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信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT

ZYBRIVO® (SINTILIMAB) RECEIVES POSITIVE CHMP OPINION FOR FIRST-LINE TREATMENT OF NON-SQUAMOUS NON-SMALL CELL LUNG CANCER

This announcement is made by Innovent Biologics, Inc. (the "**Company**" or "**Innovent**", 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 Zybrivo® (sintilimab) has received its first positive opinion from the Committee for Medicinal Products for Human Use (the "**CHMP**") of the European Medicines Agency ("**EMA**"). The CHMP recommends marketing authorization of Zybrivo® (sintilimab), in combination with chemotherapy, for adults with advanced non-squamous non-small cell lung cancer ("**NSCLC**"). If approved by the European Commission, Zybrivo® (sintilimab) would provide eligible patients across Europe with access to another first-line treatment option. Sintilimab, as an immunotherapy, is a fully human immunoglobulin G4 ("**IgG4**") monoclonal antibody that binds to programmed cell death protein 1 ("**PD-1**").

The positive opinion is supported by results from the Phase 3 ORIENT-11 study (NCT03607539). ORIENT-11 is a randomized, multicenter, double-blind, placebo-controlled Phase 3 study that enrolled 397 adult patients with locally advanced, metastatic or recurrent non-squamous NSCLC with no epidermal growth factor receptor ("**EGFR**") or anaplastic lymphoma kinase ("**ALK**") genomic tumor aberrations, regardless of programmed death-ligand 1 (PD-L1) expression. Patients were randomized 2:1 to receive sintilimab or placebo, each in combination with pemetrexed and platinum-based chemotherapy. The primary endpoint was progression-free survival ("**PFS**"), assessed by a blinded independent radiological review committee.

In ORIENT-11, sintilimab plus chemotherapy demonstrated a 52% reduction in the hazard of disease progression or death (median PFS: 8.9 vs. 5.0 months) and a 35% reduction in the hazard of death (median overall survival (OS): 24.2 vs. 16.8 months), compared with placebo plus chemotherapy. These results demonstrate the clinical benefit of sintilimab in combination with chemotherapy and its potential to offer an additional first-line treatment option for eligible patients with advanced non-squamous NSCLC in Europe. The safety profile of sintilimab in combination with chemotherapy was consistent with the known safety profiles of PD-1 inhibitors and the chemotherapy agents used, with no new safety signals identified.

Zybrivo in combination with pemetrexed and platinum-based chemotherapy is indicated for the first-line treatment of adult non-squamous NSCLC patients with no EGFR or ALK genomic tumor aberrations, and who have:

- locally advanced NSCLC and are not candidates for curative intent surgical resection or chemoradiation, or

- metastatic NSCLC.

Innovent's mission is to empower patients worldwide with affordable, high-quality biopharmaceuticals. The positive CHMP opinion for sintilimab marks an important regulatory milestone in our international development and brings us a step closer to serving patients in Europe. Sintilimab has demonstrated clear clinical benefits in the ORIENT-11 study and, if approved, could provide an additional treatment option for patients in Europe with non-squamous non-small cell lung cancer. Building on this progress, we will continue advancing our innovative pipeline and working to bring meaningful medicines to patients around the world.

Following the CHMP's positive opinion, the European Commission is expected to issue a final decision on marketing authorization in the coming months. If approved, the authorization will be valid across all 27 European Union (EU) member states, as well as Iceland, Norway, and Liechtenstein.

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

Hong Kong, China,
November 16, 2026

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