

## DR. REDDY'S LABORATORIES LTD.

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## Dr. Reddy's successfully completes full set of clinical studies of its rituximab biosimilar for filing in the U.S., Europe

- *Following successful completion of full set of clinical studies of proposed rituximab biosimilar candidate DRL\_RI, Dr. Reddy's will now prepare to file in the United States, European Union and other regions*

**Hyderabad, India; January 20, 2023** – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; hereafter referred to as "Dr. Reddy's"), a global pharmaceutical company, announced that it has successfully completed the full set of clinical studies of its proposed rituximab biosimilar candidate, DRL\_RI, for filing in highly regulated markets such as the United States, Europe and other regions.

DRL\_RI is being developed as a biosimilar of rituximab, a cluster of differentiation 20 (CD20) directed cytolytic antibody for approval in the United States, European Union and other regions for various indications including treatment of adult patients with rheumatoid arthritis, non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, pemphigus vulgaris, granulomatosis with polyangiitis and microscopic polyangiitis.

Dr. Reddy's rituximab biosimilar has already been approved for marketing in India and over 25 emerging markets. The company undertook further clinical development to meet regulatory requirements of highly regulated markets. With the successful completion of these clinical studies, Dr. Reddy's is now preparing to file Biologics License Application (BLA) / Marketing Authorisation Application (MAA) dossiers with various regulatory authorities globally.

**Dr. Jayanth Sridhar, Global Head of Biologics at Dr. Reddy's, said:** "This is a very important milestone in our biosimilars journey. The successful completion and positive outcome of these clinical studies highlights our capability for global clinical development of biosimilar products for highly regulated and global markets. These results underscore our commitment to developing high quality biosimilars and reinforce the potential of DRL\_RI as a safe and effective treatment option to patients across the globe."

Dr. Reddy's is currently collaborating with its partner Fresenius Kabi to commercialise its proposed biosimilar of rituximab in the United States. The company intends to commercialise the product in Europe and other geographies directly.

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### About Dr. Reddy's clinical studies for its proposed biosimilar of rituximab, DRL\_RI:

1. RI-01-003: This study demonstrated pharmacokinetic equivalence and similarity in pharmacodynamics, safety and immunogenicity between DRL\_RI and EU reference medicinal product\* and U.S. reference product\*\*.
2. RI-01-006 (FLINTER): This study demonstrated efficacy equivalence and similarity in safety and immunogenicity between DRL\_RI and EU reference medicinal product\* in patients with Low Tumour Burden Follicular Lymphoma
3. RI-01-007: This study demonstrated similar safety and immunogenicity profile between the DRL\_RI, EU reference medicinal product\* and U.S. reference product\*\* groups upon single transition from either of them, in subjects with active rheumatoid arthritis.

\*EU reference medicinal product is MabThera®

\*\*U.S. reference product is Rituxan®

MabThera® and Rituxan® are registered trademarks of Roche.

### About Dr. Reddy's biosimilars programme:

Dr. Reddy's biosimilars business is part of our key strategic initiatives expected to drive both near-term and future growth. Over the last 20 years, our Biologics team has developed into a fully integrated organisation with robust capabilities in the development, manufacture and commercialisation of a range of biosimilar products in oncology and immunology. We have a current portfolio of six commercial products marketed in India and over 25 Emerging Markets. In addition, we have several products in the pipeline in oncology and auto-immune diseases in various stages of development for global launches across regulated as well as emerging markets. We recently announced the successful completion of Phase I study and initiation of Phase III study of DRL\_TC, our proposed biosimilar of tocilizumab, for global markets. We are also ramping up manufacturing capacity to support our global expansion plans.

**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: [www.drreddys.com](http://www.drreddys.com).

**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

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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, 2022. The company assumes no obligation to update any information contained herein.