

DR. REDDY'S LABORATORIES LTD.

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CONTACT

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Dr. Reddy's proposed rituximab biosimilar application accepted for review by USFDA, EMA and MHRA

- In January 2023, the company had announced the successful completion of the full set of clinical studies of its proposed rituximab biosimilar candidate DRL_RI, with the intention to file in the United States, European Union and other regions*
- Following dossier submission in April 2023, the regulatory agencies have now accepted the dossier for review*

Hyderabad, India; July 12, 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 its Biologics License Application (BLA) for its proposed biosimilar rituximab candidate DRL_RI has been accepted for a substantive review by the U.S. Food and Drug Administration (USFDA). This closely follows acceptance of its rituximab biosimilar dossier for review by two other regulatory agencies – the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).

In January 2023, [Dr. Reddy's had announced](#) the successful completion of 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, European Union, and other regions. The submission of its dossier in April 2023 was based on a comprehensive data package including robust structural and functional analytical comparison data using multiple orthogonal techniques, pre-clinical, and head-to-head clinical studies that demonstrate similarity in pharmacokinetics, pharmacodynamics, safety, efficacy and immunogenicity with the EU* and U.S.** reference products.

DRL_RI is being developed as a biosimilar of Rituxan® / MabThera® (rituximab), a cluster of differentiation 20 (CD20) directed cytolytic antibody. Rituxan® / MabThera® is approved for various indications including for the treatment of adult patients with rheumatoid arthritis, non-Hodgkin's lymphoma, chronic lymphocytic leukemia, pemphigus vulgaris, granulomatosis with polyangiitis and microscopic polyangiitis.

Dr. Jayanth Sridhar, Global Head of Biologics at Dr. Reddy's, said: "This milestone underscores our capability for global clinical development of high-quality biosimilar products for highly regulated and global markets. It also reinforces the potential of DRL_RI as a safe and effective treatment option for patients across the globe. Development and commercialisation of biological drugs is an important growth lever for our business. We expect

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to bring many more biosimilar and other critical biological products to meet patient needs as we work towards our goal of serving over 1.5 billion patients by 2030.”

Dr. Reddy's rituximab biosimilar has already been approved for marketing in India and over 25 emerging markets. The company is currently collaborating with its partner Fresenius Kabi, a global health care company that specializes in biopharmaceuticals, clinical nutrition, medical technologies, and I.V. generic drugs for critical and chronic conditions, to commercialise its proposed biosimilar of rituximab in the United States. The company intends to commercialise the product in Europe and other geographies directly.

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 long-term 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 27 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. Recently, we announced the successful completion of Phase I study and initiation of Phase III study of DRL_TC, our proposed biosimilar of tocilizumab via both the subcutaneous and intravenous routes, for global markets. We are also ramping up manufacturing capacity to support our global expansion plans.

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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. For more information, log on to: 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 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, 2023. The company assumes no obligation to update any information contained herein.