Zydus receives final approval from USFDA for Glatiramer Acetate Injection, the generic version of Copaxone® 20 mg/ml, 40 mg/ml, Single-Dose Prefilled Syringes

Ahmedabad, India, 08 May, 2025

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) for Glatiramer Acetate Injection, 20 mg/mL and 40 mg/mL, single-dose prefilled syringes.

Zydus' generic Glatiramer Acetate Injection is an FDA-approved, AP-rated substitutable generics of Copaxone® 20 mg/ml, 40 mg/ml and indicated for the treatment of relapsing forms of Multiple Sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Zydus' generic Glatiramer Acetate Injection, developed in collaboration with Chemi S.p.A., will be manufactured entirely in Europe.

"Zydus, together with Chemi, is proud to receive FDA approval for a substitutable generic version for this important therapy," said Dr Sharvil Patel, Managing Director, Zydus Lifesciences. "This approval underscores Zydus' leadership in bringing complex, differentiated generics to market, reinforcing our commitment to providing a comprehensive range of therapeutic choices for patients."

Dr. Francesco De Santis, Chairman of Italfarmaco Group said, "Together with our partner Zydus, we are proud to expand the availability of a cost-effective, high-quality generic treatment option for patients with relapsing-forms of Multiple Sclerosis."

Punit Patel, President & CEO Zydus Pharmaceuticals USA Inc., speaking on the development said, "The approval of Glatiramer Injection showcases our expertise in developing complex medications and reinforces our dedication to providing accessible, high-quality healthcare solutions."

Glatiramer Acetate Injection had annual sales of US$ 719mn in the United States (IQVIA MAT Mar-2025). The group now has 426 approvals and has so far filed 492* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st March, 2025)*

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
Regd. Office : 'Zydus Corporate Park',
Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar),
Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382
481, Gujarat, India. | Phone : +91-79-71800000,
+91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878

About Zydus
Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 27,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit www.zyduslife.com

About CHEMI SpA
CHEMI SpA ("CHEMI") is Milan, Italy based a leading company in the chemical-pharmaceutical area, wholly owned by the Italfarmaco Group. CHEMI specialized in the development, production and sales of high quality generic Active Pharmaceutical Ingredient (APIs), complex to make generics, and peptides, with full manufacturing capabilities from API Synthesis to finished dosage formulation of injectable drugs. CHEMI has prominent experience in the development of Low-Molecular-Weight Heparin (LMWHs) and polysaccharide derivatives, peptides, oncological products. For more information on CHEMI please visit https://www.chemi.com/

About Italfarmaco Group
Italfarmaco is a specialty pharmaceutical company engaged in the discovery, development, manufacturing and marketing of branded prescription and nonprescription products in more than 60 countries on 5 continents employing 4000 people worldwide. Italfarmaco's research and development expertise is best demonstrated through its HDAC inhibitor development programs, addressing new therapeutic treatments of specialty and rare diseases. Through both marketed drugs and compounds in development, Italfarmaco is dedicated to serving patients whose needs remain largely unmet.

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