SEQ_NO	2	Date of announcement	2025/04/02	Time of announcement	14:36:16

Subject: The Company announces the completion of Clinical Study Report (CSR) for Phase 1/Dose Expansion Trial of Silmitasertib in the Treatment of Basal Cell Carcinoma.

Date of events: 2025/04/02 To which item it meets: paragraph 53

Statement

1.Date of occurrence of the event:2025/04/02
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:
Our company has finalized the Clinical Study Report (CSR) for the Phase 1 and dose expansion study of the investigational drug Silmitasertib (CX-4945) as a monotherapy for advanced basal cell carcinoma (BCC). The last patient’s last visit occurred on January 25, 2024. Key highlights from the CSR are outlined below:
A.Enrollment and Objectives:
The trial enrolled 25 patients, including 20 patients diagnosed with locally advanced BCC (laBCC) and 5 patients with metastatic BCC (mBCC).
1.The primary objective was to determine the recommended Phase 2 dose (RP2D) and the dosing regimen of CX-4945.
2.The secondary objectives included safety and tolerability assessment, preliminary evaluation of antitumor efficacy, and tumor tissue sampling in laBCC patients to analyze the impact of CX-4945 on the Hedgehog (Hh) signaling pathway.
B.Efficacy analysis:
1.Among the 22 patients eligible for efficacy analysis, three laBCC patients achieved partial response (PR) with tumor shrinkage exceeding 30%. Additionally, 10 patients achieved stable disease (SD), including 2 mBCC and 8 laBCC cases. Regardless of duration, the combined rates of patients with observed CR, PR, and SD was 80% for mBCC and 65% for laBCC.
2.All enrolled patients eligible for efficacy analysis had received prior treatment with Smoothened (SMO) inhibitor. Among them, 6 patients (27.3%) had previously failed first-line therapy and progressed despite receiving PD-1 inhibitors (e.g., Libtayo or Keytruda) as second-line treatment.
3.The median progression-free survival (PFS) was 9.2 months for laBCC patients and 3.7 months for mBCC patients. The median duration of disease control (DDC) was 10.3 months for laBCC and 7.5 months for mBCC.
C.Safety analysis:
1.CX-4945 (1,000 mg orally, twice daily) demonstrated long-term safety in the treatment of recurrent BCC, with a study drug discontinuation rate due to adverse events (AEs) of 24%. The rate is lower than the 30-40% observed with first-line SMO inhibitors.
2.Two late-stage patients achieved a PFS exceeding 21 months with CX-4945: One of the patients, who was previously treated with SMO inhibitor for three months and discontinued due to toxicities, experienced a PR with CX-4945, with the primary lesion nearly disappearing visually and a PFS reaching 653 days.
The second patient, despite a temporary treatment interruption due to comorbidities, achieved a PFS of 667 days. CX-4945 significantly prolongs survival in patients with advanced cancer, carrying profound significance for both the patients and the Senhwa team.
3.A total number of 138 treatment-emergent adverse events (TEAEs) related to CX-4945 were reported, mostly mild to moderate, with the most common being diarrhea (84%), nausea (56%), and vomiting (28%).
D.Conclusion:
1.The study results indicate that CX-4945 monotherapy provides extensive clinical benefits to patients with recurrent or treatment-refractory advanced BCC, demonstrating consistent antitumor activity with substantial potential for further development.
2.CX-4945 targets CK2, which may reduce GLI1 levels within the downstream segment of the Hh pathway. This contrasts with SMO inhibitors that target Smoothened, functioning upstream within the Hh pathway. CX-4945’s unique mechanism of action suggests its potential irrespective of upstream pathway activation or resistance arising from Smoothened mutations.
3.Since February 2021, Libtayo (an anti-PD-1 medication) has been approved as a second-line treatment for advanced BCC by the FDA. Preliminary data suggest that CX-4945 achieves robust disease control in mBCC patients, with a combined rates of observed CR, PR, and SD, regardless of duration, reaching 80%. For reference, the disease control rate (DCR) of Libtayo is 63% by independent central review and 70% by investigator assessment. Moreover, CX-4945 has a lower study drug discontinuation rate due to AEs, compared to first-line treatments including Vismodegib and Sonidegib,

suggesting superior tolerability.
Our company is committed to actively pursuing licensing opportunities and conducting a thorough assessment of CX-4945’s potential applications, both as a monotherapy and in combination with Libtayo. We aim to further explore its full potential across related indications and first-line treatment opportunities, with the goal of bringing better treatment options to patients.
(2)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 material 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.