Evive Biotech and Acrotech Biopharma Announce FDA Approval of Ryzneuta™ (Efbemalenograstim alfa Injection) for Chemotherapy-Induced Neutropenia (CIN)

-Ryzneuta™ is the first non-pegylated granulocyte colony-stimulating factor *approved by both the US Food and Drug Administration (FDA) and China National Medical Products Administration (NMPA) for treatment for CIN*

- Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

November 22, 2023, New Jersey – Evive Biotech (Evive), a global biopharmaceutical company devoted to developing novel biologic therapies and a subsidiary of Yifan Pharmaceutical Co. Ltd., and Acrotech Biopharma (Acrotech), a New Jersey-based and wholly-owned subsidiary of Aurobindo Pharma USA Inc., today announced that on November 16, 2023 the U.S. Food and Drug Administration (FDA) approved Ryzneuta™ (Efbemalenograstim alfa) indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. The approval was based on results of the two pivotal Phase 3 Study GC-627-04 [NCT02872103] and Study GC-627-05 [NCT03252431] completed in the United States and Europe. Ryzneuta™ is a novel long-acting Granulocyte colony-stimulating factor (G-CSF), which can stimulate the proliferation, differentiation, and release of neutrophil precursors. It helps to enhance the immune function of cancer patients and prevent the side effects of neutropenia caused by chemotherapy.

Study GC-627-05, is a multi-center, randomized, multi-dose, active-controlled study comparing the efficacy and safety of Ryzneuta™ and Neulasta™ (Pegfilgrastim). The trial met its primary and secondary endpoints, of efficacy and safety.

Neutropenia is a common side effect of chemotherapy and is characterized by persistently low levels of neutrophils (a type of white blood cell with infection-fighting functions) due to the use of chemotherapy and other types of anti-cancer drugs, which increases the risk of adverse reactions such as infection and fever in cancer patients during chemotherapy. Ryzneuta™ is a novel dimeric G-CSF long-acting fusion protein without PEGylation or Tween-80. Due to its unique molecular structure, Ryzneuta™ may possess stronger G-CSF receptor activation properties and avoid the potential problem (such as allergic reactions) caused by PEG or Tween-80.

“Ryzneuta™ is the first innovative biologics independently developed by Evive Biotech, and this approval proves that the Evive R&D team has the capability to independently carry out the global development of innovative biologics, including preclinical research, regulatory affairs, clinical research, manufacturing following international standard, as well as commercialization,” said Simon Li, M.D., Ph.D., CEO & CMO of Evive. “We look forward

to working with Acrotech to bring this novel treatment to more cancer patients with CIN in the US."

"Ryzneuta™ is a new treatment option that has demonstrated its efficacy and safety building 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," said Dr. John Glaspy, Principal Investigator of the Ryzneuta global clinical trial program and professor of medicine at the Jonsson Comprehensive Cancer Center of the University of California, Los Angeles School of Medicine, "and I am proud of the achievement made by Evive team and the devotion of the patients and research teams involved in these studies. We hope that this promising therapy will benefit more CIN patients."

"Acrotech is very excited on the approval of Ryzneuta™ and is preparing to commercialize the product in the near future. We believe Ryzneuta™ will offer patients suffering from CIN a very compelling and accessible treatment option. We will leverage our strong and well-established commercial footprint to promote this unique treatment to key stakeholders." said Dr. Ashish Anvekar, President of Acrotech Biopharma.

In May this year, Ryzneuta® was approved and launched in China. In addition, the facility producing Ryzneuta® has successfully passed the on-site GMP inspections conducted by ANVISA and EMA. In the near future, Ryzneuta® is expected to receive more regulatory approvals, which will enable Ryzneuta® to help and provide worldwide cancer patients a much-needed effective first-line treatment and alternative therapy.

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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 IgG2-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-center, randomized, multi-dose, active-controlled study comparing the efficacy and safety of the drug.

About Evive Biotech and Yifan Pharma

Evive Biotech, a subsidiary of Yifan Pharma, 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. To learn more about Evive Biotech, visit www.evivebiotech.com.

Yifan Pharmaceutical is an innovative R&D and production company focusing on the pharmaceutical and health sectors. Our vision is to develop innovative drugs with definite clinical values, to help disease-afflicted patients regain health. Currently, we are focusing on four business areas, i.e., biologics, small molecules, synthetic biologics, and special traditional Chinese medicines (TCMs), expanding our product R&D pipelines and innovating drugs for disease treatment to address unmet medical needs.

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.