Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2024/07/12	Time of announcement	13:51:10

Subject: The abstract of Phase Ib expansion study of CX-5461 in patients with solid tumors and BRCA2 and/or PALB2 mutation has been accepted at 2024 ESMO Congress

Date of events: 2024/07/12 To which item it meets: paragraph 53

Statement:

1.Date of occurrence of the event:2024/07/12
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)The 2024 European Society for Medical Oncology (ESMO) Congress (ESMO Congress 2024) will be held in Barcelona, Spain, from September 13 to 17, 2024, welcoming both in-person and virtual participations. This congress will showcase the latest cutting-edge cancer translational data and provide a platform for oncology professionals and scientists to network and share research and innovations. The ESMO Congress is a cornerstone event in oncology, recognized globally for its significant contributions to cancer treatment and research. It is one of the top three cancer medical conferences worldwide, alongside ASCO and AACR. The abstract of the expansion study data with the Company’s first-in class drug candidate Pidnarulex (CX-5461), in treating various solid tumors with BRCA1, BRCA2, and/or PALB2 gene deficiencies is carried out by its partner Princess Margaret Cancer Centre in Canada has been accepted for poster presentation at the 2024 European Society for Medical Oncology in Barcelona , Spainand online. Due to compliance with the ESMO’s embargo policy on abstract confidentiality, the title of the abstract will be made available via the ESMO website by end of July;the full abstract content and relevant data will be disclosed on online via the ESMO website at 00:05 CEST on Monday, 9 September 2024.
(2)This clinical trial is designed as an open-label, multi-national, multi-center trial, divided into a Main Study Cohort and an Exploratory Cohort. They will respectively enroll patients with BRCA2 and/or PALB2 gene deficiencies in various tumors (pancreatic, breast, ovarian, and prostate cancers), as well as patients with BRCA1 gene deficiencies and/or other HRD gene homologous recombination defects in ovarian cancer. The primary endpoint of this trial is to determine the optimal drug dosage for cancer patients with specific gene deficiencies, while the secondary endpoints are set to assess the safety and tolerability of Pidnarulex (CX-5461) and to evaluate its late onset toxicity, anti-tumor activity, and improvements in subjects' quality of life. Patients enrolled in this clinical trial have received 2-10 lines of different treatment regimens, including those who have developed resistance to platinum-based chemotherapy drugs, shown ineffectiveness to PARP inhibitors, and have no other treatment options available in the advanced stage. The clinical benefits observed in patients receiving Pidnarulex (CX-5461) treatment greatly encouraged both the clinical teams in Taiwan and Canada. There are terminal cancer patients in this trial found still in stable conditions continuing to receive Pidnarulex (CX-5461) treatment, highlighting its alignment with the trend of precision medicine in new drug development.
(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 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.