Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2025/09/05	Time of announcement	13:41:34

Subject	Senhwa announces the NCI-sponsored clinical trial of CX-5461 granted IND clearance for Phase 1b/2 trial targeting MYC aberrant B-cell lymphoma.
Date of events	2025/09/05
To which item it meets	paragraph 53

Statement

1.Date of occurrence of the event:2025/09/05
2.Company name:Senhwa Biosciences Inc.
3.Relationship to the Company (please enter ”head office” or ”subsidiaries”):Headquarter
4.Reciprocal shareholding ratios:Not applicable
5.Cause of occurrence:
(1)The IND application for the aforementioned clinical trial was announced by the Company on August 7, 2025. Details of the trial’s objectives and study design are available in the material information disclosure released on that date.
(2)CX-5461 is a global first-in-class small-molecule innovative drug. It selectively binds to and stabilizes G-quadruplex (G4) structures. In early clinical trials in hematologic malignancies, CX-5461 demonstrated encouraging activities in patients with B-cell lymphoma. In vivo and in vitro analysis further showed that CX-5461 suppresses MYC gene expression and inhibits tumor cell proliferation. CX-5461 represents the potential of a next-generation targeted anticancer therapy, offering breakthrough treatment opportunities particularly for refractory lymphomas. The upcoming clinical trial will focus on patients with specific subtypes of aggressive B-cell non-Hodgkin’s lymphoma harboring MYC gene aberrations. Eligible subjects include those who have previously received at least one line of therapy for Burkitt lymphoma (BL) or two lines of therapy for diffuse large B-cell lymphoma (DLBCL) and who currently lack effective treatment options. This study will evaluate dose escalation and assess efficacy, aiming to provide a potential breakthrough solution for this area of high unmet medical need.
(3)According to data from the market research firm BioSpace, global sales of B-cell lymphoma-related drugs reached USD 4.9 billion in 2024 and are projected to reach USD 8.9 billion by 2035, expanding steadily at a compound annual growth rate (CAGR) of 5.79% over the next decade. In particular, there is strong demand for innovative targeted therapies among patients with relapsed and refractory lymphoma, representing a significant market gap. With its differentiated mechanism of action and precision medicine potential, Senhwa’s CX-5461 is expected to generate substantial licensing value if clinical outcomes prove favorable.
(4)A single clinical trial result does not reflect the success or failure of new drug development and launch in the future. Investors should make prudent judgments and investments.
6.Countermeasures:Upload the important information on Market Observation Post System.
7.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 9 of the Securities and Exchange Act Enforcement Rules, which brings forth a significant impact on shareholders rights or the price of the securities on public companies.):None. Drug development requires huge amount of time and investment, and there is no guarantee of success, which may put the investment at risk. Investors should make prudent judgments on investments.