

DR. REDDY'S LABORATORIES LTD.

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Dr. Reddy's successfully completes Phase 1 study of DRL_TC, a proposed biosimilar of tocilizumab

- *Tocilizumab is an important anti-rheumatic agent used in the treatment of adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs)*
- *Phase 1 study conducted by Dr. Reddy's demonstrated pharmacokinetic equivalence and similarity in pharmacodynamic parameters, safety and immunogenicity between Dr. Reddy's proposed biosimilar candidate (DRL_TC) and European Union (EU) reference medicinal product* and United States (U.S.) reference product***
- *Global Phase 3 study is being initiated to compare efficacy, safety, tolerability and immunogenicity of DRL_TC with the reference product*

Hyderabad, India; December 19, 2022 – 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 tocilizumab biosimilar candidate, DRL_TC, successfully met its primary and secondary endpoints in a Phase 1 study. This Phase 1 study used a subcutaneous formulation to evaluate the pharmacokinetic equivalence, safety and immunogenicity of Dr. Reddy's tocilizumab biosimilar candidate in comparison to reference products.

The Phase 1 study entitled 'A Single Dose, Double-Blind, Two-Period, Crossover, Comparative Pharmacokinetic Study of Three Tocilizumab Products Administered by the Subcutaneous Route to Normal Healthy Volunteers' met all primary and secondary endpoints. Pharmacokinetic equivalence of DRL_TC to the EU reference medicinal product* and the U.S. reference product** was successfully demonstrated. The clinical trial also confirmed the similarity between DRL_TC and the EU* and U.S.** reference products in terms of pharmacodynamic parameters and found no noteworthy differences in safety and immunogenicity across these three treatment groups.

The successful outcome of this study represents an important milestone in Dr. Reddy's commitment to making high-quality biosimilar products more accessible and affordable to healthcare providers and patients around the world. Dr. Reddy's is developing the proposed tocilizumab biosimilar as both subcutaneous and intravenous formulations.

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Jayanth Sridhar, Global Head of Biologics at Dr. Reddy's, said: "Tocilizumab is an important anti-rheumatic agent that has a unique place in treating patients with rheumatoid arthritis and other diseases. We are excited to continue our journey in developing this biosimilar and making this product affordable to patients across the globe. My congratulations to the team especially for the way they navigated multiple challenges during the COVID-19 period in conducting the trial. We look forward to following this up with other agents that solve for critical patient needs in the auto-immune disease area."

The company is initiating a global Phase 3 study with the aim of comparing the efficacy, safety, tolerability and immunogenicity of DRL_TC with the reference product in patients with moderate to severe active rheumatoid arthritis.

*EU reference medicinal product is RoActemra®

**U.S. reference product is Actemra®

Actemra® and RoActemra® are registered trademarks of Chugai Seiyaku Kabushiki Kaisha Corp., a member of the Roche Group.

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. In 2007, Dr. Reddy's launched the world's first biosimilar rituximab in India under the brand name Reditux. 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. This includes the imminent Biological Product Licence Application filing for Rituximab in regulated 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.

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",

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