



## **Shilpa Medicare Limited**

### **Corporate & Admin Office:**

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CIN: L85110KA1987PLC008739

**Date: 28 January 2026**

To,

Corporate Relationship Department,  
BSE Limited  
Phiroze Jeejeebhoy Towers,  
Dalal Street, Fort,  
**Mumbai-400 001**

National Stock Exchange of India Ltd.  
Exchange Plaza, 5<sup>th</sup> Floor,  
Plot No.C/1, G Block  
Bandra Kurla Complex, Bandra (E)  
**Mumbai-400 051**

**Stock Code: NSE: SHILPAMED/BSE-530549**

Dear Sir/Madam,

**Sub: Press Release**

**Ref: - Intimation under Regulation 30 of the SEBI (LODR) Regulations, 2015**

Pursuant to Regulation 30 read with other applicable provisions of the SEBI Listing Regulations, please find enclosed a press release of Shilpa Biologicals Pvt Ltd., a Material Subsidiary of Shilpa Medicare Ltd., and mAbTree Biologics on achieving a Major U.S. FDA Milestone as Flagship Breakthrough Biologic Secures Orphan Drug Designation for Rare Blood Cancers.

This information is also available on the website at [www.vbshilpa.com](http://www.vbshilpa.com)

This is for your information and records.

**For SHILPA MEDICARE LIMITED**

**Ritu Tiwary**  
**Company Secretary & Compliance Officer**

## Shilpa Medicare and mAbTree Biologics receive FDA Orphan Drug Designation, Advancing Treatment for Rare Blood Cancers

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Basel, Switzerland and Raichur, India - January 28, 2026

**Shilpa Biologicals Pvt Ltd**, a part of the **Shilpa Medicare Group**, together with **mAbTree Biologics AG**, today announced a major regulatory milestone as the **U.S. Food and Drug Administration (FDA)** granted **Orphan Drug Designation (ODD)** to their **flagship breakthrough biologic product**, an investigational monoclonal antibody being developed for the treatment of **Essential Thrombocythemia (ET)** and **Polycythemia Vera (PV)**—rare, chronic blood cancers with significant unmet medical need.

The Orphan Drug Designation recognizes both the seriousness of ET and PV and the **potential of this first-in-class, immunology-driven biologic** to modify disease progression rather than merely manage symptoms. The designation provides meaningful regulatory and commercial incentives, including **development support, tax credits, and market exclusivity upon approval**.

“This milestone marks a defining moment for Shilpa’s Biologics journey and validates the strength of our collaboration with mAbTree Biologics,” said **Dr. Sridevi, Chief Executive Officer of Shilpa Biologicals Pvt. Ltd.** “The FDA’s recognition of our flagship biologic underscores the quality of the science and our ability to translate innovation into globally relevant critical care programs. We are advancing rapidly toward clinical development and see strong potential beyond rare blood cancers.”

Patients with ET and PV often require lifelong treatment. Existing therapies—including aspirin, interferon-alpha, hydroxyurea, and JAK inhibitors—have improved disease management; however, **a significant proportion of patients become refractory or intolerant over time**, reinforcing the need for therapies that directly address disease biology.

“Receiving Orphan Drug Designation from the FDA is a strong validation of the differentiated mechanism behind this program,” said **Raj Andhuvan, Chief Executive Officer of mAbTree Biologics AG.** “By targeting immune dysregulation—now recognized as a central driver of disease persistence in myeloproliferative neoplasms—this biologic has the potential to establish a new therapeutic paradigm in rare blood cancers.”

The investigational biologic targets a **previously underexplored immune-evasion pathway implicated in MPN biology**, offering the potential for **durable disease control** and a **clearly differentiated clinical profile**. Following this regulatory milestone, **Shilpa Biologicals and mAbTree Biologics AG will advance the program through IND-enabling studies**, with the objective of initiating **first-in-human clinical trials** in patients with ET and PV.

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## About Shilpa Biologicals Pvt Ltd

Shilpa Biologicals, part of the **Shilpa Medicare Group**, is a global biopharmaceutical company with **end-to-end capabilities in biologics discovery, development, and manufacturing**, focused on building a pipeline of innovative and globally competitive biologics.

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## About mAbTree Biologics AG

mAbTree Biologics AG is a Basel-based biotechnology company focused on the discovery and development of **next-generation immunology-driven biologics** for patients with serious and underserved diseases.