## **Press Release**



## DR. REDDY'S LABORATORIES LTD.

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## Dr. Reddy's enters into collaboration with Henlius for commercialization of HLX15 (daratumumab), a biosimilar candidate to Darzalex® & Darzalex Faspro® in the U.S., and Europe

Dr. Reddy's gets exclusive rights to commercialize the subcutaneous as well as intravenous formulations of HLX15 in the U.S. and Europe

**Hyderabad, India; February 06, 2025-** Dr. Reddy's Laboratories SA, wholly-owned subsidiary of Dr. Reddy's Laboratories Ltd. (BSE: 500124 | NSE: DRREDDY | NYSE: RDY | NSEIFSC: DRREDDY, along with its subsidiaries hereafter referred to as "Dr. Reddy's"), today announced that it has entered into a license agreement with Shanghai Henlius Biotech, Inc. (2696.HK) related to the development and commercialization of HLX15, Henlius's investigational daratumumab biosimilar candidate to Darzalex® & Darzalex Faspro®.

HLX15 is a recombinant anti-CD38 fully human monoclonal antibody injection, with intravenous as well as subcutaneous formulations. HLX15 is being developed as a biosimilar of Darzalex® & Darzalex Faspro®\*, which are indicated for the treatment of multiple myeloma.

The agreement combines Dr. Reddy's global commercial presence with Henlius' proven capabilities in developing biosimilars for markets worldwide. Under the terms of the agreement, Henlius will be responsible for development, manufacturing and commercial supply, and may receive up to a total of \$131.6 million, including an upfront payment of \$33 million and milestone payments. In addition, Henlius is eligible to receive royalties on annual net sales of the product. Dr. Reddy's gets exclusive rights to commercialize the subcutaneous as well as intravenous formulations of HLX15 in the United States (U.S.) and Europe.

Erez Israeli, Chief Executive Officer of Dr. Reddy's, said: "We are pleased to collaborate with Henlius to make this daratumumab biosimilar available to patients in the U.S. and Europe. Over the years, we have created a portfolio of biosimilar products that are being marketed in several emerging markets. The launch of our pegfilgrastim through our collaborator in the U.S. in 2023, and bevacizumab in the United Kingdom last year marked the start of our biosimilars journey in regulated markets. Last year, we also signed a collaboration with Alvotech for the commercialization of their denosumab biosimilar in the U.S. and Europe. This latest collaboration with Henlius further progresses our regulated markets journey in biosimilars. Additionally, oncology has been a top focus therapy area for us. We look forward to leveraging

our strong commercial capabilities in these markets to ensure patients receive access to best-in-class therapies and affordable treatment options."

"This collaboration with Dr. Reddy's on HLX15 is a significant step in our response to global health needs and improving access to advanced biologics," <u>said Dr. Jason Zhu, Executive Director and Chief Executive Officer of Henlius.</u> "Dr. Reddy's has a long-standing dedication to oncology, driven by the purpose of 'Good Health Can't Wait', and is committed to timely access to affordable and high-quality medicines, which complement Henlius' focus on addressing unmet medical needs in research and development. We are confident that this partnership will enhance the global market competitiveness of both organizations in oncology treatment, ultimately allowing us to reach and support more patients around the world."

## **About HLX15:**

HLX15 is a fully human anti-CD38 IgG1κ monoclonal antibody independently developed by Henlius, and is a biosimilar candidate to Darzalex® & Darzalex Faspro®\*. In accordance with the biosimilar guidelines of NMPA, EMA, and USFDA, HLX15 is being developed following the principles of stepwise development. HLX15 and reference daratumumab are considered comparable based on analytical similarity assessment and pre-clinical studies. In June 2024, the Phase 1 clinical study (NCT05679258) of HLX15 was successfully completed, meeting its primary endpoint. The findings indicate that HLX15 had similar pharmacokinetic characteristics, as well as comparable safety and immunogenicity profiles to the US-, EU-, and CN-sourced daratumumab. Comparative efficacy studies are currently underway.

\*Darzalex® & Darzalex Faspro® are registered trademarks of Johnson & Johnson.

About Henlius: Henlius (2696.HK) is a global biopharmaceutical company with the vision to offer high-quality, affordable and innovative biologic medicines for patients worldwide with a focus on oncology, autoimmune diseases and ophthalmic diseases. Up to date, 6 products have been launched in China, 4 have been approved for marketing in overseas markets, and 4 marketing applications have been accepted for review in China, the U.S. and the EU, respectively. Since its inception in 2010, Henlius has built an integrated biopharmaceutical platform with core capabilities of high-efficiency and innovation embedded throughout the whole product life cycle including R&D, manufacturing and commercialization. It has established global innovation centre and Shanghai-based commercial manufacturing facilities certificated by China, the EU and U.S. GMP. Henlius has pro-actively built a diversified and high-quality product pipeline covering over 50 molecules and has continued to explore immuno-oncology combination therapies with proprietary HANSIZHUANG (anti-PD-1 mAb) as the backbone. To date, the company's launched products include HANLIKANG (rituximab), the first China-developed biosimilar, HANQUYOU (trastuzumab, trade name: HERCESSI™ in the U.S., Zercepac® in Europe), a China-developed mAb biosimilar approved in China, Europe and U.S., HANDAYUAN (adalimumab), HANBEITAI (bevacizumab), HANSIZHUANG (serplulimab, trade name: Hetronifly® in the EU), the world's first anti-PD-1 mAb for the first-line treatment of SCLC, and HANNAIJIA (neratinib). What's more, Henlius has conducted over 30 clinical studies for 16 products, expanding its presence in major markets as well as emerging markets. To learn more about Henlius, visit https://www.henlius.com/en/index.html and connect with us on LinkedIn at https://www.linkedin.com/company/henlius/.

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. For more information, log on to: <a href="https://www.drreddys.com">www.drreddys.com</a>.

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Disclaimer: This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults, currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2024. The company assumes no obligation to update any information contained herein.