Press Release

DR. REDDY'S LABORATORIES LTD.
8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CONTACT	
INVESTOR RELATIONS	**MEDIA RELATIONS**
AISHWARYA SITHARAM AISHWARYASITHARAM@DRREDDYS.COM	PRIYA K PRIYAK@DRREDDYS.COM

Dr. Reddy's receives European Commission Approval for AVT03 (denosumab), a Proposed Biosimilar of Prolia® and Xgeva®

Hyderabad India; November 24, 2025– Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; along with its subsidiaries together referred to as "Dr. Reddy's"), today announced that the European Commission (EC) has granted marketing authorization for AVT03, a biosimilar of Prolia® (denosumab) and Xgeva® (denosumab).

Prolia® is a prescription medicine used to treat osteoporosis in women who have been through menopause and in men who are at increased risk of fractures, bone loss linked to hormone ablation in men with prostate cancer at increased risk of fractures and bone loss associated with long-term treatment with systemic glucocorticoid [1]. Xgeva® is a prescription medicine used to prevent bone complications in adults with advanced cancer involving bone and for the treatment of adults and skeletally mature adolescents with giant cell tumour of bone [2].

The EC decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) adopted in September 2025 and was based on a totality of evidence, including analytical comparisons, pharmacokinetic and pharmacodynamic data, and outcomes from a confirmatory clinical trial. The EC decision is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

In May 2024, Dr. Reddy's and Alvotech entered into a license and supply agreement for the commercialization of AVT03. Under the agreement, Alvotech will develop and manufacture AVT03, while Dr. Reddy's is responsible for registration and commercialization in applicable markets, including the U.S. and Europe. Dr. Reddy's commercialization rights are exclusive for the U.S., and semi-exclusive for Europe and the UK. Upon approval Dr. Reddy's will offer the biosimilar under the tradenames Acvybra® (denosumab) 60 mg/mL solution for injection in a pre-filled syringe and Xbonzy® (denosumab) 70 mg/mL solution for injection in a vial.

About AVT03

AVT03 is a human monoclonal IgG2 antibody and biosimilar candidate to Prolia® and Xgeva®, which are both denosumab but in different presentations. Denosumab targets and binds with high affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from

occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction[1].

References

1. Amgen Inc. Prolia® (Denosumab): Prescribing Information. Downloaded from: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Prolia/prolia_pi.pdf

2. Amgen Inc. Xgeva® (Denosumab): Prescribing Information. Downloaded from: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/xgeva/xgeva_pi.pdf

Use of trademarks

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance.

Over the last 25 years, our Biologics team has developed into a fully integrated organization with robust capabilities in the development, manufacture and commercialization of a range of biosimilar products in oncology and immunology. We have a current portfolio of six commercial products marketed in India, with some products marketed in more than 30 other countries. In addition, we have several products in the pipeline in oncology and auto-immune diseases in various stages of development for global launches across developed as well as emerging markets. We are also ramping up manufacturing capacity to support our global expansion plans. In 2024, we launched our first biosimilar in the United Kingdom, Versavo® (biosimilar bevacizumab). This follows our launch of pegfilgrastim in the U.S and Europe through our partner. Our biosimilars business has a key role to play in driving both near-term and long-term growth.

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