

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*

# Innovent

信達生物製藥

**INNOVENT BIOLOGICS, INC.**

*(Incorporated in the Cayman Islands with Limited Liability)*

**(Stock Code: 1801)**

## **VOLUNTARY ANNOUNCEMENT**

### **THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION APPROVES THE SUPPLEMENTAL NEW DRUG APPLICATION FOR CYRAMZA® (RAMUCIRUMAB) FOR THE TREATMENT IN PATIENTS WITH HEPATOCELLULAR CARCINOMA**

This announcement is made by Innovent Biologics, Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business updates of the Group.

The board of directors of the Company (the “**Board**”) is pleased to see that the National Medical Products Administration (“**NMPA**”) of China has approved the supplemental New Drug Application (“**sNDA**”) for CYRAMZA® (ramucirumab) in patients with hepatocellular carcinoma (“**HCC**”) who have an alpha fetoprotein of  $\geq 400$  ng/mL and have been treated with sorafenib. In March 2022, CYRAMZA (ramucirumab) was approved by the NMPA in combination with paclitaxel for second-line treatment in patients with advanced or metastatic, gastric or gastro-esophageal junction adenocarcinoma (“**GC**”), making it the first and only targeted drug approved for the second-line treatment of GC in China.

CYRAMZA (ramucirumab) has been discovered and developed by Eli Lilly and Company (“**Lilly**”). In March 2022, the Company and Lilly expanded their strategic partnership in oncology, which includes an agreement for the Company to obtain the sole commercialization rights of CYRAMZA® (ramucirumab) once approved in China, which positions the Company to be fully responsible for the pricing, importation, marketing, distribution and detailing of this product. With this further expanded oncology product portfolio, the Company intends to use its experienced oncology commercial team to leverage its broad commercial coverage in hospitals and pharmacies at various tiers and to provide integrated patient solutions with strong synergies to cancer patients in China.

This new approval was based on the results of the REACH-2 study, a global randomized, double-blind, placebo-controlled Phase 3 clinical trial. The REACH-2 study is the first Phase 3 clinical trial in HCC to obtain positive results in a biomarker-enriched population known for poor prognosis. On the primary endpoint of overall survival (“OS”), treatment with CYRAMZA significantly improved the OS of patients compared to placebo (HR: 0.71; 95% CI: 0.53-0.95; P=0.020). The median OS was 8.5 months with CYRAMZA, compared to 7.3 months with placebo. On the secondary endpoint of PFS, median PFS was significantly improved with CYRAMZA (2.8 months vs 1.6 months for placebo (HR: 0.45; 95% CI: 0.34-0.60; P<0.0001)). Objective response rate (“ORR”) was numerically higher with CYRAMZA compared to placebo (4.6% vs 1.1%). Disease control rate (“DCR”) was higher with CYRAMZA than with placebo (59.9% vs 38.9%). CYRAMZA was well-tolerated in Chinese patients and the overall patient population. The safety and efficacy profile of CYRAMZA in Chinese population was consistent with that observed in previously reported global studies.

Primary liver cancer (“PLC”) is a common malignancy of the digestive system worldwide, among which about half of all new cases and deaths occur in China. The main pathological types of liver cancer are HCC, which accounts for 85 to 90%, and a small number of cases of intrahepatic cholangiocarcinoma (“ICC”) and HCC-ICC mixed liver cancer. In China, HCC is primarily caused by hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection. There are approximately 410,000 new cases in HCC in China yearly and the number of deaths are nearly the same. Most patients will experience disease progression after current first-line therapy and are left with limited treatment options. The Company is excited about the approval of CYRAMZA<sup>®</sup>, the first innovative drug proven to have clinical benefits for biomarker-enrichment population of patients with HCC. This differentiated product will potentially be an exciting treatment option and bring new hope to Chinese patients with advanced HCC. The successive approvals of CYRAMZA<sup>®</sup> in second-line GC/GEJ and HCC this year enable us to provide integrated patient solutions with strong portfolio synergies while enhancing our leading franchise in these two large cancer indications.

### **About CYRAMZA<sup>®</sup> (ramucirumab)**

CYRAMZA<sup>®</sup> is an antiangiogenic therapy. It is a vascular endothelial growth factor (VEGF) Receptor 2 antagonist that binds specifically to VEGFR-2, thereby blocking the binding of the receptor ligands (VEGF-A, VEGF-C, and VEGF-D) – which may slow tumor growth. In recent years, studies have shown that the VEGF pathway is an important signaling pathway involved in tumor angiogenesis, and it is also the main target pathway in targeted therapy of liver cancer. From the existing research results, the single drug use of compounds targeting the VEGF pathway can bring survival benefits to patients and is a very promising treatment method in the treatment of liver cancer.

In March 2022, CYRAMZA<sup>®</sup> (ramucirumab) in combination with paclitaxel was approved by the NMPA for second-line treatment in patients with advanced or metastatic, gastric or gastro-esophageal junction (GEJ) adenocarcinoma.

In October 2022, CYRAMZA<sup>®</sup> (ramucirumab) was approved by the NMPA in patients with HCC who have an alpha fetoprotein (AFP) of  $\geq 400$  ng/mL and have been treated with sorafenib.

## About the Company's Strategic Cooperation with Lilly

the Company entered into a strategic collaboration with Lilly focused on biological medicine in March 2015 – a groundbreaking partnership between a Chinese pharmaceutical company and a multinational pharmaceutical company. Under the agreement, Lilly and the Company will co-develop and commercialize oncology medicines, including Tyvyt® (sintilimab injection) in China. In October 2015, the two companies announced the extension of their existing collaboration to include co-development of three additional oncology antibodies targeting oncology indications. In August 2019, the Company further entered into a licensing agreement with Lilly to develop and commercialize a potentially global best-in-class diabetes medicine in China. This collaboration with Lilly indicates that the Company has established a comprehensive level of cooperation between China's innovative pharmaceuticals sector and the international pharmaceuticals sector in fields such as Research & Development (R&D), Chemical, Manufacturing and Control (CMC), clinical development and commercialization. In August 2020, Lilly and the Company announced a global expansion of their strategic alliance for sintilimab, whereby Lilly obtained an exclusive license for sintilimab for geographies outside of China and plans to pursue registration of sintilimab in the U.S. and other geographies outside of China. In March 2022, Lilly and the Company entered into a fifth agreement to expand strategic partnership in oncology, in which the Company obtained the sole commercialization rights to import, market, promote, distribute and detail CYRAMZA® (ramucirumab) and selpercatinib once approved in Mainland China, and a right of first negotiation for potential future commercialization of pirtobrutinib in Mainland China.

By Order of the Board  
**Innovent Biologics, Inc.**  
**Dr. De-Chao Michael Yu**  
*Chairman and Executive Director*

Hong Kong, China,  
October 10, 2022

*As at the date of this announcement, the Board comprises Dr. De-Chao Michael Yu as Chairman and Executive Director and Mr. Ronald Hao Xi Ede as Executive Director, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Dr. Kaixian Chen and Mr. Gary Zieziula as Independent Non-executive Directors.*