

Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2024/10/14	Time of announcement	06:31:37
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Subject	FDA issues Study May Proceed letter for the Pilot Study of Pidnarulex Pharmacodynamics in patients with advanced solid tumors, NCI-sponsored				
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Date of events Statement	2024/10/12	To which item it meets	paragraph 53		
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- 1.Date of occurrence of the event:2024/10/12
- 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 submission of the clinical trial mentioned above was announced by the company on September 18, 2024. For details regarding the purpose, design, and planning of this clinical trial, please refer to the announcement made on that day.
 - (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 that 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 positions it as a potential therapeutic for various cancers. On December 1, 2022, 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. Following extensive discussions and strategic planning, the initiative has now been officially implemented. With funding from NCI the clinical trial to set to expedite the development of Pidnarulex, aimed to address the unmet need of late-stage cancer treatment.
 - (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.