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Zydus and Synthon to commercialise novel 505(B)(2) oncology product in US market

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Zydus will be responsible for the NDA submission and commercialisation of the product in the US



India-based Zydus Lifesciences (including its subsidiaries and affiliates), has signed an exclusive development, licensing, supply and commercialisation 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 commercialisation 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, “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."

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