Xuanzhu Biopharmaceutical Co., Ltd.
軒竹生物科技股份有限公司

(a joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2575)

VOLUNTARY ANNOUNCEMENT

NG-350A GRANTED FAST TRACK DESIGNATION BY THE U.S. FDA

The board of directors (the "**Board**") of Xuanzhu Biopharmaceutical Co., Ltd. (the "**Company**" or "**Xuanzhu Biopharmaceutical**", together with its subsidiaries, the "**Group**") is pleased to announce that NG-350A, a product licensed from Akamis Bio Ltd. ("**Akamis**"), a clinical-stage oncology company, was granted Fast Track designation by the U.S. Food and Drug Administration ("**FDA**") for the treatment of mismatch repair-proficient (pMMR) locally advanced rectal cancer (LARC). The Group holds exclusive rights to develop, produce and commercialize NG-350A in Greater China. For details of the license agreement with Akamis and NG-350A, see "Business – Our License and Asset Acquisition Arrangements – Our In-licensing and Asset Acquisition Agreements – Agreement with Akamis to In-license an Oncolytic Viral Vector Asset" in the prospectus of the Company dated October 6, 2025.

ABOUT FAST TRACK DESIGNATION

FDA Fast Track designation is a method for expediting the development and approval of potential drugs. Drugs granted Fast Track designation are intended to treat serious conditions and address unmet medical needs. They may be the first treatment for a specific condition, offer significant clinical advantages over existing therapies, or enhance safety for existing therapies.

ABOUT NG-350A

NG-350A is a clinical-stage, intravenously delivered T-SIGn® therapeutic designed to drive intratumoral expression of a CD40 agonist monoclonal antibody triggering the activation of antigen-presenting cells (APCs) resident in solid tumors and their draining lymph nodes. Once activated, APCs recruit T cells into the vicinity of the tumor to deliver a potent anti-tumor immune response. Akamis has evaluated NG-350A's safety, tolerability, and preliminary efficacy as a monotherapy (FORTITUDE study) and in combination with pembrolizumab (FORTIFY study) in patients with metastatic or advanced epithelial tumors. Across these studies, NG-350A has demonstrated a consistent safety and tolerability profile, as well as strong evidence of tumor-selective delivery, replication and transgene expression.

NG-350A is currently being evaluated in the Phase Ib FORTRESS clinical study (NCT06459869) in combination with chemoradiotherapy (CRT) in adult patients with mismatch repair-proficient (pMMR) locally advanced rectal cancer (LARC) and at least one risk factor for local or distant recurrence or with oligometastatic disease.

ABOUT THE COMPANY

Xuanzhu Biopharmaceutical, a subsidiary of Sihuan Pharmaceutical Holdings Group Ltd. ("**Sihuan Pharmaceutical**"), is an innovative pharmaceutical company rooted in China with a global vision. Focusing on major disease areas such as digestive diseases, oncology, and non-alcoholic steatohepatitis, Xuanzhu Biopharmaceutical is committed to developing, manufacturing, and commercializing Category 1 novel drugs with core proprietary intellectual property rights. The Company boasts a world-class R&D team comprised of key personnel with extensive experience in novel drug development. The Company possesses two R&D systems, small molecule drugs and large molecule biologics. These two engines drive the Company's innovative development, resulting in a unique domestic product pipeline encompassing small molecule drugs, large molecule biologics, and antibody-drug conjugates (ADCs). Guided by unmet clinical needs, the Company is committed to becoming a leading innovative pharmaceutical company with independent R&D, production, and sales capabilities.

ABOUT SIHUAN PHARMACEUTICAL

Founded in 2001 and listed on the Main Board of The Stock Exchange of Hong Kong Limited in 2010, Sihuan Pharmaceutical is an international medical aesthetic and pharmaceutical company led by innovation, with an independent and leading research and development technology platform, a rich global product pipeline, strong product registration capability, a full dosage form production platform with high efficiency and low cost and a mature and excellent sales system. Adhering to the overall strategic goal for the "full promotion of a two-wheel drive strategy of its medical aesthetics and biopharmaceutical businesses", Sihuan Pharmaceutical endeavors to build itself into a leading medical aesthetics and biopharmaceutical company in China.

This announcement is being made by the Company on a voluntary basis to update the investing public on the Group's latest business development, and does not constitute, and is not intended to be, an advertisement regarding the use of any medicine, surgical appliance, medical equipment, treatment or orally consumed product.

By order of the Board
Xuanzhu Biopharmaceutical Co., Ltd.
Ms. Xu Yanjun
Chairperson of the Board and executive Director

Hong Kong, October 28, 2025

As of the date of this announcement, the board of directors of the Company comprises (i) Ms. Xu Yanjun, Dr. Li Jia Kui and Dr. Shih Cheng-Kon as executive Directors; (ii) Ms. Li Huiying, Mr. Yu Lifeng and Ms. Chen Yanling as non-executive Directors; and (iii) Mr. Liu Shuo, Ms. Wang Yu and Mr. Fan Chi Chiu as independent non-executive Directors.