## Historical Information

Provided by: Senhwa Biosciences, Inc.

| | | | | | |
|---|---|---|---|---|---|
| SEQ_NO | 1 | Date of announcement | 2024/07/11 | Time of announcement | 14:12:08 |

Subject: Senhwa Biosciences Announces IND Submission to US FDA for the PhaseI/II study of Silmitasertib in children /dearyoung adults with relapsed refractory solid tumors.

Date of events: 2024/07/11 To which item it meets: paragraph 53

Statement

1.Date of occurrence of the event:2024/07/11
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)High CK2 activity is noted across several pediatric cancers, including neuroblastoma, Ewing sarcoma, rhabdomyosarcoma, osteosarcoma, medulloblastoma, and liposarcoma. Recent study has shown that CK2 is one of the key kinases that is essential for maintaining the stabilization of MYCN protein, the oncogenic driver in neuroblastoma. In view of the anti-tumor activity of CK2 inhibitor, the Beat Childhood Cancer Research Consortium at The Pennsylvania State University regards Silmitasertib (CX-4945) high therapeutic potential of treating pediatric cancers.
(2)This phase I/II study is funded by the Four Diamonds Foundation, with Senhwa Biosciences providing the investigational drug, Silmitasertib (CX-4945).
(3)Neuroblastoma is the most common type of solid malignant tumor in children, aside from brain tumors and lymphomas. Over 90% of cases are diagnosed before the age of 5. Due to its rapid growth, neuroblastoma can easily invade the bone marrow, bones, liver, soft tissues, distant lymph nodes, the brain, and the skin. 70% of patients already have metastatic disease by the time symptoms appear, and the 20-year survival rate is only around 30%. In the US, there are 700-800 new cases each year, accounting for about 6% of childhood cancers, meeting the definition of a rare disease.
Senhwa Biosciences is planning to apply for Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPD) for Silmitasertib (CX-4945) for the treatment of neuroblastoma. If these designations are granted and the drug is successfully commercialized, the company would obtain a Priority Review Voucher (PRV). The holder of a PRV can designate any future human drug application to receive priority review, potentially shortening the review time to 6 months, which could accelerate the timeline for the company (or its partners) to bring other products to market.
The clinical trial design also includes Ewing's sarcoma and osteosarcoma, which are common pediatric bone cancers with poor prognoses, representing unmet medical needs.
(4)The clinical trial is conducted in two phases: the first phase focuses on establishing the safety and dosage of Silmitasertib (CX-4945) in pediatric patients with relapsed or refractory solid tumors, while the second phase evaluates its efficacy and potential as a novel treatment option.
The details of the trial design are as follows:
a.Study Title: A Phase I/II Investigator-Initiated Trial (IIT) of Silmitasertib (CX-4945) in Combination with Chemotherapy for the Treatment of Relapsed/Refractory Pediatric and Adolescent Solid Tumors.
b.Enrollment: The initial plan is for 59 patients (18 in Phase I, 41 in Phase II). If there are initial clinical benefits, the Four Diamonds Foundation will sponsor a follow-up trial of 55 patients with Ewing sarcoma by purchasing the drug from the company.
c.Treatment Regimen: All subjects will receive 21-day cycles of Silmitasertib twice a day combined with chemotherapy.
d.Primary Objectives:
- Phase I Dose Escalation: 1. To determine the safety of Silmitasertib (CX-4945) in combination with chemotherapy in children with relapsed/ refractory solid tumors including neuroblastoma, Ewing sarcoma, and osteosarcoma; 2. To find the recommended Phase 2 dose (RP2D).
- Phase II: 1. To evaluate the overall response rate (ORR) of Silmitasertib (CX-4945) in cohorts of relapsed/refractory neuroblastoma and Ewing sarcoma.
(5)The Beat Childhood Cancer Research Consortium is a globally renowned pediatric cancer research and treatment alliance, comprising scientists

and clinicians from leading North American medical research institutions and children's hospitals, with a network of over 50 hospitals in the US. They focus on conducting clinical trials and international collaborations to bring hope for children with treatment-resistant or relapsed cancers, and have previously helped obtain approvals for high-risk relapsed neuroblastoma treatments.
(6)Despite medical and technological advancements, the global mortality rate for childhood and adolescent cancers remains high, with over 80,104 children dying from cancer in 2020 worldwide. In the US alone, an average of 1,600 children die from cancer each year, underscoring the urgent need for more effective cancer treatments.
(7)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.