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 NEW DRUG APPLICATION FOR SELPERCATINIB FOR THE TREATMENT OF PATIENTS WITH *RET*-DRIVEN LUNG AND THYROID CANCERS

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 New Drug Application ("**NDA**") for selpercatinib (40mg & 80mg capsules) for the treatment of adult patients with metastatic rearranged during transfection ("***RET***") fusion-positive non-small cell lung cancer ("**NSCLC**"), adult and pediatric patients 12 years of age and older with advanced or metastatic *RET*-mutant medullary thyroid cancer ("**MTC**") who require systemic therapy, and adult and pediatric patients 12 years of age and older with advanced or metastatic *RET* fusion-positive thyroid cancer ("**TC**") who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Selpercatinib is a selective and potent *RET* kinase inhibitor that was 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 selpercatinib once approved in China, positioning 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, with our experienced oncology commercial team, will leverage our broad commercial coverage in hospitals and pharmacies at various tiers to provide integrated patient solutions with strong synergies to cancer patients in China.

Selpercatinib was globally the first *RET* inhibitor granted accelerated approved by The U.S. Food and Drug Administration ("**FDA**") in May 2020, under the brand name Retevmo. In November 2021, the NDA for selpercatinib was accepted by the Center for Drug Evaluation ("**CDE**") of NMPA in China and was granted priority review to expedite the review process. The NDA approval was based on the data from the global LIBIRETTO-001 study and the data of Chinese patient population in the LIBRETTO-321 study.

Selpercatinib was evaluated in the Phase I/II LIBRETTO-001 study, the largest clinical trial ever reported in patients with *RET*-driven cancer. The major efficacy outcome measures were confirmed overall response rate ("**ORR**") and duration of response ("**DoR**"). The updated results in patients with NSCLC and thyroid cancer were published at the 2022 European Lung Cancer Congress (ELCC) and the European Society for Medical Oncology (ESMO) Congress 2022, respectively.

Selpercatinib has demonstrated potent and durable antitumor activity with a favorable safety profile in patients with locally advanced or metastatic *RET* fusion-positive NSCLC, advanced or metastatic *RET*-altered MTC and advanced *RET* fusion-positive TC.

- In patients with NSCLC, the IRC-assessed ORR was 84.1%(95%CI:73, 92), median DoR was 20.2 months (95% CI:13, NE), median PFS was 22 months (95% CI:14, NE). Pre-treated patients (N=247) achieved an ORR of 61.1% (95% CI:55, 67), with a median DoR of 28.6 months (95% CI:20, NE) and a median PFS of 24.9 months (95% CI:19, NE).

- In cabozantinib/vandetanib (cab/van) naïve patients (N=142) and cab and/or van pre-treated patients with MTC (N=151), IRC-assessed ORRs were 81.0% and 73.5%, respectively. Despite a median follow-up of approximately two years, DoR and PFS data is still immature, with response ongoing in most naïve patients. Pre-treated patients achieved a median PFS of 34 months (95% CI:26, NE) and DoR has not been reached yet.

- In naïve patients with TC (N=12), the IRC-assessed ORR was 92% (95%CI:62, 100), median DoR was 20.2 months (95% CI:15, NE), PFS in 1 year was 100% (95% CI:100, 100). In pre-treated patients with TC (N=22), the IRC-assessed ORR was 77% (95%CI:55, 92), median DoR was 18 months (95% CI:10, NE), PFS in one year was 69% (95% CI:43, 85).

- Selpercatinib was well-tolerated with most adverse events ("**AE**") being low grades which are manageable and reversible. 3-4% of patients discontinued treatment due to treatment-related AEs.

The LIBRETTO-321 study is an open-label, multicenter, Phase II study to assess the safety and efficacy of selpercatinib in participants in China with *RET* fusion-positive solid tumors. Of the 77 enrolled patients, 47 had *RET* fusion-positive NSCLC, 29 had *RET*-mutant MTC and one had *RET* fusion-positive TC. The results have been published in *Therapeutic Advances in Medical Oncology* in July (NSCLC part) and in August (MTC/TC part) respectively in 2022.

The safety and efficacy profile of selpercatinib in the Chinese population was consistent with that observed in previously reported global studies.

- After 9.7 months of median follow-up, IRC-assessed ORR in the primary analysis set (**PAS**) of patients with NSCLC (N = 26) was 69.2% (95%CI:48.2, 85.7) and 94.4% of responses were ongoing; the ORR was 87.5% and 61.1% in treatment-naïve and pre-treated patients, respectively.

- After 8.7 months of median follow-up, IRC-assessed ORR in the PAS of patients with MTC (N = 26) was 57.7% (95%CI: 36.9, 76.6) and 93.3% of responses were ongoing; the ORR was 58.8% (95%CI:32.9, 81.6) and 55.6% (95%CI:21.2, 86.3) in treatment-naïve and pre-treated patients, respectively.

- One treatment-naïve patient with TC was treated for 23.4 weeks and achieved a confirmed partial response (**PR**) at week eight. A maximum tumor burden shrinkage of 43% was determined by the IRC and the response was ongoing at cutoff.

- Selpercatinib was well-tolerated with most AEs being low grades which are manageable and reversible. Three (3.9%) patients discontinued therapy due to treatment-related AEs.

Genomic alterations in the *RET* kinase, which include fusions and activating point mutations, lead to overactive *RET* signaling and uncontrolled cell growth. *RET* fusions have been identified in approximately 1%-2% of NSCLC; and 10-20% of papillary thyroid cancers. Activating *RET* point mutations account for approximately 60% of sporadic MTC and approximately 90% of familial MTC. *RET* fusions have been identified in about 1.4% of Chinese patients with NSCLC and the incident cases are above 10,000 every year. And the positive rate of *RET* fusion in the Chinese TC patient population is about 6.03% with about 3,484 new cases each year in China; the positive rate of *RET* fusion in the Chinese sporadic MTC and familial MTC are approximately 42% and 88.8% with about 1,795 new cases each year in China. In the past, there have been limited targeted therapies available for *RET* fusion-positive cancers that achieved satisfactory efficacy. Globally, selpercatinib is the first *RET* inhibitor approved, and the Company is pleased to see its strong and durable response in line with good tolerability in clinical studies. This approval in Mainland China marks another milestone for targeted therapies and will bring a new treatment option with high quality to *RET* fusion positive cancer patients in China. For the Company, the addition of a high-value commercialized product in our TKI business unit ("**BU**") will further enhance the synergy value in our pipeline portfolio as well as our franchise in certain cancer types. The Company is committed to our partnership with Lilly to accelerate the launch of innovative medicines to benefit more cancer patients in China as soon as possible.

About Selpercatinib

Selpercatinib is a selective and potent *RET* kinase inhibitor with CNS activity. In the U.S., selpercatinib was approved by FDA in May 2020, under the brand name Retevmo, as the first therapy specifically indicated for the treatment of adult patients with metastatic *RET* fusion-positive NSCLC, adult and pediatric patients 12 years of age and older with advanced or metastatic *RET*-mutant MTC who require systemic therapy, and adult and pediatric patients 12 years of age and older with advanced or metastatic *RET* fusion-positive TC who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). In Sept 2022, the FDA granted an accelerated approval for a tumor-agnostic indication for Selpercatinib in adult patients with locally advanced or metastatic solid tumors with a *RET* gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. Selpercatinib, is the first and only *RET* inhibitor to get this indication. In addition to the tumor-agnostic approval, the FDA has granted traditional approval for Retevmo in adult patients with locally advanced or metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC).

About the Company's strategic cooperation with Lilly

The Company entered into a strategic collaboration with Lilly, focusing 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), and 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 10th, 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.