

Zydus and Synthon entered into exclusive licensing and supply agreement for Ozanimod Capsules (generic version of ZEPOSIA®) for the U.S. market

Ahmedabad, India and Nijmegen, Netherlands, September 04, 2025

Zydus Lifesciences Ltd. (including its subsidiaries and affiliates), a global innovation-driven healthcare company, today announced that its wholly owned subsidiary, Zydus Lifesciences Global FZE, has entered into an exclusive licensing and supply agreement with Synthon BV of the Netherlands for Ozanimod Capsules (a generic version of ZEPOSIA®) for the U.S. market. Synthon has a pending abbreviated new drug application in the United States, seeking approval for Ozanimod Capsules indicated for relapsing forms of multiple sclerosis.

Under the terms of this agreement, Synthon will be responsible for obtaining final regulatory approval for its Ozanimod Capsules product, and thereafter, for the manufacture and supply of the product. Zydus will be responsible for the commercialization of the product in the USA. As one of the first filers, Synthon has received tentative approval within 30 months from U.S. Food and Drug Administration (FDA), making the product eligible for a shared 180-day exclusivity upon market entry.

ZEPOSIA® (Ozanimod) is a sphingosine 1-phosphate receptor modulator 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. It is also approved for moderately to severely active ulcerative colitis (UC) in adults. ZEPOSIA® is a trademark of Receptos, LLC, a Bristol Myers Squibb company.

Speaking on the development, President and Chief Executive Officer of Zydus Pharmaceuticals (USA) Inc., Punit Patel said, "This collaboration with Synthon enables us to bring this important treatment to the U.S. market. This collaboration reinforces our strategic focus on advancing care in therapeutic areas and reflects our commitment to making essential medicines more accessible to patients."

Anish Mehta, Chief Executive Officer, Synthon BV, commented "This collaboration with Zydus for Ozanimod capsules continues to underscore our proven expertise in developing first-to-market, complex generic products. We are pleased to strengthen our partnership with Zydus as we continue advancing our strategic commitment to expanding access to essential medicines."



**PRESS
RELEASE**

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The total addressable market opportunity of Ozanimod Capsules in the U.S is approximately US \$637 million as per the IQVIA MAT July 2025.

About Zydus

Zydus Lifesciences Ltd. with an overarching purpose of empowering people with the 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 28,000 people worldwide, including 1,500 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 Synthon

Synthon is a vertically integrated, global leader in the development and manufacturing of complex generics. For over three decades, the Company has established a proven track record of launching differentiated, complex products at market formation. Synthon has a global footprint with direct presence in eight countries, including four R&D labs as well as four manufacturing sites located in Spain, Czech Republic, Argentina, and Chile. The Company is headquartered in the Netherlands and has approximately 1,600 employees. With a portfolio of over 70 molecules, and diversified base of more than 200 customers serving around 100 countries, Synthon is delivering on its mission of Enabling Affordable Medicines Globally. Follow us on LinkedIn.

For further information, please visit <https://www.synthon.com/>



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