

11<sup>th</sup> World Congress on

# BIOSIMILARS AND BIOLOGICS

May 20-21, 2019 | Miami, USA



## Sandra Simic

Ewopharma, Croatia

### Role of biologics in treatment of IBD

**B**iologics that target autoimmune responses and inflammatory injury pathways have a marked beneficial impact on the management of many chronic diseases, including rheumatoid arthritis, psoriasis, ankylosing spondylitis and inflammatory bowel disease. Crohn disease (CD) and ulcerative colitis (UC) belong to chronic inflammatory bowel diseases, which are induced by autoimmune processes. While CD is characterized by over-activity of Th1, ILC1, and MAIT cells, UC is mediated by exaggerated activities of Th2 and ILC2 cells and cytokines they produce. Knowledge of the pathogenesis enabled a rational therapy based mostly on biologics and small molecules. The use of biologic therapies for the treatment of IBD is rapidly expanding, owing to the good efficacy and safety profiles of these drugs, and the better understanding of the initial targets of altered immune regulation and activity. The major targets of most biologic therapies are cytokines, B cells, and co-stimulation molecules. Anti-cytokines include anti-tumor necrosis factor (TNF)- $\alpha$ , anti-interleukin (IL)-1, and anti-IL-6 molecules. B-cell depletion includes use of anti-CD20

antibodies and B cell receptor (BCR) modulation by the B-lymphocyte stimulator (BLyS). TNF is the principal proinflammatory cytokine in both diseases (CD and UC). Anti-TNF monoclonal antibodies, mostly infliximab or adalimumab were therefore introduced to their treatment. Approximately 50-70 % of CD and more than 33 % of UC patients respond to primary treatment only, which resulted in the development of other biologics and small molecules. Out of them, monoclonal antibodies targeting adhesive molecules (vedolizumab, etrolizumab) and p40 chains shared by IL12 and IL23 (ustekinumab) have been already in clinical practice. There are also other small molecules in clinical trials: mongsersen, tafacitinib, and ozanimod. Mongsersen supports immunosuppressive activity of TGF $\beta$ ; it has been tried for the treatment of CD. Tafacitinib inhibits activity of JAK kinases; it was shown to be effective in UC management. Ozanimod interferes with migrations of activated T cells to the site of inflammation and is a promising drug for the UC treatment.

### Biography

Sandra Simic is graduated pharmacist from University of Pharmacy and biochemistry Zagreb, Croatia and holds international accredited MBA postgraduate diploma from COTRUGLI Business School. She started her career in pharmaceutical industry 14 years ago and has been in charge of several positions included project management, key account, marketing and sales management. She has extensive experience in marketing and sales of original biologics (adalimumab and vedolizumab) in European markets. Currently she works as Biogen Biosimilars Commercial Lead in company Ewopharma which is representative partner for Biogen biosimilars program in central and eastern Europe— and is responsible for commercial operations of 3 Biogen TNF- $\alpha$  inhibitors in Croatian market.

[sandra.simic123@gmail.com](mailto:sandra.simic123@gmail.com)