020, 38, s. 8502.
- 21 O'Donnell, K. K. – Raje, N. S.: New monoclonal antibodies on the horizon in multiple myeloma. *Ther Adv Hematol*, 2017, 8, s. 41–53.
- 22 Offner, S. – Hofmeister, R. – Romanik, A., et al.: Induction of regular cytolytic T cell synapses by bispecific single-chain antibody constructs on MHC class I-negative tumor cells. *Mol Immunol*, 2006, 43, s. 763–771.
- 23 Hipp, S. – Tai, Y. T. – Blanset, D., et al.: A novel BCMA/CD3 bispecific T-cell engager for the treatment of multiple myeloma induces selective lysis in vitro and in vivo. *Leukemia*, 2017, 31, s. 1743–1751.
- 24 Goldstein, R. L. – Goyos, A. – Li, C. M., et al.: AMG 701 induces cytotoxicity of multiple myeloma cells and depletes plasma cells in cynomolgus monkeys. *Blood Adv*, 2020, 4, s. 4180–4194.
- 25 Cooper, D. – Madduri, D. – Lentzsch, S., et al.: Safety and preliminary clinical activity of REGN5458, an anti-BCMA x anti-CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma. *Blood*, 2019, 134, s. 3176.

- 26 Krishnan, A. Y. – Garfall, A. L. – Mateos, M. V., et al.: Updated phase 1 results of teclistamab, a B-cell maturation antigen (BCMA) × CD3 bispecific antibody, in relapsed/refractory multiple myeloma (MM). *J Clin Oncol*, 2021, 39, s. 8007.
- 27 Costa, L. J. – Wong, S. W. – Bermúdez, A., et al.: First clinical study of the B-cell maturation antigen (BCMA) 2+1 T cell engager (TCE) CC-93269 in patients (pts) with relapsed/refractory multiple myeloma (RRMM): interim results of a phase 1 multicenter trial. *Blood*, 2019, 134 (suppl. 1), s. 143.
- 28 Raje, N. S. – Jakubowiak, A. – Gasparetto, C., et al.: Safety, clinical activity, pharmacokinetics, and pharmacodynamics from a phase I study of PF-0686135, a B-cell maturation antigen (BCMA)-CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma (RRMM). *Blood*, 2019, 134, s. 1869.
- 29 Bradno, J. N. – Maric, I. – Hartman, S. D., et al.: T cells genetically modified to express an anti-B-cell maturation antigen chimeric antigen receptor cause remissions of poor-prognosis relapsed multiple myeloma. *J Immunotherapy*, 2020, 43, s. 100–107.
- 30 Raje, N. – Berdeja, J. – Lin, Y., et al.: Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. *N Engl J Med*, 2019, 380, s. 1726–1737.
- 31 Mohyuddin, G. R. – Rooney, A. – Balmaceda, N., et al.: Chimeric antigen receptor T-cell therapy in multiple myeloma: a systematic review and meta-analysis of 950 patients. *Blood Adv*, 2021, 5, s. 1097–1101.
- 32 Costello, C. L. – Cohen, A. D. – Patel, K. K., et al.: Study of the safety and response of P-BCMA-101 CAR-T cells in patients with relapsed/refractory (rr) multiple myeloma (MM) (PRIME) with novel therapeutic strategies. *Blood*, 2020, 136 (suppl. 1), s. 29–30.
- 33 Raje, N. – Berdeja, J. – Lin, Y., et al.: Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. *N Engl J Med*, 2019, 380, s. 1726–1737.
- 34 Shah, N. – Chari, A. – Scott, E., et al.: B-cell maturation antigen (BCMA) in multiple myeloma: Rationale for targeting and current therapeutic approaches. *Leukemia*, 2020, 34, s. 985–1005.
- 35 Munshi, N. C. – Larry, D. – Anderson, J., et al.: Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial Kar-Ma results. *J Clin Oncol*, 2020, 38, s. 8503.
- 36 Zhao, W. H. – Liu, J. – Wang, B. Y., et al.: A phase 1, open-label study of LCAR-B38M, a chimeric antigen receptor T cell therapy directed against B cell maturation antigen, in patients with relapsed or refractory multiple myeloma. *J Hematol Oncol*, 2018, 11, s. 141.
- 37 Wang, B.-Y. – Zhao, W.-H. – Liu, J., et al.: Long-term follow-up of a phase 1, first-in-human open-label study of LCAR-B38M, a structurally differentiated chimeric antigen receptor T (CAR-T) cell therapy targeting B-cell maturation antigen (BCMA), in patients (pts) with relapsed/refractory multiple myeloma (RRMM). *Blood*, 2019, 134, s. 579.
- 38 Berdeja, J. G. – Madduri, D. – Usmani, S. Z., et al.: Update of CARTITUDE-1: A phase Ib/II study of JNJ-4528, a B-cell maturation antigen (BCMA)-directed CAR-T-cell therapy, in relapsed/refractory multiple myeloma. *J Clin Oncol*, 2020, 38, s. 8505.

Venetoklax v léčbě akutní myeloidní leukemie

MUDr. Zdeněk Koříšek, Ph.D. Klinika hematoonkologie, Fakultní nemocnice Ostrava

- 1 Yates, J. W. – Wallace, H. J. Jr. – Ellison, R. R. – Holland, J. F.: Cytosine arabinoside (NSC-63878) and daunorubicin (NSC-83142) therapy in acute nonlymphocytic leukemia. *Cancer Chemother Rep*, 1973, 57, s. 485–488.
- 2 Thomas, E. D. – Buckner, C. D. – Banaji, M., et al.: One hundred patients with acute leukemia treated by chemotherapy, total body irradiation, and allogeneic marrow transplantation. *Blood*, 1977, 49, s. 511–533.
- 3 Fenaux, P. – Mufti, G. J. – Hellstrom-Lindberg, E., et al.: Azacitidine prolongs overall survival compared with conventional care regimens in elderly patients with low bone marrow blastcount acute myeloid leukemia. *J Clin Oncol*, 2010, 28, s. 562–569.
- 4 García-Aranda, M. – Pérez-Ruiz, E. – Redondo, M.: Bcl-2 inhibition to overcome resistance to chemo- and immunotherapy. *Int J Mol Sci*, 2018, 19, s. 3950.
- 5 Lagadinou, E. D. – Sach, A. – Callahan, K., et al.: BCL-2 inhibition targets oxidative phosphorylation and selectively eradicates quiescent human leukemia stem cells. *Cell Stem Cell*, 2013, 12, s. 329–341.
- 6 Bogenerber, J. M. – Delman, D. – Hansen, N., et al.: Ex vivo activation of BCL-2 family inhibitors ABT-199 and ABT-737 combined with 5-azacytidine in myeloid malignancies. *Leuk Lymphoma*, 2015, 56, s. 226–229.
- 7 DiNardo, C. D. – Pratz, K. – Pullarkat, V., et al.: Venetoclax combined with decitabine or azacitidine in treatment-naïve, elderly patients with acute myeloid leukemia. *Blood*, 2019, 133, s. 7–17.
- 8 Wei, A. H. – Strickland, S. A. Jr. – Hou, J. Z., et al.: Venetoclax combined with low-dose cytarabine for previously untreated patients with acute myeloid leukemia: results from a phase Ib/II study. *J Clin Oncol*, 2019, 37, s. 1277–1284.
- 9 DiNardo, C. D. – Jonas, B. A. – Pullarkat, V., et al.: Azacitidine and venetoclax in previously untreated acute myeloid leukemia. *N Engl J Med*, 2020, 383, s. 617–629.
- 10 Wei, A. H. – Montesinos, P. – Ivanov, V., et al.: Venetoclax plus LDAC for newly diagnosed AML ineligible for intensive chemotherapy: a phase 3 randomized placebo-controlled trial. *Blood*, 2020, 135, s. 2137–2145.
- 11 DiNardo, C. D. – Lachowicz, C. A. – Takahashi, K., et al.: Venetoclax combined with FLAG-Ida induction and consolidation in newly diagnosed and relapsed or refractory acute myeloid leukemia. *J Clin Oncol*, 2021, 39, s. 2768–2778.
- 12 Maiti, A. – Qiao, W. – Sasaki, K., et al.: Venetoclax with decitabine vs intensive chemotherapy in acute myeloid leukemia: a propensity score matched analysis stratified by risk of treatment-related mortality. *Am J Hematol*, 2021, 96, s. 282–291.

22. pražské hematologické dny – zpráva ze sympozia společnosti Pfizer: Management léčby přípravkem Mylotarg u pacientů s akutní myeloidní leukemií

- 1 Lambert, J. – Pautas, C. – Terré, Ch., et al.: Gemtuzumab ozogamicin for de novo acute myeloid leukemia: final efficacy and safety updates from the open-label, phase III ALFA-0701 trial. *Haematologica*, 2019, 104, s. 113–119.
- 2 Fournier, E. – Duployez, N. – Décourneau, B., et al.: Mutational profile and benefit of gemtuzumab ozogamicin in acute myeloid leukemia. *Blood*, 2020, 135, s. 542–546.
- 3 Lambert, J. – Pautas, C. – Terré, Ch., et al.: Gemtuzumab ozogamicin for de novo acute myeloid leukemia: final efficacy and safety updates from the open-label, phase III ALFA-0701 trial. *Haematologica*, 2019, 104, s. 113–119.
- 4 Lambert, J. – Lambert, J. – Nibourel, O., et al.: MRD assessed by WT1 and NPM1 transcript levels identifies distinct outcomes in AML patients and is influenced by gemtuzumab ozogamicin. *Oncotarget*, 2014, 5, s. 6280–6288.
- 5 Souhrn údajů o přípravku Mylotarg. Dostupné z: https://www.ema.europa.eu/en/documents/product-information/mylotarg-epar-product-information_c5.pdf, vyhledáno 10. 2. 2022.
- 6 Rölling, C., et al.: Německá doporučení pro AML, 2019.
- 7 Kapp-Schwoerer, S. – Weber, D. – Corbacioglu, A., et al.: Impact of gemtuzumab ozogamicin on MRD and relapse risk in patients with NPM1-mutated AML: results from the AMLSG 09-09 trial. *Blood*, 2020, 136, s. 3041–3050.

Pokročilý endometriální karcinom a inovativní léčba

prof. MUDr. Jindřich Fínek, Ph.D. MHA Onkologická a radioterapeutická klinika FN a LF UK, Plzeň

- 1 Makker, V. – Colombo, N. – Casado Herraez, A., et al.; for the Study 309–KEYNOTE-775 Investigators: Lenvatinib plus pembrolizumab for advanced endometrial cancer. *N Engl J Med*, 2022, 386, s. 437–448.
- 2 www.swod.cz

Terapie časného HER2 pozitivního karcinomu prsu

doc. MUDr. Iveta Kolářová, Ph.D. Klinika onkologie a radioterapie, Fakultní nemocnice Hradec Králové

doc. MUDr. Jaroslav Vaňásek, CSc. Onkologické centrum Multiscan Pardubice

- 1 Hyuna, S. – Ferlay, J. – Siegel, R. L., et al.: Global Cancer Statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*, 2021, 71, s. 209–249.
- 2 Giuliano, M. – Trivedi, M. V. – Schiff, R.: Bidirectional crosstalk between the estrogen receptor and human epidermal growth factor receptor 2 signaling pathways in breast cancer: molecular basis and clinical implications. *Breast Care*, 2013, 8, s. 256–262.
- 3 Kolarova, I. – Vanasek, J. – Odrazka, J., et al.: Therapeutic significance of hormone receptor positivity in patients with HER-2 positive breast cancer. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub*, 2019, 163, s. 285–292.
- 4 Gusterson, B. A. – Gelber, R. D. – Goldhirsch, A., et al.: Prognostic importance of c-erbB-2 expression in breast cancer. International (Ludwig) Breast Cancer Study Group. *J Clin Oncol*, 1992, 10, s. 1049–1056.
- 5 Chia, S. – Norris, B. – Speers, C., et al.: Human epidermal growth factor receptor 2 overexpression as a prognostic factor in a large tissue microarray series of node-negative breast cancers. *J Clin Oncol*, 2008, 26, s. 5697–5704.
- 6 Harris, L. – Fritzsche, H. – Mennel, R., et al.: American Society of Clinical Oncology 2007 update of recommendations for the use of tumor markers in breast cancer. *J Clin Oncol*, 2007, 25, s. 5287–5312.
- 7 Llombart-Cussac, A. – Cortés, J. – Paré, L., et al.: HER2-enriched subtype as a predictor of pathological complete response following trastuzumab and lapatinib without chemotherapy in early-stage HER2-positive breast cancer (PAMELA): an open-label, single-group, multicentre, phase 2 trial. *Lancet Oncol*, 2017, 18, s. 545–554.
- 8 Burstein, H. J.: Adjuvant systemic therapy for HER2-positive breast cancer. Dostupné z: <https://www.uptodate.com/contents/adjuvant-systemic-therapy-for-her2-positive-breast-cancer>, vyhledáno 9. 3. 2022.
- 9 Sikov, W.: Neoadjuvant therapy for patients with HER2-positive breast cancer. Dostupné z: <https://www.uptodate.com/contents/neoadjuvant-therapy-for-patients-with-her2-positive-breast-cancer>, vyhledáno 9. 3. 2022.
- 10 Moja, L. – Tagliabue, L. – Balduzzi, S., et al.: Trastuzumab containing regimens for early breast cancer. *Cochrane Database Syst Rev*, 2012, 2012, s. CD00624.
- 11 Pivot, X. – Romieu, G. – Deble, M., et al.: 6 months versus 12 months of adjuvant trastuzumab for patients with HER2-positive early breast cancer (PHARE): a randomised phase 3 trial. *Lancet Oncol*, 2013, 14, s. 741–748.
- 12 Cameron, D. – Piccart-Gebhart, M. J. – Gelber, R. D., et al.: 11 years' follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive early breast cancer: final analysis of the HERceptin Adjuvant

- (HERA) trial. *Lancet*, 2017, 389, s. 1195–1205.
- 13 Earl, H. M. – Hiller, J. – Vallier, A.-L., et al.: 6 versus 12 months of adjuvant trastuzumab for HER2-positive early breast cancer (PERSEPHONE): 4-year disease-free survival results of a randomised phase 3 non-inferiority trial. *Lancet*, 2019, 393, s. 2599–2612.
 - 14 Chan, A. – Moy, B. – Mansi, J., et al.: Final efficacy results of neratinib in HER2-positive hormone receptor-positive early-stage breast cancer from the phase III ExteNET trial. *Clin Breast Canc*, 2021, 21, s. 80–91.e7.
 - 15 Von Minckwitz, G. – Huang, Ch.-S. – Mano, M. S., et al.: Trastuzumab emtansine for residual invasive HER2-positive breast cancer. *N Engl J Med*, 2019, 380, s. 617–628.
 - 16 Denduluri, N. – Somerfield, M. R. – Chavez-MacGregor, M., et al.: Selection of optimal adjuvant chemotherapy and targeted therapy for early breast cancer: ASCO Guideline Update. *J Clin Oncol*, 2021, 39, s. 685–693.
 - 17 Piccart, M. – Procter, M. – Fumagalli, D., et al.: Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer in the APHINITY trial: 6 years' follow-up. *J Clin Oncol*, 2021, 39, s. 1448–1457.
 - 18 Von Minckwitz, G. – Procter, M. – De Azambuja, E., et al.: Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer. *N Engl J Med*, 2017, 377, s. 122–131.
 - 19 Martin, M. – Holmes, F. A. – Ejretnsen, B., et al.: Neratinib after trastuzumab-based adjuvant therapy in HER2-positive breast cancer (ExteNET): 5-year analysis of a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol*, 2017, 18, s. 1688–1700.
 - 20 Chan, A. – Moy, B. – Mansi, J., et al.: Final efficacy results of neratinib in HER2-positive hormone receptor-positive early-stage breast cancer from the phase III ExteNET trial. *Clinical Breast Cancer*, 2021, 21, s. 80–91.e7.
 - 21 Harbeck, N.: Neoadjuvant and adjuvant treatment of patients with HER2-positive early breast cancer. *Breast*, 19, 1. 2022, článek v tisku, S0960-9776(22)00006-6.
 - 22 Nitz, U. A. – Gluz, O. – Christgen, M., et al.: De-escalation strategies in HER2-positive early breast cancer (EBC): final analysis of the WSG-ADAPT HER2+/HR- phase II trial. *Ann Oncol*, 2017, 28, s. 2768–2772.
 - 23 Gluz, O. – Nitz, U. – Christgen, M., et al.: De-escalated chemotherapy versus endocrine therapy plus pertuzumab + trastuzumab for HR+/HER2+ early breast cancer (BC): First efficacy results from the neoadjuvant WSG-TP-II study. *J Clin Oncol*, 2020, 38, suppl. 15, s. 515–515.
 - 24 Piccart, M. J. – Hilbers, F. S. – Bliss, J. M., et al.: Road map to safe and well-designed de-escalation trials of systemic adjuvant therapy for solid tumors. *J Clin Oncol*, 2020, 38, s. 4120–4129.

Metastatický triple negativní karcinom prsu – deprese začíná ustupovat

prof. MUDr. Petra Tesařová, CSc. Onkologická klinika 1. LF UK a Všeobecné fakultní nemocnice, Praha

- 1 Almansour, N. M.: Triple-negative breast cancer: a brief review about epidemiology, risk factors, signaling pathways, treatment and role of artificial intelligence. *Front Mol Biosci*, 2022, 9, 836417, doi: 10.3389/fmolb.2022.836417.
- 2 Howard, F. M. – Olopade, O. I.: Epidemiology of triple-negative breast cancer: a review. *Cancer J*, 2021, 27, s. 8–16.
- 3 Livasy, C. A. – Karaca, G. – Nanda, R., et al.: Phenotypic evaluation of the basal-like subtype of invasive breast carcinoma. *Mod Pathol*, 2006, 19, s. 264–271.
- 4 Burstein, M. D. – Tsimelzon, A. – Poage, G. M., et al.: Comprehensive genomic analysis identifies novel subtypes and targets of triple-negative breast cancer. *Clin Cancer Res*, 2015, 21, s. 1688–1698.
- 5 Bertucci, F. – Finetti, P. – Cervera, N., et al.: How basal are triple-negative breast cancers? *Int J Cancer*, 2008, 123, s. 236–240.
- 6 Prat, A. – Parker, J. S. – Karginova, O., et al.: Phenotypic and molecular characterization of the claudin-low intrinsic subtype of breast cancer. *Breast Cancer Res*, 2010, 12, s. R68.
- 7 Cheang, M. C. U. – Martin, M. – Nielsen, T. O., et al.: Quantitative hormone receptors, triple-negative breast cancer (TNBC), and molecular subtypes: A collaborative effort of the BIG-NCI NABCG. *J Clin Oncol*, 2012, 30, suppl. 15, s. 1008.
- 8 Lin, N. U. – Vanderplas, A. – Hughes, M. E., et al.: Clinicopathologic features, patterns of recurrence, and survival among women with triple-negative breast cancer in the National Comprehensive Cancer Network. *Cancer*, 2012, 118, s. 5463–5472.
- 9 Amir, E. – Clemons, M. – Freedman, O. C., et al.: Tissue confirmation of disease recurrence in patients with breast cancer: Pooled analysis of two large prospective studies. *J Clin Oncol*, 2010, 28, suppl. 15, s. 1007.
- 10 Tung, N. M. – Boughey, J. C. – Pierce, L. J., et al.: Management of hereditary breast cancer: American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Guideline. *J Clin Oncol*, 2020, 38, s. 2080–2106.
- 11 Tutt, A. – Tovey, H. – Cheang, M. C. U., et al.: Carboplatin in BRCA1-mutated and triple-negative breast cancer BRCAAness subgroups: the TNT Trial. *Nat Med*, 2018, 24, s. 628–637.
- 12 Egger, S. J. – Chan, M. M. K. – Luo, Q. – Wilken, N.: Platinum-containing regimens for triple-negative metastatic breast cancer. *Cochrane Database Syst Rev*, 2020, 10, CD013750.
- 13 Cortes, J. – Cescon, D. W. – Rugo, H. S., et al.: Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. *Lancet*, 2020, 396, s. 1817–1828.
- 14 Cortes, J. – Cescon, D. W. – Rugo, H. S., et al.: Final results of KEYNOTE-355: Randomized, double-blind, phase 3 study of pembrolizumab + chemotherapy vs placebo + chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer. *SABCS*, 2021, GS1-02.
- 15 Schmid, P. – Adams, S. – Rugo, H. S., et al.: Atezolizumab and nab-paclitaxel in advanced triple-negative breast cancer. *N Engl J Med*, 2018, 379, s. 2108–2121.
- 16 Emens, L. A. – Adams, S. – Barrios, C. H., et al.: First-line atezolizumab plus nab-paclitaxel for unresectable, locally advanced, or metastatic triple-negative breast cancer: IMpassion130 final overall survival analysis. *Ann Oncol*, 2021, 32, s. 983–993.
- 17 Miles, D. – Gilgorov, J. – André, F., et al.: Primary results from IMpassion131, a double-blind, placebo-controlled, randomised phase III trial of first-line paclitaxel with or without atezolizumab for unresectable locally advanced/metastatic triple-negative breast cancer.
- 18 Ann Oncol, 2021, 32, s. 994–1004.
- 19 Adams, S. – Schmid, P. – Rugo, H. S., et al.: Pembrolizumab monotherapy for previously treated metastatic triple-negative breast cancer: cohort A of the phase II KEYNOTE-086 study. *Ann Oncol*, 2019, 30, s. 397–404.
- 20 Robson, M. – Im, S. A. – Senkus, E., et al.: Olaparib for metastatic breast cancer in patients with a germline BRCA mutation. *N Engl J Med*, 2017, 377, s. 523–533.
- 21 Litton, J. K. – Rugo, H. S. – Ettl, J., et al.: Talazoparib in patients with advanced breast cancer and a germline BRCA mutation. *N Engl J Med*, 2018, 379, s. 753–763.
- 22 Diéras, V. – Han, H. S. – Kaufman, B., et al.: Vilaparib with carboplatin and paclitaxel in BRCA-mutated advanced breast cancer (BROCADE3): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol*, 2020, 21, s. 1269–1282.
- 23 Olivier, T. – Prasad, V.: Sacituzumab govitecan in metastatic triple negative breast cancer (TNBC): Four design features in the ASCENT trial potentially favored the experimental arm. *Transl Oncol*, 2022, 15, s. 101248.
- 24 Bardia, A. – Hurvitz, S. A. – Tolaney, S. M., et al.: Sacituzumab govitecan in metastatic triple-negative breast cancer. *N Engl J Med*, 2021, 384, s. 1529–1541.
- 25 Bardia, A. – Mayer, I. A. – Vahdat, L. T., et al.: Sacituzumab govitecan-hziy in refractory metastatic triple-negative breast cancer. *N Engl J Med*, 2019, 380, s. 741–751.
- 26 Gennari, A. – André, F. – Barrios, C. H., et al.: ESMO Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer. *Ann Oncol*, 2021, 32, s. 1475–1495.

Imunoterapie v první linii léčby nemalobuněčného karcinomu plic

MUDr. Leona Koubková Pneumologická klinika 2. LF UK a FN v Motole, Praha

- 1 Reck, M. – Rodríguez-Abreu, D. – Robinson, A. G., et al.: Updated analysis of KEYNOTE-024: Pembrolizumab versus platinum-based chemotherapy for advanced non-small-cell lung cancer with PD-L1 tumor proportion score of 50% or greater. *J Clin Oncol*, 2019, 37, s. 537–546.
- 2 Reck, M. – Rodríguez-Abreu, D. – Robinson, A. G., et al.: Five-year outcomes with pembrolizumab versus chemotherapy for metastatic non-small-cell lung cancer with PD-L1 tumor proportion score ≥ 50 . *J Clin Oncol*, 2021, 39, s. 2339–2349.
- 3 Mok, T. S. K. – Wu, Y. L. – Kudaba, I., et al.: Pembrolizumab versus chemotherapy for previously untreated, PD-L1-expressing, locally advanced or metastatic non-small-cell lung cancer (KEYNOTE-042): A randomised, open-label, controlled, phase 3 trial. *Lancet*, 2019, 393, s. 1819–1830.
- 4 Cho, B. C. – Wu, Y. L. – Lopes, G., et al.: FP13.04 KEYNOTE-042 3-year survival update: 1L pembrolizumab vs platinum-based chemotherapy for PD-L1+ locally advanced/metastatic NSCLC. *J Thorac Oncol*, 2021, 16, s. S225–S226.
- 5 Sezer, A. – Kılıçkap, S. – Gümrük, M., et al.: LBA52 EMPOWER-Lung 1: Phase III first-line (1L) cimiplimab monotherapy vs platinum-doublet chemotherapy (chemo) in advanced non-small cell lung cancer (NSCLC) with programmed cell death-ligand 1 (PD-L1) $\geq 50\%$. *Ann Oncol*, 2020, 31, s. S1182–S1183.
- 6 Herbst, R. – De Marinis, F. – Giaccone, G., et al.: FP13.03 IMpower110: Updated OS analysis of atezolizumab vs platinum-based chemotherapy as first-line treatment in PD-L1 selected NSCLC. *J Thorac Oncol*, 2021, 16, s. S224–S225.
- 7 Garassino, M. C. – Gadgeel, S. – Esteban, E., et al.: Patient-reported outcomes following pembrolizumab or placebo plus pemtrexed and platinum in patients with previously untreated, metastatic, non-squamous non-small-cell lung cancer (KEYNOTE-042): A randomized, double-blind, phase 3 study (Oncology pRogram by InnovENT anti-PD-1-11). *J Thorac Oncol*, 2020, 15, s. 1636–1646.
- 8 Gray, J. – Rodríguez-Abreu, D. – Powell, S. F., et al.: FP13.02 Pembrolizumab + pemetrexed-platinum vs pemetrexed-platinum for metastatic NSCLC: 4-Year follow-up from KEYNOTE-189. *J Thorac Oncol*, 2021, 16, s. S224.
- 9 Gadgeel, S. – Rodríguez-Abreu, D. – Felip, E., et al.: KRAS mutational status and efficacy in KEYNOTE-189: Pembrolizumab (pembro) plus chemotherapy (chemo) vs placebo plus chemo as first-line therapy for metastatic non-squamous NSCLC. *Ann Oncol*, 2019, 30, s. x164–x165.
- 10 Garassino, M. – Rodríguez-Abreu, D. – Gadgeel, S., et al.: OA04.06 Evaluation of TMB in KEYNOTE-189: Pembrolizumab plus chemotherapy vs placebo plus chemotherapy for nonsquamous NSCLC. *J Thorac Oncol*, 2019, 14, s. S216–S217.
- 11 Nishio, M. – Barlesi, F. – West, H., et al.: Atezolizumab plus chemotherapy for first-line treatment of nonsquamous NSCLC: Results from the randomized phase 3 IMpower132 trial. *J Thorac Oncol*, 2021, 16, s. 653–664.
- 12 Reck, M. – Mok, T. S. K. – Nishio, M., et al.: Atezolizumab plus bevacizumab and chemotherapy in non-small-cell lung cancer (IMpower150): Key subgroup analyses of patients with EGFR mutations or baseline liver metastases in a randomised, open-label phase 3 trial. *Lancet Respir Med*, 2019, 7, s. 387–401.
- 13 Yang, Y. – Wang, Z. – Fang, J., et al.: Efficacy and safety of sintilimab plus pemtrexed and platinum as first-line treatment for locally advanced or metastatic nonsquamous NSCLC: A randomized, double-blind, phase 3 study (Oncology pRogram by InnovENT anti-PD-1-11). *J Thorac Oncol*, 2020, 15, s. 1636–1646.
- 14 Lu, S. – Wang, J. – Yu, Y., et al.: Tislelizumab plus chemotherapy as first-line treatment for locally advanced or metastatic nonsquamous non-small cell lung cancer (RATIONALE 304): A randomized phase 3 trial. *J Thorac Oncol*, 2021, 16, s. 1512–1522.
- 15 Zhou, C. – Chen, G. – Huang, Y., et al.: Camrelizumab plus carboplatin and pemetrexed versus chemotherapy alone in chemotherapy-naïve patients with advanced non-squamous non-small-cell lung cancer (Camel): A randomised, open-label, multicentre, phase 3 trial. *Lancet Respir Med*, 2021, 9, s. 305–314.
- 16 Zhou, C. – Wang, Z. – Sun, Y., et al.: LBA4 GEMSTONE-302: A phase III study of platinum-based chemotherapy (chemo) with placebo or CS1001, an anti-PDL1 antibody, for first-line (1L) advanced non-small cell lung cancer (NSCLC). *Ann Oncol*, 2020, 31, s. S1386.
- 17 Robinson, A. G. – Vicente, D. – Tafreshi, A., et al.: 970 First-line pembrolizumab plus chemotherapy for patients with advanced squamous NSCLC: 3-year follow-up from KEYNOTE-407. *J Thorac Oncol*, 2021, 16, s. S748–S749.
- 18 Jotte, R. – Cappuzzo, F. – Vynnychenko, I., et al.: Atezolizumab in combination with carboplatin and nab-paclitaxel in advanced squamous NSCLC (Mpower131): Results from a randomized phase III trial. *J Thorac Oncol*, 2020, 15, s. 1351–1360.
- 19 Zhou, C. – Ren, S. – Chen, J., et al.: 960 Camrelizumab or placebo plus carboplatin and paclitaxel as first-line treatment for advanced squamous NSCLC (Camel-sq): A randomized, double-blind, multicenter, phase III trial. *J Thorac Oncol*, 2021, 16, s. S748.
- 20 Wang, J. – Lu, S. – Yu, X., et al.: Tislelizumab plus chemotherapy vs chemotherapy alone as first-line treatment for advanced squamous non-small-cell lung cancer: A phase 3 randomized clinical trial. *JAMA Oncol*, 2021, 7, s. 709–717.
- 21 Zhou, C. – Wu, L. – Fan, Y., et al.: LBA56 ORIENT-12: Sintilimab plus

- gemcitabine and platinum (GP) as first-line (1L) treatment for locally advanced or metastatic squamous non-small-cell lung cancer (sqNSCLC). *Ann Oncol*, 2020, 31, s. 51186.
- 22 Hellmann, M. D. – Paz-Ares, L. – Bernabe Caro, R., et al.: Nivolumab plus ipilimumab in advanced non-small-cell lung cancer. *N Engl J Med*, 2019, 381, s. 2020–2031.
 - 23 Paz-Ares, L. G. – Ciuleanu, T.-E. – Lee, J.-S., et al.: Nivolumab (NIVO) plus ipilimumab (IPI) versus chemotherapy (chemo) as first-line (1L) treatment for advanced non-small cell lung cancer (NSCLC): 4-year update from CheckMate 227. *J Clin Oncol*, 2021, 39, suppl., abstrakt 9016.
 - 24 Rizvi, N. A. – Cho, B. C. – Reinmuth, N., et al.: Durvalumab with or without tremelimumab vs standard chemotherapy in first-line treatment of metastatic non-small cell lung cancer: The MYSTIC phase 3 randomized clinical trial. *JAMA Oncol*, 2020, 6, s. 661–674.
 - 25 Paz-Ares, L. – Ciuleanu, T.-E. – Cobo, M., et al.: First-line nivolumab plus ipilimumab combined with two cycles of chemotherapy in patients with non-small-cell lung cancer (CheckMate 9LA): An international, randomised, open-label, phase 3 trial. *Lancet Oncol*, 2021, 22, s. 198–211.
 - 26 Carbone, D. – Ciuleanu, T. – Cobo, M., et al.: OA09.01 First-line nivolumab + ipilimumab + chemo in patients with advanced NSCLC and brain metastases: results from CheckMate 9LA. *J Thorac Oncol*, 2021, 16, dostupné z: <https://doi.org/10.1016/j.jtho.2021.08.061>, vyhledáno 2. 3. 2022.
 - 27 AstraZeneca: Imfinzi and tremelimumab with chemotherapy demonstrated overall survival benefit in POSEIDON trial for 1st-line Stage IV non-small cell lung cancer. 2021. Dostupné z: <https://www.astrazeneca.com/media-centre/press-releases/2021/imfinzi-and-tremelimumab-showed-survival-in-POSEIDON.html>, vyhledáno 2. 3. 2022.
 - 28 Boyer, M. – Şendur, M. A. N. – Rodríguez-Abreu, D., et al.: Pembrolizumab plus ipilimumab or placebo for metastatic non-small-cell lung cancer with PD-L1 tumor proportion score ≥ 50%: Randomized, double-blind phase III KEYNOTE-598 study. *J Clin Oncol*, 2021, 39, s. 2327–2338.
 - 29 AstraZeneca: Update on the Phase III NEPTUNE trial of Imfinzi plus tremelimumab in Stage IV non-small cell lung cancer. 2019. Dostupné z: <https://www.astrazeneca.com/media-centre/press-releases/2019/>
 - 30 Gadgeel, S. – Grey, J. – Rizzo, M. T., et al.: Pemetrexed and platinum plus pembrolizumab in patients with metastatic non-squamous non-small cell lung cancer by tumor burden at baseline: A post-hoc efficacy analysis of KEYNOTE-189. *Cancer Res*, 2021, 81, suppl. 13, s. 442.
 - 31 Reck, M. – Remon, J. – Hellmann, M. D.: First-line immunotherapy for non-small-cell lung cancer. *J Clin Oncol*, 2022, 40, s. 586–597.
 - 32 Reck, M. – Ciuleanu, T.-E. – Cobo, M., et al.: First-line nivolumab plus ipilimumab with two cycles of chemotherapy versus chemotherapy alone (four cycles) in advanced non-small-cell lung cancer: CheckMate 9LA 2-year update. *ESMO Open*, 2021, 6, s. 100273, doi: 10.1016/j.esmo.2021.100273.
 - 33 Brahmer, J. R. – Rodriguez-Abreu, D. – Robinson, A. G., et al.: LBA51-KEYNOTE-024 5-year OS update: first-line (1L) pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score (TPS) ≥ 50%. *Ann Oncol*, 2020, 31, suppl. 4, s. S1142–S1215.

Léčba karcinomu ledviny v roce 2022

doc. MUDr. Tomáš Büchler, Ph.D. Onkologická klinika 1. LF UK a Fakultní Thomayerovy nemocnice, Praha

- 1 Dušek, L. – Mužík, J. – Kubásek, M., et al.: *Epidemiologie zhoubných nádorů v České republice*. Masarykova univerzita, 2005, dostupné z: <http://www.svod.cz>, vyhledáno 3. 3. 2019.
- 2 Choueiri, T. K. – Tomczak, P. – Park, S. H., et al.: Adjuvant pembrolizumab after nephrectomy in renal-cell carcinoma. *N Engl J Med*, 2021, 385, s. 683–694.
- 3 Zhoubný novotvar ledviny (C64). *Modrá Knihy České Onkologické Společnosti*. 28. aktualizace, MOÚ Brno, 2022, platnost od 1. 3. 2022.
- 4 Motzer, R. J. – Tannir, N. M. – McDermott, D. F., et al.: Nivolumab plus ipilimumab versus sunitinib in advanced renal-cell carcinoma. *N Engl J Med*, 2018, 378, s. 1277–1290.
- 5 Rini, B. I. – Powles, T. – Atkins, M. B., et al.: Atezolizumab plus bevacizumab versus sunitinib in patients with previously untreated metastatic renal cell carcinoma (IMmotion151): a multicentre, open-label, phase 3, randomised controlled trial. *Lancet*, 2019, 393, s. 2404–2415.
- 6 Motzer, R. J. – Penkov, K. – Haanen, J., et al.: Avelumab plus axitinib versus sunitinib for advanced renal-cell carcinoma. *N Engl J Med*, 2019, 380, s. 1103–1115.
- 7 Rini, B. I. – Plimack, E. R. – Stus, V., et al.: Pembrolizumab plus axitinib versus sunitinib for advanced renal-cell carcinoma. *N Engl J Med*, 2019, 380, s. 1116–1127.
- 8 Motzer, R. – Alekseev, B. – Rha, S-Y., et al.: Lenvatinib plus pembrolizumab or everolimus for advanced renal cell carcinoma. *N Engl J Med*, 2021, 384, s. 1289–1300.
- 9 Choueiri, T. K. – Powles, T. – Buroto, M., et al.: Nivolumab plus cabozantinib versus sunitinib for advanced renal-cell carcinoma. *N Engl J Med*, 2021, 384, s. 829–841.
- 10 McDermott, D. F. – Huseni, M. A. – Atkins, M. B., et al.: Clinical activity and molecular correlates of response to atezolizumab alone or in combination with bevacizumab versus sunitinib in renal cell carcinoma. *Nat Med*, 2018, 24, s. 749–757.
- 11 Pal, S. K. – Tangen, C. – Thompson, I. M. Jr., et al.: A comparison of sunitinib with cabozantinib, crizotinib, and savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial. *Lancet*, 2021, 397, s. 695–703.
- 12 Lee, C.-H. – Voss, M. H. – Carlo, M. I., et al.: Nivolumab plus cabozantinib in patients with non-clear cell renal cell carcinoma: Results of a phase 2 trial. *J Clin Oncol*, 2021, 39, s. 4509–4509.

Biosimilární bevacizumab v léčivém přípravku Oyavas 25 mg/ml koncentrát pro infuzní roztok

doc. MUDr. Jiří Slíva, Ph.D. Ústav farmakologie, 3. LF UK, Praha

- 1 Hornsi, J. – Daud, A.I.: Spectrum of activity and mechanism of action of VEGF/PDGFR inhibitors. *Cancer Control*, 2007, 14, s. 285–294.
- 2 Borgstrom, P. – Gold, D. P. – Hillan, K. J. – Ferrara, N.: Importance of VEGF for breast cancer angiogenesis in vivo: implications from intravital microscopy of combination treatments with an anti-VEGF neutralizing monoclonal antibody and doxorubicin. *Anticancer Res*, 1999, 19, s. 4203–4214.
- 3 Fernando, N. H. – Hurwitz, H. I.: Inhibition of vascular endothelial growth factor in the treatment of colorectal cancer. *Semin Oncol*, 2003, 30, suppl. 6, s. 39–50.
- 4 Ignoffo, R. J.: Overview of bevacizumab: a new cancer therapeutic strategy targeting vascular endothelial growth factor. *Am J Health Syst Pharm*, 2004, 61, suppl. 5, s. S21–S26.
- 5 Gordon, M. S. – Margolin, K. – Talpaz, M., et al.: Phase I safety and pharmacokinetic study of recombinant human anti-vascular endothelial growth factor. *Cancer*, 2000, 88, s. 2029–2036.
- 6 Lu, J. F. – Bruno, R. – Eppler, S., et al.: Clinical pharmacokinetics of bevacizumab in patients with solid tumors. *Cancer Chemother Pharmacol*, 2008, 62, s. 779–786.
- 7 Garnier-Violette, N. – Rixe, O. – Paintaud, G., et al.: Pharmacokinetics of bevacizumab in haemodialysis. *Nephrol Dial Transplant*, 2007, 22, s. 975.
- 8 Horimatsu, T. – Miyamoto, S. – Morita, S., et al.: Pharmacokinetics of oxaliplatin in a hemodialytic patient treated with modified FOLFOX-6 plus bevacizumab therapy. *Cancer Chemother Pharmacol*, 2011, 68, s. 263–266.
- 9 Garcia, J. – Hurwitz, H. I. – Sandler, A. B., et al.: Bevacizumab (Avastin(R)) in cancer treatment: A review of 15 years of clinical experience and future outlook. *Cancer Treat Rev*, 2020, 86, s. 102017.
- 10 Li, M. – Kroetz, D. L.: Bevacizumab-induced hypertension: Clinical presentation and molecular understanding. *Pharmacol Ther*, 2018, 182, s. 152–160.
- 11 Bevacizumab + sunitinib: microangiopathic haemolytic anaemia. A serious drug interaction between 2 cancer drugs. *Prescrip Int*, 2009, 18, s. 165.
- 12 Kitagawa, Y. – Osumi, H. – Shinozaki, E., et al.: Clinical utility of polyethylene glycol conjugated granulocyte colony-stimulating factor (PEG-G-CSF) for preventing severe neutropenia in metastatic colorectal cancer patients treated with FOLFOXIRI plus bevacizumab: a single-center retrospective study. *BMC Cancer*, 2020, 20, s. 358.
- 13 Nose, Y. – Kagawa, Y. – Hata, T., et al.: Neutropenia is an indicator of outcomes in metastatic colorectal cancer patients treated with FTD/TPI plus bevacizumab: a retrospective study. *Cancer Chemother Pharmacol*, 2020, 86, s. 427–433.