

Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO 1 Date of announcement 2025/07/16 Time of announcement 06:28:55

Subject Senhwa Biosciences announces first patient dosed in NCI-sponsored pilot study of Pidnarulex (CX-5461) pharmacodynamics in patients with advanced solid tumors.

Date of events 2025/07/15 To which item it meets paragraph 53

1.Date of occurrence of the event:2025/07/15
2.Company name:Senhwa Biosciences Inc.
3.Relationship to the Company (please enter "head office" or "subsidiaries"):Headquarter
4.Reciprocal shareholding ratios:Headquarter
5.Cause of occurrence:
(1)Senhwa Biosciences' new drug Pidnarulex (CX-5461) has been selected for inclusion in the five-year joint development program, known as the NCI Experimental Therapeutics (NExT) Program, led by the National Cancer Institute (NCI) under the National Institutes of Health(NIH) in the United States. The first patient has been successfully dosed in the monotherapy trial at the NIH Clinical Center in Bethesda, Maryland, USA. The study will assess Rad51 response induced by Pidnarulex (CX-5461) in patients with and without homologous repair deficiency (HRD) genetic mutations. This pilot study also aims to explore potential biomarkers associated with the synthetic lethality of Pidnarulex (CX-5461), facilitating the identification of patients who are more responsive to Pidnarulex (CX-5461) treatment and supporting the expansion of its therapeutic applications.
(2)Pidnarulex (CX-5461) is an innovative first-in-class small molecule developed by Senhwa Biosciences. It acts by selectively targeting and stabilizing G-quadruplexes (G4s), preventing their unwinding and triggering replication-dependent DNA damage, ultimately resulting in cancer cell apoptosis. The frequent presence of G4 structures in tumors, especially in transcriptionally active genes, implies their potential functional involvement in the development of cancer. By targeting G4s and triggering DNA damage in cancer cells, Pidnarulex (CX-5461) emerges as a potential therapeutic candidate with significant promise across multiple cancer indications.
Statement (3)Led by the National Cancer Institute (NCI), this project covers clinical study design, funding, and operational resources. Following the collaboration agreement finalized between Senhwa Biosciences and the NCI in March 2023, the project has undergone rigorous expert review and multi-party planning, now officially launching patient enrollment. The clinical trial intends to recruit 40 patients and requires resources for clinical trial site operations, pharmacokinetic (PK) assessments, biomarker analyses, along with multiple execution-related elements such as regulatory compliance, data management, and electronic platform implementation. With financial sponsorship backed by the NCI, Senhwa anticipates offsetting approximately USD 4.8 million in clinical development investments, effectively alleviating its R&D expenditures and accelerating the advancement of new drug development. The support from the NCI highlights the significant potential of CX-5461 in the field of emerging therapeutic targets, and reflects the international recognition of Taiwan's biotech achievements, further enhancing Senhwa's visibility and its strategic presence in the global landscape of anti-cancer therapeutic innovation.
(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.