

Production of biosimilar romiplostim

Mohadeseh Haji Abdolvahab*, Sedigheh Kolivand and Neda Jalili

Motamed Cancer Institute, Iran

Immune thrombocytopenia (ITP) is an autoimmune disorder that causes the body's immune system to destroy its own platelets. Platelets are cells in the blood that stop bleeding and form blood clots. A very low platelet count can cause severe bruising and bleeding. Since many patients become resistant to standard treatments (corticosteroids, danazol, azathioprine, splenectomy), there is an urgent need for alternative treatments. Researchers used various recombinant drugs to cure this disease, all of which were unsuccessful for some reason, until increasing the half-life of therapeutic peptides by combining them with the crystalline structures of the antibody fragment (Fc) led to the creation of a new family of molecules called "peptide antibodies".

The 60 kDa recombinant Romiplostim peptide was finally generated by linking multiple copies of an active TPO-binding peptide sequence to a carrier Fc fragment.

In clinical trials, romiplostim was effective in improving thrombocytopenia in patients with chronic ITP, was well tolerated, and did not induce cross-reacting antibodies. Romiplostim was recently approved for the treatment of adults with chronic ITP. Romiplostim, sold worldwide under the brand name Nplate, is a fusion protein analog of thrombopoietin (TPO) that binds to the human TPO receptor and activates intracellular transcriptional pathways through c-Mpl to increase platelet production. This drug is now a monopoly of America and is produced by Amgen pharmaceutical company. The high cost of this drug in Iran and the lack of access to all patients, the need to localize this drug is strongly felt.

Keywords: Immune thrombocytopenia (ITP), Autoimmunity, Romiplostim, Recombinant Protein, Fusion Protein

Biography

Mohadeseh Haji Abdolvahab is graduated from Utrecht University, the Netherlands in the field of Pharmaceutical Biotechnology. After that he continued his research as a postdoc at NCBI, Radboud UMC, the Netherlands. Then, he worked at MSD and followed by Amgen as a BCR specialist and scientist, respectively, to enhance his experiences in Pharmaceutical industry. After that, he returned to Iran and completed another postdoctoral at Tarbiat Modares University. Currently he is working as an assistant professor in Motamed Cancer Research Institute. As a head of recombinant protein group, he is working on different biosimilar projects.

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