International Research Journal of Pharmacy and Pharmacology
ISSN 2251-0176
2020
Vol.8 No.6

Availability and affordability of novel biological therapy in Serbia for patients with metastatic colorectal cancer

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Abstract

Patients with metastatic colorectal cancer (mCRC) have typically overall survival (OS) of approximately 30 months, if multi disciplinary team approach was applied. The first-line treatment comprises cytotoxic agents, a fluoropyrimidines in various protocols, combined with irinotecan or oxaliplatin. Additional benefit, in the terms of clinical outcome for such patients, is shown by adding the monoclonal antibodies (bevacizumab, as anti-VEGF and cetuximab and panitumumab as anti-EGFR). Second-line treatment comprehends adding the anti-angiogenic fusion protein aflibercept or anti-VEGFR2 antibody ramucirumab to the first line protocols. The third line treatment is multi-targeted kinase inhibitor regorafenib. In Serbia, all cytotoxic drugs and monoclonal antibodies bevacizumab and cetuximab, are reimbursed for mCRC patients. Aflibercept, ramucirumab and regorafenib are not on the National Health Insurance Fund (NHIF) reimbursement list. Therefore, we conducted a retrospective randomized case series study, in the large tertiary health care hospital in Serbia. It was concluded that patients with added reimbursed monoclonal antibodies, had 6-month longer OS in five-year period, associated with significantly higher direct medical costs and ICER that was three-fold higher than informal willingness to pay threshold of Serbia. Costs could be significantly decreased only when bevacizumab biosimilars would be available on the Serbian market, but not prior than in 2022, when European Avastin patent expires. European patent on Erbitux expired in 2014; there aren't any biosimilar competitors in Europe approaching the horizon. Aflibercept is the only third-line treatment option that is registered but not reimbursed in Serbia, and ramucirumab and regorafenib are not registered. As a conclusion, it could be said that novel third-line biological treatment is neither available nor reimbursed for the Serbian patients with mCRC. New patent expiration of the monoclonal antibodies is expecting to allow biosimilar market entry and generate significant savings to the NHIF, which is expected to increase the affordability for mCRC treatment.

Biography:

Aleksandra Kovacevic has completed her PhD in clinical and experimental pharmacology in 2016. She is a pharmacist, specialist for pharmaceutical technology and pharmaco economy. She is an assistant professor of pharmacology and clinical pharmacology at the Military Medical Academy Medical Faculty, University of Defense, Belgrade. She has published more than 35 papers in reputed journals and has been serving as an editorial board member of repute. Viktorija Dragojevic- Simic has completed her PhD in experimental pharmacology and toxicology in 2001. She MD, clinical pharmacologist. She is a full professor in pharmacology and clinical pharmacology at the Military Medical Academy Medical Faculty, University of Defense, Belgrade. She has published more than 100 papers in reputed journals and has been serving as an editorial board member of repute.

Speaker Publications:

1.Aleksandra Kovacevic (2016) Do health reforms impact cost consciousness of Health care professionals? Results from a nation-wide survey in the Balkans 33 (1), 8.

2.Aleksandra Kovacevic (2015) End-of-life costs of medical care for advanced stage cancer patients. Balkan Medical 72 (4), 334-341.
3.Aleksandra Kovacevic (2015) Tacrolimus concentration/dose ratio as a therapeutic drug monitoring strategy: the influence of gender and comedication . Vojnosanitetski pregled 72 (9), 813-822.
4.Aleksandra Kovacevic (2018) The efficacy of amifostine against multiple-dose doxorubicin-induced toxicity in rats. International journal of molecular sciences 19 (8), 2370.

33rd World Congress on Pharmacology; Webinar -August 26-27, 2020.

Abstract Citation:

Aleksandra Kovacevic, Availability and affordability of novel biological therapy in Serbia for patients with metastatic colorectal cancer, Pharmacology 2020, 33rd World Congress on Pharmacology; Webinar - August 26-27, 2020.

(https://pharmacology.pharmaceuticalconferences.com/abstract/2020/availability-and-affordability-of-novel-biological-therapy-in-serbia-for-patients-with-metastatic-colorectal-cancer)