

Zydus and Synthon sign an exclusive development, licensing, supply and commercialization agreement for a novel 505(B)(2) oncology product for the US market

Ahmedabad, India and Nijmegen, Netherlands, February 12, 2025

Zydus Lifesciences Ltd. (including its subsidiaries and affiliates), a global innovation driven healthcare company announced that it has signed an exclusive development, licensing, supply and commercialization agreement with Synthon BV of the Netherlands for a novel 505(B)(2) Oncology product for an undisclosed target.

Under the terms of this agreement, Synthon will be responsible for the development, manufacturing and supply of the finished product. Zydus will be responsible for the NDA submission and commercialization of the product in the US. This 505(B)(2) Oncology product will likely be filed in 2026 and will be offering additional strengths that is intended to provide reduced pill burden, flexibility for dose adjustment and enhanced patient compliance.

Speaking on the development, Managing Director of Zydus Lifesciences Ltd., Dr. Sharvil Patel said, “We are pleased to partner with Synthon for the commercialization of this complex drug product in the US market. The partnership will bring access to a high unmet need therapy area. We are certain that by pooling our resources and knowledge, we will meet critical needs of patients and stakeholders.”

Anish Mehta, CEO of Synthon BV, stated, “This 505(B)(2) product is another example of Synthon’s superior complex product development capabilities and represents a strategic move toward more complex and clinically differentiated products. We are excited to strengthen our partnership with Zydus, who will bring this critical medicine to market to provide patients with important treatment alternatives for this extremely challenging condition.”

The addressable market size of Reference Product is approximately US\$1.5 billion as per IQVIA MAT Dec 2024.

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 has a significant presence in cancer related therapies and offers a wide range of solutions with cytotoxic, supportive & targeted drugs. 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



**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 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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