

Press release

Evive Biotech and APOGEPHA announce collaboration to market Efbemalenograstim alfa (F-627) in Germany and Switzerland

July 4, 2022, Singapur/Dresden – Evive Biotech (“Evive”), a global biopharmaceutical company developing novel biologic therapies and APOGEPHA Arzneimittel GmbH (APOGEPHA), a Dresden based pharmaceutical company announce that they have entered into an exclusive long-term license agreement for the commercialization of Efbemalenograstim alfa (F-627) in Germany and Switzerland. F-627 is a novel dimeric G-CSF long-acting fusion protein without pegylation. Due to its unique structure, the product may possess stronger G-CSF receptor activating properties and improved efficacy compared to filgrastim and pegfilgrastim ¹.

Under the terms of the agreement, Evive will be responsible for submission of the dossier and application of MAA of F-627 in Germany and communications with the European Medicines Agency (EMA). Following approval of a Marketing Authorization Application (MAA), APOGEPHA will leverage its broad experiences in development and marketing in different medical fields to consult and advise the relevant health care professionals. APOGEPHA will also support Evive regarding additional post approval studies as well as the market access process in Germany.

“We are pleased to initiate our partnership with APOGEPHA in Germany and Switzerland, Evive’s significant footprint in Europe on the commercialization of F-627,” said Dr. Simon Li, CEO and CMO of Evive. Efbemalenograstim alfa is a novel dimeric G-CSF fusion protein that increases the production of white blood cells (neutrophils) to boost the immune system. It is naturally long-acting without the use of pegylated subunits and is proven to be a safe and

efficacious alternative to current G-CSFs, offering a new hope for millions of cancer patients globally. We believe APOGEPHA has the commercial presence and proven track record in marketing and sales of innovative prescription drugs and look forward to working with them to bring this novel life-changing treatment to patients in Germany and Switzerland.”

Dr. Dirk Pamperin, General Manager of APOGEPHA commented: “We are very pleased to have entered into this agreement with Evive Biotech; the licensing of F-627 for Germany and Switzerland is a significant addition to APOGEPHA’s portfolio of differentiated products”. He added, Efbemalenograstim alfa is an excellent treatment option with evident benefits and high potential to improve the therapy of cancer patients significantly.

Evive Biotech’s MAA for F-627 (Efbemalenograstim alfa) was accepted for review by EMA in September 2021. Efbemalenograstim alfa is also currently under review of the FDA in US and the NMPA in China. APOGEPHA will submit the dossier with Swiss Medic in July 2022.

Notes for editors

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About F-627

F-627 (efbemalenograstim alfa) is developed for the treatment of chemotherapy-induced neutropenia (CIN) in cancer patients after chemotherapy. Neutropenia is a common side-effect of chemotherapy and is a condition characterized by low levels of neutrophils, a type of white blood cell that fights infection. F-627 is a recombinant fusion protein containing G-CSF at the amino terminal and human IgG2-Fc fragment at the carboxyl terminal. F-627 is expressed in Chinese Hamster Ovary (CHO) cells. F-627 exists as a homodimer with two G-CSF-Fc molecules covalently linked through disulfide bonds formed between the Fc moiety of the molecule. Through specific binding to its receptor, G-CSF receptor, F-627 stimulates survival, proliferation, differentiation, and function of neutrophil precursors and mature neutrophils. F-627 strengthens the immune system's ability to fight infection by increasing the production of neutrophils, preventing potential chemotherapy dose reductions and delays that may compromise treatment outcomes. The three F-627 pivotal trials are all multi-center, randomized, multi-dose, active-controlled study comparing the efficacy and safety of F-627.

About Evive Biotech

Evive Biotech is a global biopharmaceutical company devoted to developing a portfolio of novel biological therapies for patients worldwide. We leverage our proprietary technology platforms to advance a series of innovative drug candidates for oncology, inflammatory and metabolic diseases. Founded in 2004, we currently have operations in the US, Singapore, and China. As the first biopharmaceutical company to build a platform bringing innovative therapies from China to the world, Evive adopts a holistic approach to drug development, combining exceptional research and commercialization capabilities with our world-class in-house manufacture and regulatory expertise as well as extensive international management experience. Through partnerships with industry, physicians, and regulatory authorities, we strive to bring revolutionary remedies to the global markets quickly and efficiently to address unmet medical needs, making a real and lasting difference to patients and their families worldwide.

About APOGEPHA Arzneimittel GmbH

APOGEPHA Arzneimittel GmbH is a family-owned German pharmaceutical company with about 150 employees and its headquarters in Dresden. The company specialised in urology an uro-oncology and has long lasting experience as well as high expertise in in development, marketing, and sales of innovative products. With its highly skilled sales team the company reaches Health Care Professionals with scientific sound information to bring best treatment options to patients. APOGEPHA's products are sold in 25 markets worldwide. With F-627 APOGEPHA enlarges its portfolio in the field of oncology.

For more company information, please visit www.apogepha.com

^{i 1} Glapsy J, Daley W, Bondarenko I, Rutty D, Chen J. *Blood*. 2021;138(Suppl 1):4290.