Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	2	Date of announcement	2024/09/13	Time of announcement	07:01:31

Subject: US FDA Grants Rare Pediatric Disease Designation (PRDD) to Senhwa Biosciences Silmitasertib for Pediatric Neuroblastoma.

Date of events: 2024/09/12 To which item it meets: paragraph 53

Statement:

1.Date of occurrence of the event:2024/09/12
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)On September 12, 2024, the Company received an official letter from the U.S. Food and Drug Administration (FDA), granting Senhwa Biosciences’ investigational new drug Silmitasertib (CX-4945) the ”Rare Pediatric Disease Designation” (RPDD) for the treatment of pediatric malignant tumors - neuroblastoma. This is the recognition obtained again after Silmitasertib (CX-4945) received RPDD in medulloblastoma from the FDA in July 2020, demonstrating the great potential of Silmitasertib (CX-4945) in the development of treatments for rare pediatric cancers.
(2)Neuroblastoma is the most common malignant solid tumor in children, aside from brain tumors and lymphomas, with over 90% diagnosed before the age of five. Due to its rapid growth, it can easily invade the bone marrow, bones, liver, soft tissues, distant lymph nodes, brain, and skin. About 70% of affected children have already metastasized by the time symptoms appear, and the 20-year survival rate is only 30%. In the United States, there are an average of 700 to 800 new cases each year, accounting for approximately 6% of childhood cancers, meeting the definition of a rare disease. With the RPDD granted for this new indication of Silmitasertib (CX-4945), if it’s successfully approved for marketing in the future, it will qualify for a Priority Review Voucher (PRV). The holder of this voucher can designate one human drug application for priority review, which is expected to significantly shorten the review period to six months, potentially accelerating the marketing timeline for the company (or its partners).
(3)For more information about the FDA's approval for Senhwa Biosciences’ Silmitasertib (CX-4945) to conduct Phase 1/2 clinical trial in humans for recurrent/refractory pediatric solid tumors, including neuroblastoma, Ewing sarcoma, and osteosarcoma, as well as the objectives and design of this trial, please refer to the company’s material information released on August 7, 2024, and July 11, 2024.
(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 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.