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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 THE TREATMENT OF RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA OR SMALL LYMPHOCYTIC LYMPHOMA

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 non-covalent (reversible) Bruton’s tyrosine kinase (“**BTK**”) inhibitor, Jaypirca® (pirtobrutinib), has received approval by the National Medical Products Administration of China (NMPA) for a new indication for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (“**CLL/SLL**”) after at least one line of systemic therapy including a BTK inhibitor.

Pirtobrutinib is a highly selective kinase inhibitor that utilizes a novel non-covalent binding mechanism to extend the benefit of targeting the BTK pathway in CLL/SLL patients previously treated with a covalent BTK inhibitor (ibrutinib, acalabrutinib, or zanubrutinib).^{1,2} Pirtobrutinib received approval from the U.S. Food and Drug Administration (FDA) in January 2023 as a non-covalent (reversible) BTK inhibitor. In October 2024, pirtobrutinib was approved in China as a monotherapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (“**MCL**”) who have previously received at least two prior systemic therapies, including a BTK inhibitor.

The approval of this new indication is based on results from the international, multicenter, randomized, Phase 3 BRUIN CLL-321 study. BRUIN CLL-321 is the world’s first randomized Phase 3 trial conducted in patients with CLL/SLL who had previously been treated with a covalent BTK inhibitor (cBTKi). The study enrolled a total of 238 patients and evaluated the efficacy and safety of pirtobrutinib monotherapy versus investigator’s choice of idelalisib plus rituximab (“**IdelaR**”) or bendamustine plus rituximab (“**BR**”). The results demonstrated that pirtobrutinib significantly prolonged median progression-free survival (PFS) compared with the investigator’s choice regimen (14.0 months vs 8.7 months; hazard ratio [HR] = 0.54). In addition, the discontinuation rate due to treatment-related adverse events was lower with pirtobrutinib (5.2% vs 21.1%), further supporting its efficacy and tolerability advantages in patients previously treated with a covalent BTK inhibitor.³

The approval of Jaypirca[®] (pirtobrutinib) in China for CLL/SLL represents a significant breakthrough in this field, which ensures that CLL/SLL patients in China have timely access to this global therapeutic innovation. We will fully leverage the Company's leading brand presence and commercialization capabilities in oncology, to accelerate the accessibility of this innovative therapy, thereby benefiting more cancer patients in need.

About BRUIN CLL-321

BRUIN CLL-321 is a Phase 3, randomized, open-label study of Jaypirca versus investigator's choice of IdelaR or BR in covalent BTK inhibitor pre-treated patients with relapsed and refractory CLL/SLL. The trial enrolled 238 patients, who were randomized 1:1 to receive Jaypirca (200 mg orally, once daily) or investigator's choice of either IdelaR or BR per labeled doses. This trial's primary endpoint is progression-free survival (PFS) per 2018 International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria, as assessed by blinded independent review committee (IRC). Secondary endpoints include PFS, as assessed by investigator; overall response rate (ORR) and duration of response (DoR); event-free survival; overall survival (OS) and time to next treatment (TTNT); safety and tolerability; and patient-reported outcomes (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 studies), non-covalent (reversible) inhibitor of the enzyme BTK.² BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including MCL and chronic lymphocytic leukemia (CLL).^{4,5}

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

About CLL/SLL

CLL and SLL are forms of slow-growing non-Hodgkin lymphoma that develop from white blood cells known as lymphocytes.⁶ In China, CLL represents approximately 6% – 7% of non-Hodgkin lymphoma cases.⁷ SLL is identical to CLL from a pathologic and immunophenotypic standpoint, with the main difference between them being the location of the cancer cells. In CLL, the cancer cells are present in the blood, and in SLL, the cancer cells are found in the lymph nodes.⁶

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

Hong Kong, China,
February 27, 2026

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 and Ms. Qian Zhang as Executive Directors, and Dr. Charles Leland Cooney, Ms. Joyce I-Yin Hsu, Mr. Gary Zieziula, Dr. Shun Lu, Mr. Shuyun Chen and Dr. Stephen A. Sherwin as Independent Non-executive Directors.

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