信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

INSIDE INFORMATION ANNOUNCEMENT
INNOVENT ANNOUNCES INCLUSION IN THE CHINA NATIONAL REIMBURSEMENT DRUG LIST (2022 VERSION) OF TYVYT® IN TWO NEW INDICATIONS, OLVEREMATINIB FOR THE FIRST LISTING, BYVASDA®, HALPRYZA® AND SULINNO® IN MULTIPLE NEW INDICATIONS

This announcement is made by Innovent Biologics, Inc. (the "**Company**" or "**Innovent**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The board of directors (the "**Director(s)**") of the Company (the "**Board**") is pleased to announce that, five products (including new indications) of the Company have been included in the updated National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2022 Version) ("**NRDL**"). This includes: two additional indications of PD-1 inhibitor TYVYT® (sintilimab injection) were included (NRDL negotiation list); olverematinib was included for the first time (NRDL negotiation list); multiple additional indications of BYVASDA® (bevacizumab injection), HALPRYZA® (rituximab injection), and SULINNO® (adalimumab injection) were included (NRDL general list). The updated NRDL will officially take effect on March 1, 2023.

New Products and Indications Included in the Updated NRDL

TYVYT®: the only PD-1 inhibitor for the first-line treatment of five high-incidence cancer types included in the NRDL

TYVYT® (sintilimab injection): an innovative PD-1 inhibitor co-developed by Innovent and Eli Lilly and Company. Six indications of TYVYT® (sintilimab injection) for the treatment of lung cancer, liver cancer, gastric cancer, esophageal cancer, Hodgkin's lymphoma, etc. have been approved and included in the NRDL. In particular, two additional indications of TYVYT® (sintilimab injection) for the treatment of gastric cancer and the treatment of esophageal cancer have been included in the NRDL for the first time, further enhancing the accessibility of this novel immunotherapy to a wider group of cancer patients. TYVYT® (sintilimab injection) is the first and the only PD-1 inhibitor for gastric cancer included in the NRDL, as well as the only PD-1 inhibitor for the first-line treatment of five high-incidence cancer types (non-squamous non-small cell lung cancer, squamous non-small cell lung cancer, liver cancer, gastric cancer, esophageal cancer) included in the NRDL.

The updated NRDL reimbursement scope of TYVYT® (sintilimab injection) include:

- For the treatment of unresectable locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma;
- For the treatment of unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma;
- For the treatment of unresectable locally advanced or metastatic non-squamous non-small cell lung cancer lacking EGFR or ALK driver gene mutations;
- For the treatment of unresectable locally advanced or metastatic squamous non-small cell lung cancer;
- For the treatment of unresectable or metastatic hepatocellular carcinoma with no prior systematic treatment;
- For the treatment of relapsed or refractory classic Hodgkin's lymphoma after two lines or later of systemic chemotherapy.

Olverembatinib: first listing in the NRDL of the exclusive third generation BCR-ABL inhibitor in China

Olverembatinib: an innovative third generation oral BCR-ABL inhibitor co-commercialized by Innovent and Ascentage Pharma (6855.HK). Olverembatinib has been included in the NRDL for the first time for adult patients with T315I-mutant chronic-phase chronic myeloid leukemia ("**CML-CP**") and accelerated-phase chronic myeloid leukemia ("**CML-AP**").

The introduction of BCR-ABL tyrosine kinase inhibitors ("**TKIs**") has significantly improved the clinical practice and management of chronic myeloid leukemia ("**CML**"), allowing treatment-compliant patients to achieve long-term survival. However, acquired resistance to TKIs remains a major challenge in the treatment of CML. Patients with CML harboring the T315I mutation are resistant to all current first and second generation BCR-ABL inhibitors. Olverembatinib, as the only approved third generation BCR-ABL inhibitor in China and the only therapy for CML harboring the T315I mutation, has been included in the NRDL for the first time. This fulfills the treatment gap in T315I-mutant CML, and further improves the accessibility and affordability of the medicine.

Inclusion of New Indications for Three Antibody Drugs in the general NRDL

Several new indications of three antibody drugs, i.e. BYVASDA® (bevacizumab injection), HALPRYZA® (rituximab injection) and SULINNO® (adalimumab injection), have been included in the NRDL, which will benefit a broader group of cancer patients and patients with autoimmune diseases. Details are as follows:

BYVASDA® (bevacizumab injection):

- A total of seven indications have been approved and included in the NRDL (including three new indications) for the treatment of non-small cell lung cancer, colorectal cancer, glioblastoma, hepatocellular carcinomas (in combination with atezolizumab), epithelial ovarian, fallopian tube or primary peritoneal cancer (new indication), cervical cancer (new indication), and hepatocellular carcinomas as a new drug (new indication, in combination with sintilimab).

HALPRYZA® (rituximab injection):

- HALPRYZA® (rituximab injection) is newly included in the NRDL for the maintenance therapy for previously untreated follicular lymphoma and the treatment of chronic lymphocytic leukemia. HALPRYZA® (rituximab injection) has been approved in China for the treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukemia, all of which are included in the NRDL.

SULINNO® (adalimumab injection):

- A total of eight approved indications (including two new indications) have been included in the NRDL for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriasis, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, crohn's disease (new indication) and pediatric crohn's disease (new indication).

Note: Please refer to the NRDL (2022 Version) for the detailed description of the indications involved in the announcement.

In recent years, China government has been persistently promoting the reform of healthcare system for the healthier and better life of people in China, and has achieved conspicuous success. Against such a backdrop and the Company's mission of 'developing high-quality biopharmaceuticals that are affordable to ordinary people', the Company has been highly responsive to China's drug policy and reform. The Company hope to continue to work together with the government to improve drug affordability and accessibility, and bring more high-quality drugs to patients and their families.

About Sintilimab

Sintilimab, marketed as TYVYT® (sintilimab injection) in China, is a PD-1 immunoglobulin G4 monoclonal antibody co-developed by the Company and Eli Lilly. Sintilimab is a type of immunoglobulin G4 (IgG4) monoclonal antibody, which binds to PD-1 molecules on the surface of T-cells, blocks the PD-1/PD-Ligand 1 (PD-L1) pathway, and reactivates T-cells to kill cancer cells. Innovent is currently conducting more than 20 clinical studies of sintilimab to evaluate its safety and efficacy in a wide variety of cancer indications, including more than 10 registrational or pivotal clinical trials.

In China, sintilimab has been approved and included in the National Reimbursement Drug List (NRDL) for six indications. Approved indications of sintilimab include:

- In combination with cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil for the first-line treatment of unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma;

- In combination with fluorouracil and platinum-based chemotherapy for the first-line treatment of unresectable locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma;

- In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of unresectable locally advanced or metastatic non-squamous non-small cell lung cancer lacking EGFR or ALK driver gene mutations;

- In combination with gemcitabine and platinum chemotherapy, for the first-line treatment of unresectable locally advanced or metastatic squamous non-small cell lung cancer;

- In combination with bevacizumab for the first-line treatment of unresectable locally advanced or metastatic hepatocellular carcinoma;

- For the treatment of relapsed or refractory classic Hodgkin's lymphoma after two lines or later of systemic chemotherapy.

In addition, Innovent has the regulatory submission for sintilimab in combination with bevacizumab biosimilar and chemotherapy for EGFR-TKI failed EGFR-mutated non-squamous non-small cell lung cancer under review in the China's National Medical Products Administration ("**NMPA**").

Additionally, two clinical studies of sintilimab have met their primary endpoints, including:

- Phase 2 study of sintilimab monotherapy as second-line treatment of esophageal squamous cell carcinoma;

- Phase 3 study of sintilimab monotherapy as second-line treatment for squamous non-small cell lung cancer with disease progression following platinum-based chemotherapy.

About Olverembatinib

Developed by Ascentage Pharma with support from the National Major New Drug Discovery and Manufacturing Program in China, the orally active, third-generation BCR-ABL inhibitor olverembatinib is the first China-approved third-generation BCR-ABL inhibitor targeting drug-resistant CML. Olverembatinib can effectively target a spectrum of BCR-ABL mutants, including the T315I mutation.

In November 25, 2021, olverembatinib was approved by the NMPA of China for the treatment of adult patients with TKI-resistant CML-CP or CML-AP harboring the T315I mutation as confirmed by a validated diagnostic test. In March 2021, it was granted the Breakthrough Therapy designation by the CDE for the treatment of patients with CML-CP who are resistant and/or intolerant of first- and second-generation TKIs.

In July 2021, the Company and Ascentage Pharma reached the agreement regarding the joint development and commercialization of olverembatinib in China.

About BYVASDA® (bevacizumab injection)

BYVASDA® (bevacizumab injection) is a bevacizumab biosimilar and a recombinant humanized anti-VEGF monoclonal antibody drug. Vascular endothelial growth factor (VEGF) is an important factor in angiogenesis that is highly expressed by the endothelial cells in most human tumors. An anti-VEGF antibody binds VEGF-A selectively with high affinity and blocks its binding to VEGF-2 receptors on the surface of vascular endothelial cells, thereby inhibiting signaling pathways such as PI3K-Akt/PKB and Ras-Raf-MEK-ERK, producing anti-tumor effects by inhibiting the growth, proliferation and migration of vascular endothelial cells, blocking angiogenesis, reducing vascular permeability, blocking blood supply to tumor tissues, inhibiting the proliferation and metastasis of tumor cells and inducing apoptosis in tumor cells. In China, BYVASDA® (bevacizumab injection) is approved and included in NRDL for seven indications including advanced non-small cell lung cancer, metastatic colorectal cancer, adult recurrent glioblastoma, advanced or unresectable hepatocellular carcinoma, epithelial ovarian, fallopian tube, or primary peritoneal cancer and cervical cancer.

About HALPRYZA® (rituximab injection)

HALPRYZA® (rituximab injection) is a rituximab biosimilar and a recombinant anti-CD20 monoclonal antibody drug. Rituximab binds to the CD20 antigen on the surface of B lymphocytes and mediates complement-dependent cytotoxicity (CDC) and antibody-dependent cellular cytotoxicity (ADCC). Normal and malignant B cells are targeted for destruction by the antibody, thereby achieving anti-tumor and immunosuppressive therapeutic effects. In China, HALPRYZA® (rituximab injection) has been approved and included in the NRDL for the treatment of various subtypes of non-Hodgkin's lymphoma and chronic lymphocytic leukemia.

About SULINNO® (adalimumab injection)

SULINNO® (adalimumab injection) is an adalimumab biosimilar and a fully humanized recombinant human anti-TNF-α monoclonal antibody. TNF, a proinflammatory cytokine mainly produced by activated macrophages, natural killer cells and T lymphocytes, is involved in inflammatory and immune responses. Anti-TNF-α antibody can bind to human TNF-α monomer or trimer, subsequently block the binding of TNF-α to the cellular surface receptor, p55 and p75, and neutralize the cytotoxic effect of TNF-α, ultimately resulting in the inhibition of the release of TNF-α mediated inflammatory factors and cytokines, the adhesion and infiltration of inflammatory cells, the proliferation of fibroblasts and the activation of osteoclasts. In China, SULINNO® (adalimumab injection) had been approved and included in NRDL for the treatment of eight indications including ankylosing spondylitis, psoriasis, rheumatoid arthritis, uveitis, pediatric plaque psoriasis, polyarticular juvenile idiopathic arthritis, crohn's disease and pediatric crohn's disease.

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

Hong Kong, China, January 18, 2023

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.