Press Release

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Dr. Reddy's successfully completes Phase I study (IV route) 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 I 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** by the intravenous route (IV)***
- ***In December 2022, the company had announced the successful completion of the Phase I study of DRL_TC via the subcutaneous route***
- ***Global Phase III study is being initiated to compare efficacy, safety, tolerability and immunogenicity of DRL_TC with the reference product***

Hyderabad, India; June 05, 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 tocilizumab biosimilar candidate, DRL_TC, successfully met its primary and secondary endpoints in a Phase I study. This Phase I study used an intravenous (IV) formulation to evaluate the pharmacokinetic equivalence, safety and immunogenicity of Dr. Reddy's tocilizumab biosimilar candidate in comparison to reference products.

The Phase I study entitled 'A Phase I, Double Blind, Randomized, Parallel-group, Single dose, Three arm, Comparative Pharmacokinetic and Pharmacodynamic Study of Dr. Reddy's Tocilizumab (DRL_TC), USA sourced Reference Tocilizumab (Actemra®) and EU sourced Reference Tocilizumab (RoActemra®) Administered by the Intravenous Route to Normal Healthy Male 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 make high-quality biosimilar products more accessible and affordable to healthcare providers and patients around the world.

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Dr. Reddy's is developing the proposed tocilizumab biosimilar as both intravenous and subcutaneous formulations.

Dr. 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. By developing the formulation in both subcutaneous and intravenous formulations, we aim to reach more patients around the world. With our recent milestones in our proposed biosimilars of tocilizumab and rituximab, our partner's launch of pegfilgrastim in the U.S and Europe, we look forward to maintaining our momentum as part of our goal to serve over 1.5 billion patients by 2030."

Dr Reddy's has already demonstrated pharmacokinetic equivalence and similarity in pharmacodynamic parameters, safety and immunogenicity by subcutaneous route. The company is now initiating a global Phase III 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 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. In December 2022, we announced the successful completion of Phase I study and initiation of Phase III study of DRL_TC, our proposed biosimilar of tocilizumab via the subcutaneous route, for global markets. In January 2023, we announced the successful completion of the full set of clinical studies of our rituximab biosimilar for filing in the U.S. and Europe. We are also ramping up manufacturing capacity to support our global expansion plans.

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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.

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