Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2024/08/07	Time of announcement	06:51:55

Subject: Senhwa receives FDA Study May Proceed letter for the PhaseI/II study of Silmitasertib in children and young adults with relapsed refractory solid tumors.

Date of events: 2024/08/06 To which item it meets: paragraph 53

Statement:

1.Date of occurrence of the event:2024/08/06
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)The submission of the clinical trial mentioned above was announced by company on July 11, 2023. For details regarding the purpose, design, and planning of this clinical trial, please refer to the announcement made on that day.
(2)The principal investigator of this investigator-initiated trial (IIT), Dr. Giselle Saulnier Sholler, is an internationally known pediatric hematology-oncology clinician and researcher. In August 2023, she was invited to serve as the division chief of Pediatric Hematology and Oncology at Penn State Health Children’s Hospital. She brought with her the Beat Childhood Cancer Research Consortium, a worldwide network of more than 55 universities and children’s hospitals dedicated to discovering new therapies and cures for children with cancer. The research consortium has enrolled more than 1,800 pediatric cancer patients in more than 23 trials, and has previously helped a drug obtain FDA approval for high-risk relapsed neuroblastoma treatments. This phase I/II study is funded by the Four Diamonds Foundation, with Senhwa Biosciences providing the investigational drug, Silmitasertib (CX-4945).
(3)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.