Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2025/12/11	Time of announcement	06:30:52
Subject	The Company and BeOne Medicines announced a clinical supply agreement to evaluate CX-5461 plus tislelizumab in advanced solid tumor trials.				
Date of events	2025/12/10	To which item it meets	paragraph 10		

Statement

1.Date of occurrence of the event:2025/12/10
2.Counterparty to the contract or commitment:BeOne Medicines
3.Relationship with the Company:None
4.Starting and ending dates (or rescission date) of the contract or commitment:2025/12/10
5.Major content (not applicable where rescinded):
(1)The Company and BeOne Medicines , a global oncology company, have signed a clinical supply agreement to launch a global, multicenter Phase 1b/2a clinical trial. Under the terms of agreement, BeOne Medicines will provide its marketed PD-1 inhibitor tislelizumab for the combination, while the Company will supply Pidnarulex (CX-5461) and lead the clinical and regulatory operations. The study will enroll patients at multiple sites in the United States and Taiwan, assessing safety, tolerability, and preliminary efficacy of the CX-5461 plus tislelizumab combination in advanced solid tumors, including pancreatic ductal adenocarcinoma (PDAC), immune checkpoint inhibitor (ICI)-refractory melanoma cancer.
(2)CX-5461 is the World’s first G-quadruplex stabilizer with substantial evidence. Through a unique replication-stress-inducing mechanism, it selectively disrupts genomic stability in tumor cells. Recent preclinical and clinical findings suggest that CX-5461 not only exerts direct cytotoxic activity but also modulates the tumor microenvironment, enhancing immune recognition and response. By converting immunologically “cold” tumors into “hot” ones, CX-5461 may sensitize previously resistant tumors to checkpoint inhibition and broaden the clinical utility of immunotherapy. Early clinical data from ongoing trials in Canada and the U.S. have shown encouraging results.
(3)The“cold-to-hot” tumor concept represents one of the most promising frontiers in cancer immunology. This clinical collaboration between Senhwa and BeOne Medicines-combining what is regarded as a best-in-class PD-1 inhibitor—aims to leverage the mechanism of CX-5461 to overcome the current limitation in which only about 20% to 30% of cancer patients respond to immunotherapy. Furthermore, it is expected to increase Senhwa’s international visibility and generate long-term value and growth momentum as the Company expands into the immuno-oncology field.
(4)According to Precedence Research, the global cancer immunotherapy market is projected to grow from US $136.4 billion in 2025 to US $338.4 billion by 2034, with a compound annual growth rate (CAGR) of 10.65%. Additionally, Grand View Research forecasts the global immunotherapy drug market will exceed US $486 billion by 2030.
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.Restrictive covenants (not applicable where rescinded):None
7.Commitment (not applicable where rescinded):None
8.Any other important agreement (not applicable where rescinded):None
9.Effect on company finances and business:If the clinical trial progresses as planned, it is expected to have a positive impact on the Company’s financial performance and business development.
10.Concrete purpose/objective:Under the terms of the agreement, the study will assess safety, tolerability, and preliminary efficacy of the CX-5461 plus tislelizumab combination. This clinical supply agreement represents a significant milestone for Senhwa as CX-5461 enters the immuno-oncology field, and it also underscores the company’s commitment to advancing strategic combination therapies that break through the limitations with immunotherapy—bringing new hope to cancer patients worldwide.
11.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 8 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.