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Enzene obtains marketing authorisation for Romiplostim biosimilar drug in India

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For the treatment of chronic Immune Thrombocytopenic Purpura in adults



Enzene Biosciences, a subsidiary of Alkem Laboratories, has announced a successful Marketing Authorization (MA) from the Drug Controller General of India (DCGI) for its second biosimilar drug 'Romiplostim', indicated for the treatment of chronic Immune Thrombocytopenic Purpura (ITP) in adults.

In doing so, Enzene becomes the only biopharmaceutical company in India to offer all three dosage strengths of the drug (125mcg, 250mcg, and 500mcg).

ITP is a rare haematological disorder (prevalently autoimmune) with a primary clinical presentation of aberrantly low platelet levels, and symptoms including an increased bruising and bleeding tendency.

Romiplostim, a therapeutic fusion protein, acts as a thrombopoiesis stimulating factor, thereby restoring platelet levels and ameliorating the disease. As such, it remains one of the most reliable long-term treatment options for ITP patients.

Dr Himanshu Gadgil, Whole Time Director, Enzene said, "With the approval of Enzene's Romiplostim drug in India, we are happy to bring this life-saving therapy to ITP patients. Enzene is now actively developing strategic partnerships to further expand global access to this therapy."