First Clinical Experience with Infliximab Biosimilar Remsima for Crohn's Disease Patient in Latvia

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Introduction. In previous decades, inflammatory bowel disease (IBD) patients had lack of effective treatment options, but there have been significant advances in the understanding of IBD etiopathogenesis and the ability to treat patients suffering from this disease. One of the breakthrough observations over the past two decades was the identification of the critical role of tumor necrosis factor alpha (TNFα) in the treatment of Crohn's disease (CD). The first biologic agent approved for CD was infliximab, a humanised chimeric monoclonal antibody that binds to TNFα and causes apoptosis of macrophages and activated T-lymphocytes. Remsima is the first infliximab biosimilar available now in Latvia. Unfortunately there are no clinical trials with biosimilar infliximab.

Aim. The aim of the study is to demonstrate the first clinical experience with infliximab biosimilar Remsima treatment for CD.

Material and Methods. This is a prospective observation study of a 19-year old male with Crohn's disease (A1L2B3) not responding to basic treatments, due to which infliximab biosimilar Remsima infusions started. From past history: In November 2012 colonoscopy biopsy revealed Crohn's disease manifestation in colon and caecum and terminal ileitis. He was operated due to paraproctitis and pararectal fistula. The patient suffered from abdominal pain, fever, diarrhea (~ 10 times/day), loss of weight (BMI = 13.3), malnutrition, inanition, hypoproteinemia, chronic iron deficiency anemia, arthalgies. During 2 years Sulfasalazine, Mesalazine, Budesonide, Azathioprin, Metronidazole, Ciprofloxacin therapy have been tried with clear worsening indicators. The patient started to receive Remsima infusions. Responses were recorded based on the physician's global clinical assessment, physical examinations and laboratory findings.

Results. The patient was treated with one to four infusions of infliximab biosimilar Remsima at a dose of 300 mg. After the first infusion on July 14, on the third day the patient denied any complains of abdominal pain, in addition he became more active. After 2 weeks the patient received second infusion of Remsima and the diarrhea reduced to 4 times/day. After the third infusion in the 6th week there was an improvement in nutritional status and clinical conditions of the patient. BMI increased to 17.3. Due to rash all over the body and itching that appeared in the 5th week, the patient did not received the next infusion in November. Faecal calprotectin at that time was > 1000 and it was observed as a negative dynamic in the clinical status of the patient. The fourth infusion of Remsima was injected with steroids on December 21. As a result there was an improvement in the patient's clinical symptoms.

Conclusions. The patient in the present case report realized significant clinical benefit, with minimal side effects, following treatment with infliximab biosimilar. The preliminary data are supportive for this medicinal product inclusion in the broader clinical practice.