Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	2	Date of announcement	2024/09/09	Time of announcement	09:01:58

Subject: The Phase Ib expansion study abstract of CX-5461 in solid tumor patients with BRCA2 and/or PALB2 mutations is now on the ESMO 2024 website-Update URL

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

Statement

1.Date of occurrence of the event:2024/09/09
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. 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.
(2)The title of the poster abstract that has been selected for on-site and online presentation is ”Phase 1b expansion study of CX-5461 in patients with solid tumours and BRCA2 and/or PALB2 mutation.” The full abstract content has been published on the ESMO website at 00:05 CEST on September 9, 2024, at the following link: https://cslide.ctimeetingtech.com/esmo2024/attendee/confcal_2/presentation/list?q=631p
(3)The trial report states that the preliminary results of the new drug CX-5461 from Senhwa Biosciences in clinical trials in Canada and the USA indicate that out of the first 28 enrolled patients, 22 completed at least one cycle of treatment and were evaluated for dose-limiting toxicity (DLT). The patients had previously undergone multiple lines of cancer treatment, with a median of 6 lines (ranging from 2 to 10 lines) of prior therapy, including 77% of patients who had received platinum-based chemotherapy, 41% of patients who had been treated with bevacizumab, and 86% of patients who had previously received PARP inhibitors without success. These were end-stage oncology patients with no other suitable treatment options. The median number of CX-5461 treatments received by the patients was 4 doses (ranging from 2 to 36 doses).
Trial Results:
Among the 15 patients who were evaluable for drug response, 40% achieved clinical benefit, with stable disease (SD) being the best therapeutic response. Among these stable disease patients, there were 5 ovarian cancer patients, including 3 with BRCA1 somatic mutations, 1 with a BRCA1 germline mutation, and 1 with HRD-related gene mutations. All 5 patients had previously failed platinum chemotherapy and PARP inhibitor treatments, with 2 of them maintaining stable disease for at least 6 months following CX-5461 treatment.
Trial Objectives:
This clinical trial was designed as an open-label, multicenter, multinational study, divided into the Main Study Cohort and the Exploratory Cohort. It aimed to recruit patients with BRCA2 and/or PALB2 gene deficiencies from various tumor types (pancreatic cancer, ovarian cancer, prostate cancer, and breast cancer), as well as ovarian cancer patients with BRCA1 deficiencies and/or other HRD-related homologous recombination defects. The primary goal of the trial was to determine the recommended Phase II trial dose for patients with specific genetic deficiencies, while secondary endpoints include evaluating the safety, tolerability, and antitumor activity of Pidnarulex (CX-5461).
Trial Conclusion:
This Phase Ib study demonstrated that CX-5461 exhibit acceptable clinical tolerability and shows preliminary signs of activity, even in patients who had previously failed treatment with PARP inhibitors. Photosensitivity was found to be manageable through preventive measures.
(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 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.