信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

INSIDE INFORMATION

THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION APPROVES PEMAZYRE® (PEMIGATINIB) FOR THE TREATMENT OF ADULTS WITH LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA WITH A FGFR2 FUSION OR REARRANGEMENT THAT HAVE PROGRESSED AFTER AT LEAST ONE PRIOR LINE OF SYSTEMIC THERAPY

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 announce that the National Medical Products Administration ("**NMPA**") of China has approved Pemazyre® (pemigatinib) for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 ("**FGFR2**") fusion or rearrangement as confirmed by a validated diagnostic test that have progressed after at least one prior line of systemic therapy.

Pemazyre® (pemigatinib), discovered by Incyte Corporation ("**Incyte**") and licensed to the Company for development and commercialization in Mainland China, Hong Kong, Macau and Taiwan markets, is the first selective tyrosine kinase inhibitor approved for the treatment of cholangiocarcinoma, a type of biliary tract cancer, in China, representing a new milestone following its approval in Hong Kong market in January 2022, and in the Taiwan market in June 2021.

The approval in China was based on two clinical studies. One is the FIGHT-202 study, which is a Phase 2, multi-center, open-label, single-arm study (NCT02924376) evaluating the safety and efficacy of pemigatinib in adult (age ≥ 18 years) patients with previously treated, locally advanced or metastatic cholangiocarcinoma with documented FGFR2 fusion or rearrangement. The other study was a bridging study (CIBI375A201, NCT04256980) conducted in China evaluating the safety and efficacy of pemigatinib in Chinese cholangiocarcinoma patients. The primary end point was overall response rate ("**ORR**") evaluated by an independent radiological review committee ("**IRRC**") per RECIST V1.1.

In the FIGHT-202 study, as of the data cut-off date (7 April 2020), a total of 108 subjects with FGFR2 fusion/rearrangement were enrolled and orally received pemigatinib 13.5mg per day(Q3W 2 weeks on/1 week off), the IRRC-confirmed ORR was 37.0% (95% CI: 27.94%, 46.86%), including 4 complete responses. The median duration of response was 8.08 months with responses lasting ≥ 6 months in 26 of the 40 (66.0%) responding patients and ≥ 12 months in 15 (37.5%) patients. In study CIBI375A201, as of the data cut-off date (29 January 2021), among 30 efficacy evaluable Chinese subjects enrolled, the IRRC-confirmed ORR was 50%(95% CI: 31.3%,68.7%). The overall safety profiles of FIGHT-202 and the study CIBI375A201 are similar and the majority of the adverse events were grade 1 or 2 per CTCAE V5.0. Pemigatinib was generally well tolerated in Chinese patients with cholangiocarcinoma.

About Pemazyre® (pemigatinib)

In April 2020, the U.S. Food and Drug Administration ("**FDA**") approved Incyte's Pemazyre® (pemigatinib), a selective, oral inhibitor of FGFR isoforms 1, 2 and 3, for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 ("**FGFR2**") fusion or rearrangement as detected by an FDA-approved test. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Japan, Pemazyre® (pemigatinib) is approved for the treatment of patients with unresectable biliary tract cancer with a FGFR2 fusion gene, worsening after cancer chemotherapy. In Europe, Pemazyre® (pemigatinib) is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement that have progressed after at least one prior line of systemic therapy. Pemazyre® (pemigatinib) is marketed by Incyte in the United States, Europe and Japan.

In December 2018, the Company and Incyte entered into a strategic collaboration for three clinical-stage product candidates discovered and developed by Incyte, including pemigatinib (FGFR1/2/3 inhibitor). Under the terms of the agreement, the Company has received the rights to develop and commercialize the three assets in Mainland China, Hong Kong, Macau and Taiwan.

In June 2021, Taiwan Food and Drug Administration approved Pemazyre® (pemigatinib) for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement.

In January 2022, Hong Kong Department of Health approved Pemazyre® (pemigatinib) for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a FGFR fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

In April 2022, the NMPA of China approved Pemazyre® (pemigatinib) for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement as confirmed by a validated diagnostic test that have progressed after at least one prior line of systemic therapy.

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

Hong Kong, China, 6 April 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 and Dr. Kaixian Chen as Independent Non-executive Directors.