Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2025/09/16	Time of announcement	13:42:04

Subject: Senhwa's CX-5461 IND submitted for combination therapy with Sanofi/Regeneron's approved PD-1 inhibitor Cemiplimab to treat refractory MSS CRC colorectal cancer

Date of events: 2025/09/16 To which item it meets: paragraph 53

Statement

1.Date of occurrence of the event:2025/09/16
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)CX-5461 (Pidnarulex) in the NCI NExT Program
Senhwa Biosciences’ novel anticancer agent Pidnarulex (CX-5461) has been selected by the U.S. National Cancer Institute (NCI) for its five-year NExT (NCI Experimental Therapeutics) program. Following two prior trials—monotherapy for advanced solid tumors (notified of first patient enrolled on July 16, 2025) and for B-cell lymphoma with specific MYC gene aberrants (notified of IND approved by the U.S. FDA on September 5, 2025)—this third clinical trial combines CX-5461 with the approved PD-1 inhibitor Cemiplimab (Libtayo) under the NCI-NExT program.
(2)Trial design overview:
a.Title: A Phase 1 and Randomized Phase 2 Clinical Trial of Pidnarulex (CX-5461) and Cemiplimab (REGN2810) in Refractory Microsatellite Stable Colorectal Cancer.
b.Enrollment:
- Phase 1 (Safety run-in): Up to 18 patients
- Phase 2 (Randomized): 68 patients
c.Treatment Regimen:
CX-5461: Intravenous infusion on Days 1 and 8 of each 28-day cycle; treatment with CX-5461 may be continued until disease progression or unacceptable toxicity. Cemiplimab: Up to 26 cycles.
d.Objectives:
1.Primary Endpoints:
a.In Phase 1, establish the recommended Phase 2 dose (RP2D) of CX-5461 combined with Cemiplimab; determine safety and tolerability of CX-5461 alone and in combination with Cemiplimab in phase I and II.
b.In Phase 2, determine progression-free survival (PFS) of CX-5461 monotherapy and in combination with Cemiplimab in refractory, liver-metastatic MSS CRC patients.
2.Secondary Endpoints:
a.Observe and record anti-tumor activity.
b.Compare the objective response rate (ORR) and disease control rate (DCR) between monotherapy and combination therapy arms in Phase 2.
c.Compare duration of response (DoR) between arms.
d.Compare overall survival (OS) between arms.
e.Characterize the plasma pharmacokinetics (PK) of CX-5461 alone and in combination with Cemiplimab.
f.Characterize the PK of Cemiplimab.
g.Using whole-exome sequencing (WES), explore baseline and post-treatment gene signature patterns that may suggest response to CX-5461 alone or in combination with Cemiplimab.
(3)Medical Background & Unmet Need
Microsatellite stable colorectal cancer (MSS CRC) accounts for approximately 95% of all CRC cases, with a significant unmet medical need due to high incidence and mortality. The disease is increasingly diagnosed in younger populations, creating urgent demand for new treatment options to alter its clinical trajectory and deliver durable benefits. Globally, cancer immunotherapy faces several challenges: low response rates (~20–30%) for most solid tumors to immune checkpoint inhibitors (ICIs)、emergence of resistance or loss of efficacy in many patients、lack of consistent and reliable biomarkers for clinical decision-making、treatment cost and quality-of-life considerations. There are evidences in Pre-clinical studies that suggests CX-5461 can modulate the tumor microenvironment, enhancing sensitivity and efficacy to immunotherapies including anti-PD-1 and anti-PD-L1 agents. Accelerating the development of combination therapy trials and optimizing clinical trial designs may lead to improved overall treatment outcomes, offering cancer patients novel therapeutic options that enhance quality of life and extend survival.

(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.