

DR. REDDY'S LABORATORIES LTD.

8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CONTACT	
INVESTOR RELATIONS	MEDIA RELATIONS
AISHWARYA SITHARAM AISHWARYASITHARAM@DRREDDYS.COM	PRIYA K PRIYAK@DRREDDYS.COM

Dr. Reddy's announces USFDA acceptance to review its Biologics License Application (BLA) for proposed interchangeable biosimilar, Abatacept

- *Following the submission in December 2025, USFDA has accepted Dr. Reddy's 351(k) Biologics License Application (BLA) for Proposed Interchangeable biosimilar Abatacept, DRL_AB (IV for Infusion)*
- *BLA is based on a robust data package supporting similarity to Orencia® (abatacept) IV for infusion through totality of evidence including pharmacokinetic (PK) data*

Hyderabad, India, February 20, 2026 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's"), today announced that the US Food and Drug Administration (USFDA) has accepted for review, its 351 (k) Biologics License Application (BLA) IV for infusion formulation for DRL_AB, a proposed interchangeable biosimilar to ORENCIA® (abatacept) that was submitted in December 2025.

"We are proud to be the first to submit a BLA for an abatacept biosimilar which marks a significant milestone in our mission to increase patient access to critical, high-quality biologic therapies," said Milan Kalawadia, CEO, North America, at Dr. Reddy's. "We look forward to working with the FDA to bring this in-house developed biosimilar to market as a cost-effective alternative for patients and healthcare providers in the United States."

DRL_AB, once approved will be administered as an IV for infusion formulation for the treatment of adults with moderately-to-severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), and individuals aged six years and above with moderately-to-severely active polyarticular juvenile idiopathic arthritis (pJIA). The 351 (k) BLA submission includes a comprehensive data package consisting of analytical, pharmacokinetic (PK), and clinical studies.

DRL_AB Clinical Milestones:

1. Phase 1 study (AB-01-003), achieved Pharmacokinetic similarity with comparable safety and immunogenicity profiles with Orencia.
2. Pivotal Phase 3 study (AB-01-004), to compare the efficacy and safety of DRL_AB with Orencia [ongoing].

About DRL_AB

DRL_AB is a proposed biosimilar to Orencia® (abatacept) IV for infusion, a selective co-stimulation modulator, inhibits T-cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a costimulatory signal necessary for full activation of T

lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of RA, pJIA and PsA and are found in the synovium of patients with RA, pJIA and PsA.

References: [Orencia® \(abatacept\) Prescribing Information](#)

https://packageinserts.bms.com/pi/pi_orencia.pdf*

*Dr. Reddy's DRL_AB is not currently seeking approval for prophylactic treatment of aGVHD.

The reference product, Orencia® (abatacept), is a registered trademark owned by Bristol-Myers Squibb Company.

RDY-0226-BIO

.....
.....
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.

Over the last 25 years, our Biologics team has developed into a fully integrated organization with robust capabilities in the development, manufacture and commercialization of a range of biosimilar products in oncology and immunology. We have a current portfolio of six commercial products marketed in India, with some products marketed in more than 30 other countries. In addition, we have several products in the pipeline in oncology and auto-immune diseases in various stages of development for global launches across developed as well as emerging markets. We are also ramping up manufacturing capacity to support our global expansion plans. In 2024, we launched our first biosimilar in the United Kingdom, Versavo® (biosimilar bevacizumab). This follows our launch of pegfilgrastim in the U.S and Europe through our partner. We also launched our rituximab biosimilar in Europe in 2025. Our biosimilars business has a key role to play in driving both near-term and long-term growth.

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, 2025. The company assumes no obligation to update any information contained herein.