## Historical Information

Provided by: Senhwa Biosciences, Inc.

| SEQ_NO | 1 | Date of announcement | 2024/09/18 | Time of announcement | 06:23:38 |
|---|---|---|---|---|---|

Subject: Senhwa Announces IND Submission to US FDA for the Pilot Study of Pidnarulex Pharmacodynamics in Patients with Advanced Solid Tumors sponsored by the US NCI.

Date of events: 2024/09/17 To which item it meets: paragraph 53

Statement:

1.Date of occurrence of the event:2024/09/17
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 December 1, 2022, Senhwa Biosciences' new drug Pidnarulex (CX-5461) was selected to enter the five-year joint development program of the National Cancer Institute (NCI) under the National Institutes of Health (NIH) in the United States, known as the NCI Experimental Therapeutics (NExT) Program. The contract was officially signed in March 2023, with NCI funding the clinical trials to expedite the development of Pidnarulex.
(2)Pidnarulex (CX-5461), a first-in-class small molecule drug, selectively binds and stabilizes G-quadruplex (G4) structures within DNA, preventing their unwinding. The action of Pidnarulex induces replication-dependent DNA damage and leads to cancer cell death. The prevalence of G4 structures in tumor tissues, particularly within actively transcribed genes, including oncogenes, underscores their potential role in cancer development. Pidnarulex’s ability to target these structures and induce replication-dependent DNA damage position it as a potential therapeutic for various cancers. Preclinical data shows that Pidnarulex (CX-5461) has selectivity for G4 structures in human telomeres, c-KIT1, and c-MYC. These findings have sparked the NCI team to further explore the efficacy and safety of Pidnarulex (CX-5461), shaping the design and execution of this clinical trial to extensively assess its therapeutic potential and pharmacodynamic characteristics in cancer treatment. The sponsor of this investigational new rug (IND) application is DCTD at the NCI.
(3)The details of the trial design are as follows:
a.Study title: Pilot Study of Pidnarulex Pharmacodynamics in Patients with Advanced Solid Tumors
b.Enrollment: Anticipated enrollment of 40 patients (20 with homologous recombination deficiency (HRD), 20 without HRD).
c.Treatment regimen: Each cycle is 28 days, with CX-5461 325 mg/m2 administered intravenously on days 1 and 8 of each cycle.
d.Primary objective:
To assess whether Pidnarulex induces a Rad51 response in patients with and without HRD genetic mutations.
e.Exploratory biomarkers:
- DNA damage response (DDR) biomarkers, including Top2, γH2AX, pNBS1, pSer33-RPA32
- Cell cycle arrest biomarkers, including pHH3, pY15-CDK, and β-catenin
- Tumor cell apoptosis biomarkers, including γH2AX and cleaved Caspase 3
- Measurement of CX-5461's ability to bind and stabilize G4 structures
f.Secondary objectives:
- Safety and tolerability of CX-5461
- Objective response rate of CX-5461
- Pharmacokinetics (PK) of CX-5461
(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.