
Just – Evotec Biologics completes cGMP clinical manufacturing for FibroGen’s Phase I study with FG-3165

- *Just – Evotec Biologics successfully completes cGMP clinical manufacturing of FibroGen’s FG-3165 Galectin-9 Targeting Monoclonal Antibody for the Treatment of Patients with Solid Tumors*
- *FibroGen plans to begin enrollment for a Phase I study to evaluate the safety and efficacy of FG-3165 in patients with solid tumors in the second half of 2024*
- *Announcement follows product development collaboration*

Seattle, WA, USA, 03 June 2024:

Just – Evotec Biologics, Inc., the biologics segment of Evotec SE (Frankfurt Stock Exchange: EVT, MDAX/TecDAX, ISIN: DE0005664809; NASDAQ: EVO), announced today that cGMP clinical materials manufactured for FibroGen were cleared for clinical use by the United States Food and Drug Administration (“FDA”) as part of FibroGen’s Investigational New Drug (“IND”) filing. FibroGen aims to begin enrollment of their Phase I clinical trial evaluating the safety and efficacy of FG-3165 in patients with solid tumors characterized by high Gal9 levels of expression in the second half of 2024. Their proprietary FG-3165, a galectin-9 (“Gal9”) targeted monoclonal antibody (“mAb”) is under development for the treatment of solid tumors.

The announcement follows a product development collaboration between Just – Evotec Biologics and FibroGen. Just – Evotec Biologics has supported the pre-clinical and clinical development of FG-3165 with manufacture of Toxicology material and cGMP material for the upcoming Phase I clinical trial.

Dr Linda Zuckerman, Executive Vice President Global Head Biotherapeutics at Just – Evotec

Biologics, commented: “We are proud to continue our support for FibroGen’s Gal9 mAb as their promising FG-3165 oncology program approaches clinical validation. Our highly intensified antibody manufacturing platform, J.POD®, provides flexibly scalable biologics manufacturing solutions to broaden access to innovative therapeutic options.”

Rahul Rajan Kaushik, Senior Vice President of Pharmaceutical Development, Manufacturing and

Supply Chain at FibroGen, said: “The FDA’s IND clearance is an important achievement for us, and we are pleased to advance another product from our promising oncology pipeline into the clinic. Our meaningful



partnership with Just – Evotec Biologics allows us to explore the potential of FG-3165 in enhancing anti-tumor immune responses in a clinical setting.”

About FibroGen’s FG-3165

FG-3165 is a galectin-9 (“Gal9”) targeted antibody under development by FibroGen for treatment of solid tumors and potentially hematologic malignancies characterized by high Gal9 levels of expression. Gal9 has been reported to signal through multiple immune checkpoints on lymphocytes, including TIM3, VISTA, and PD-1, suppressing T and natural killer cell activation. FG-3165 selectively binds to Gal9 with high affinity and inhibits its ability to induce lymphocyte cell death, resulting in enhanced tumor cell killing.

Toxicology material as well as cGMP material for the upcoming Phase 1 clinical trial was manufactured in partnership with Just – Evotec Biologics.

About FibroGen

FibroGen, Inc. is a biopharmaceutical company focused on accelerating the development of novel therapies at the frontiers of cancer biology. Pamrevlumab, a fully human anti-CTGF monoclonal antibody, is in clinical development for the treatment of metastatic pancreatic cancer and locally advanced unresectable pancreatic cancer (LAPC). Roxadustat (爱瑞卓®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) and a Supplemental New Drug Application (sNDA) has been accepted for review by the China Health Authority. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46 is in development for the treatment of metastatic castration-resistant prostate cancer. This program also includes the development of an associated CD46-targeted PET biomarker. In addition, FibroGen has expanded its research and development portfolio to include two immuno-oncology product candidates for the treatment of solid tumors. For more information, please visit www.fibrogen.com.

About Just – Evotec Biologics

Just – Evotec Biologics, wholly owned by Evotec SE, is a first-to-industry biologics platform company that leverages AI/ML technologies and world-leading molecular design, cell line development, process intensification and continuous manufacturing strategies to advance biotherapeutics from discovery through clinical stages to commercial launch. The Just – Evotec Biologics team combines deep industry experience in the fields of data, protein, process, and manufacturing sciences including automation with highly integrated and flexible capabilities to break through the scientific and economic barriers associated with the development of protein therapeutics. Our focus is to accelerate and expand access to biotherapeutics through scientific and technological innovation for our proprietary projects and on behalf of our partners. Learn more at www.just-evotecbiologics.com.

About Evotec SE

Evotec is a life science company with a unique business model that delivers on its mission to discover and develop highly effective therapeutics and make them available to the patients. The Company’s multimodality platform comprises a unique combination of innovative technologies, data and science for the discovery, development, and production of first-in-class and best-in-class pharmaceutical products. Evotec provides high value pipeline co-creating partnerships and solutions to all Top 20 Pharma and over 800 biotechnology companies, academic institutions, as well as other healthcare stakeholders. Evotec has strategic activities in a broad range of currently underserved therapeutic areas, including e.g. neurology, oncology, as well as metabolic and infectious diseases. Within these areas of expertise, Evotec aims to create the world-leading co-owned pipeline for innovative therapeutics and has to-date established a portfolio of more than 200 proprietary and co-owned R&D projects from early discovery to clinical development. Evotec operates globally with more than 5,000 highly qualified people. The Company’s sites in Europe and the USA offer highly synergistic technologies and services and operate as complementary clusters of excellence. For additional information please go to www.evotec.com and follow us on X/Twitter [@Evotec](https://twitter.com/Evotec) and [LinkedIn](https://www.linkedin.com/company/evotec).

Forward-looking statements

This announcement contains forward-looking statements concerning future events, including the proposed offering and listing of Evotec’s securities. Words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,”



“should,” “target,” “would” and variations of such words and similar expressions are intended to identify forward-looking statements. Such statements include comments regarding Evotec’s expectations for revenues, Group EBITDA and unpartnered R&D expenses. These forward-looking statements are based on the information available to, and the expectations and assumptions deemed reasonable by Evotec at the time these statements were made. No assurance can be given that such expectations will prove to have been correct. These statements involve known and unknown risks and are based upon a number of assumptions and estimates, which are inherently subject to significant uncertainties and contingencies, many of which are beyond the control of Evotec. Evotec expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Evotec’s expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

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