Evive Enters License Agreement with Acrotech Biopharma to Commercialize Ryzneuta™ in the United States

November 22, 2022, New Jersey – Evive Biotech (Evive), a global biopharmaceutical company devoted to developing novel biologic therapies and a subsidiary of Yifan Pharmaceutical Co. Ltd., announced today that it has entered into a license agreement with Acrotech Biopharma (Acrotech), a New Jersey-based and wholly-owned subsidiary of Aurobindo Pharma USA Inc., to commercialize Ryzneuta™ (Efbemalenograstim alfa) in the US. Ryzneuta™ is a novel dimeric G-CSF long-acting fusion protein without pegylation. The Biologics License Application (BLA) of Ryzneuta™ is currently under late-stage review by the US FDA for Chemotherapy-Induced Neutropenia (CIN).

"*Despite the current options, CIN remains a significant clinical condition for most cancer patients, creating the need for more potent and convenient treatment. Due to its unique molecular structure, Ryzneuta™ may possess stronger G-CSF receptor activation properties. Additional clinical trials are being planned to demonstrate improved clinical efficacy of Ryzneuta,*" said Simon Li, M.D., Ph.D., CEO & CMO of Evive. "*Acrotech has proven and strong capacity to commercialize proprietary medications, we look forward to partnering with them for bringing this novel medicine to more cancer patients with CIN in the US.*"

Under review by the US FDA, Ryzneuta™ is developed for the treatment of 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. This important partnership builds on the comprehensive global development program of Ryzneuta™, which includes 12 clinical trials and has enrolled over 1,200 subjects to date in multiple territories including the US, EU, and China.

"We are very excited to partner with Evive to bring this valuable therapeutic option to patients. Ryzneuta™ provides Acrotech Biopharma the opportunity to expand its offerings to oncology patients and is aligned with our vision of commercializing scientifically advanced products. Additionally, expanding into CIN creates future growth opportunities for us," said Dr. Ashish Anvekar, President of Acrotech Biopharma. "We believe Ryzneuta^{TM} will offer patients suffering from CIN a very compelling and accessible treatment option."

Evive will be responsible for the ongoing development, manufacturing, registration, and supply of Ryzneuta™, while Acrotech will use its sales and commercialization capabilities to market and distribute Ryzneuta™ in the US. In addition, both companies may conduct additional development of the Product to explore further opportunities for Ryzneuta™.

In addition to the BLA submitted to US FDA, Evive's Marketing Authorization Application (MAA), and New Drug Application (NDA) for Ryzneuta™ are currently under review by European and Chinese regulators.

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Notes for editors

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About Ryzneuta™

Ryzneuta™ (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. Ryzneuta™ is a recombinant fusion protein containing G-CSF at the amino terminal and human IgG_2-Fc fragment at the carboxyl terminal. Ryzneuta™ is expressed in Chinese Hamster Ovary (CHO) cells. Ryzneuta™ exists as a homodimer with two G-CSF-Fc molecules covalently linked through disulphide bonds formed between the Fc moiety of the molecule. Through specific binding to its receptor, G-CSF receptor, Ryzneuta™ stimulates survival, proliferation, differentiation, and function of neutrophil precursors and mature neutrophils. Ryzneuta™ 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 pivotal trials of Ryzneuta™ are all multi-centre, randomized, multi-dose, active-controlled study comparing the efficacy and safety of the drug.

About Evive Biotech

Evive Biotech, a subsidiary of Yifan Pharmaceutical, 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 regulatory expertise and extensive international management experience. Through partnerships with industry, physicians, and regulatory authorities, we strive to bring revolutionary remedies to the global market quickly and efficiently to address unmet medical needs, making a real and lasting difference to patients and their families worldwide.
To learn more about Evive Biotech, visit http://www.evivebiotech.com/

About Acrotech Biopharma

Acrotech Biopharma Inc. was formed as a global platform to commercialize innovative proprietary medications. The company aims to launch scientifically advanced products to address unmet needs and deliver value to patients as well as all healthcare stakeholders. Acrotech aspires to be a patient focused, research-based organization that strives to launch treatments which are accessible to patients that need them.

To learn more about Acrotech Biopharma, visit https://acrotechbiopharma.com.