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Innovent

信達生物製藥

INNOVENT BIOLOGICS, INC.

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 1801)

VOLUNTARY ANNOUNCEMENT

JAYPIRCA® (PIRTOBRUTINIB) APPROVED IN CHINA FOR A NEW INDICATION IN CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)/SMALL LYMPHOCYTIC LYMPHOMA (SLL) ACROSS ALL LINES OF THERAPY

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 the China National Medical Products Administration (“**NMPA**”) has approved Jaypirca® (pirtobrutinib, 100 mg & 50 mg tablets), a non-covalent Bruton tyrosine kinase (“**BTK**”) inhibitor, as a monotherapy for the treatment of adult patient with chronic lymphocytic leukemia (“**CLL**”)/small lymphocytic lymphoma (“**SLL**”). This NMPA action expands the Jaypirca® indication to include patients with CLL/SLL across all lines of therapy and regardless of prior covalent BTK inhibitor treatment.

Jaypirca®, a highly selective kinase inhibitor, utilizes a novel non-covalent binding mechanism to target the BTK pathway in patients with CLL/SLL. It has been evaluated across multiple clinical studies in patients with CLL/SLL who were either previously treated with a covalent BTK inhibitor or who were BTK inhibitor-naïve, generating clinical evidence supporting its use across different CLL/SLL treatment settings.

The approval is supported by data from the global Phase 3 BRUIN CLL-313 and BRUIN CLL-314 clinical trials. BRUIN CLL-313 is the first prospective, randomized Phase 3 study to examine the efficacy and safety of a non-covalent BTK inhibitor in patients with treatment-naïve CLL/SLL. In BRUIN CLL-313, the study demonstrated a statistically significant benefit in independent review committee (“**IRC**”)-assessed progression-free survival (“**PFS**”) for pirtobrutinib compared with bendamustine plus rituximab (BR) (HR=0.199), representing an 80.1% reduction in the risk of disease progression or death¹. BRUIN CLL-314 is the first head-to-head Phase 3 CLL/SLL trial to compare covalent and non-covalent BTK inhibitors in a BTK inhibitor-naïve population, which included relapsed and refractory and treatment-naïve patients. In BRUIN CLL-314, the study met its primary endpoint of noninferiority for overall response rate (“**ORR**”) in both the intent-to-treat (“**ITT**”) population and previously treated patients. Pirtobrutinib achieved a numerically higher ORR compared to ibrutinib. Although PFS data remain immature, a trend toward PFS benefit was observed². Together, these two studies support the clinical value of pirtobrutinib across the CLL/SLL treatment continuum.

About BRUIN CLL-313

BRUIN CLL-313 is a Phase 3, global, randomized, open-label study of pirtobrutinib versus chemoimmunotherapy (BR) in people with CLL/SLL without 17p deletions who have not been previously treated. The trial enrolled 282 patients who were randomized 1:1 to receive pirtobrutinib (200mg orally, once daily) or BR per labeled doses. BR is a chemoimmunotherapy regimen used in the treatment of CLL. The primary endpoint is PFS as assessed by blinded IRC. Secondary endpoints include investigator and IRC-assessed ORR, duration of response (“DoR”), PFS, overall survival (“OS”), time to next treatment (“TTNT”), safety and tolerability and patient-reported outcomes (“PRO”).

About BRUIN CLL-314

BRUIN CLL-314 is a Phase 3, randomized, open-label noninferiority study of Jaypirca® (pirtobrutinib) versus Imbruvica® (ibrutinib) in patients with CLL/SLL who were either treatment-naïve, or who were previously treated and were BTK inhibitor-naïve. The trial enrolled 662 patients who were randomized 1:1 to receive pirtobrutinib (200mg orally, once daily) or ibrutinib (420mg orally, once daily). The primary endpoint is ORR as assessed by blinded IRC. Secondary endpoints include investigator and IRC-assessed PFS, DoR, event-free survival (EFS), and TTNT, OS, safety and tolerability, and PRO.

About Jaypirca® (Pirtobrutinib)

Jaypirca® (pirtobrutinib, formerly known as LOXO-305) (pronounced jay-pihr-kaa) is a highly selective (300 times more selective for BTK versus 98% of other kinases tested in preclinical studies³), non-covalent inhibitor of the enzyme BTK and is the first-and-only approved medicine binding to both wild-type and C481 mutated BTK³. BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including mantle cell lymphoma (MCL) and CLL^{4,5}.

In China, pirtobrutinib was developed by Eli Lilly and Company and is commercialized in mainland China by Innovent.

About Chronic Lymphocytic Leukemia (CLL/Small Lymphocytic Lymphoma (SLL))

CLL/SLL is a form of slow-growing non-Hodgkin lymphoma that develops from white blood cells known as lymphocytes^{6,7}. CLL/SLL is one of the most common types of leukemia in adults⁸. There are roughly 100,000 new cases of CLL/SLL globally each year, and the overall incidence of CLL/SLL in China is estimated at approximately 0.39 per 100,000 population^{8,9}. In CLL/SLL, the cancer cells are present in the blood.

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

Hong Kong, China,
September 28, 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.

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