

Zydus and RK Pharma enter into an exclusive licensing and commercialization agreement for a novel 505(b)(2) product of supportive oncology treatment for the USA market

Ahmedabad, India and Pearl River, NY, USA, November 26, 2025

Zydus Lifesciences Ltd. (including its subsidiaries and affiliates), a global innovation-driven healthcare company, today announced that it has entered into an exclusive licensing and commercialization 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 U.S. market, with an estimated total addressable market (TAM) of 6.2 million units, according to IQVIA data MAT September 2025.



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About Zydus

Zydus Lifesciences Ltd. is an innovative, global lifesciences company committed to empowering people with the freedom to live healthier, more fulfilled lives. The group discovers, develops, manufactures, and markets a broad range of healthcare therapies, maintaining a significant presence in cancer-related therapies, including cytotoxic, supportive, and targeted drugs. The group employs over 29,000 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 RK Pharma

RK Pharma Inc. is a privately held, US based, vertically integrated pharmaceutical company specializing in the development, manufacturing, and commercialization of complex generic products. Founded in 2018, RK Pharma employs over 1700 people and operates state-of-the-art manufacturing facilities in New York, New Jersey, and India, with a strong focus on challenging dosage forms such as sterile injectables and ophthalmic formulations. RK Pharma is dedicated to improving quality of life by providing high-quality, affordable, and effective medicines. For more details, please visit www.rkpharmainc.com



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