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Zydus and RK Pharma enter into exclusive licensing and commercialisation agreement for oncology treatment for US market

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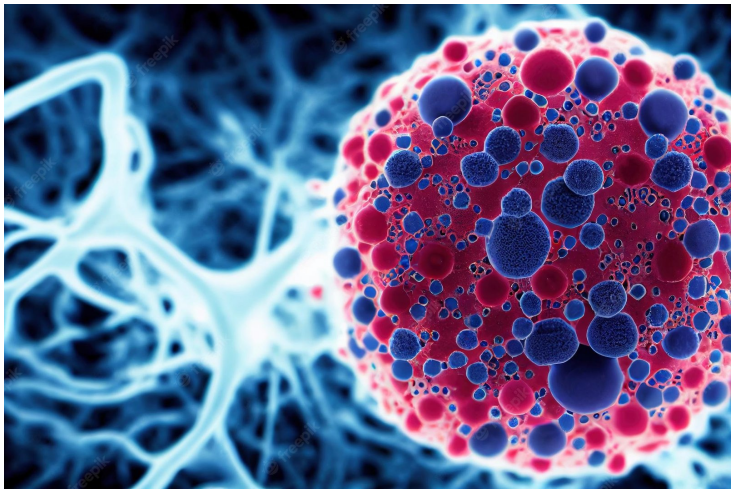
The product, developed under the 505(b)(2) pathway, is expected to be filed in 2026



Ahmedabad-based Zydus Lifesciences has entered into an exclusive licensing and commercialisation agreement with RK Pharma Inc of the US for a novel sterile injectable 505(b)(2) oncology supportive care product for the US market.

Under the terms of this agreement, RK Pharma will manufacture and supply the finished product, while Zydus will be responsible for the NDA submission and commercialization of the product in the US.

The product, developed under the 505(b)(2) pathway, is expected to be filed in 2026 and will provide a formulation that is intended to provide reduced dosing error and enhanced compliance of healthcare professionals.

Commenting on the partnership, Dr Sharvil Patel, Managing Director of Zydus Lifesciences, said “We are delighted to collaborate with RK Pharma to bring this innovative product to patients in the US. This partnership reinforces our commitment to delivering high-quality, affordable medicines and improving patient care.”

Dr Ravishanker Kovi, Founder and Executive Chairman of RK Pharma, stated, “This novel 505(b)(2) product of supportive oncology treatment highlights RK Pharma’s testament to advanced capabilities in formulation and manufacturing, particularly in specialized areas like sterile injectables and complex generics. Our collaboration with Zydus, a company with robust regulatory expertise and a powerful commercial footprint, ensures that this important therapeutic option reaches patients efficiently, reinforcing our shared mission to improve access to high-quality healthcare in the USA.

The novel 505(b)(2) product targets a significant commercial opportunity in the US market, with an estimated total addressable market (TAM) of 6.2 million units, according to IQVIA data MAT September 2025.