Historical Information

Provided by: Senhwa Biosciences, Inc.

SEQ_NO	1	Date of announcement	2025/07/09	Time of announcement	06:30:47

Subject: Announcement of Phase II clinical trial unblinding results for CX-4945 in treating community-acquired pneumonia from pan-viral infections.

Date of events: 2025/07/08 To which item it meets: paragraph 10

Statement

1.Date of occurrence of the event:2025/07/08
2.New drug name or code:Silmitasertib (CX-4945)
3.Indication:community-acquired pneumonia from pan-viral infections. (Mainly SARS-CoV-2 and Influenza Virus)
4.Planned development stages:Early terminated this study due to operational strategy considerations.
5.Current development stage:
(1)Application submission/approval/disapproval/each of clinical trials (include interim analysis):
(A)Clinical Study Design:
a.Study Title and Enrollment Information:
This study is a Phase II, randomized, double-blind, placebo-controlled trial.
It was originally designed to enroll 120 evaluable patients, randomized in a 1:1 ratio to receive either Silmitasertib (CX-4945) plus standard of care (SOC) or placebo plus SOC. However, due to early termination of the trial, a total of 44 patients were ultimately enrolled following rapid diagnostic screening. Among them, 30 patients were infected with the novel coronavirus, with 15 assigned to the CX-4945 group and 15 to the placebo group. An additional 14 patients were infected with the influenza virus, with 7 patients in each of the CX-4945 and placebo groups.
b.Primary and Secondary Endpoints and Statistical Results:
Due to the early termination of this study caused by an insufficient sample size, there were no statistically significant differences between the experimental and control groups. However, a clinical trend in treatment outcomes can still be observed, providing a reference for the design of future related clinical studies.
1.Primary Endpoint: The percentage of subjects requiring hospitalization, including emergency room visits, due to progression of CAP related to SARS-CoV-2 or influenza
The trial results showed that among 44 participants who received either CX-4945 (n=22) or placebo (n=22), none experienced hospitalization, emergency room visits, or death due to worsening community-acquired pneumonia related to COVID-19 or influenza within 29 days. There was no statistically significant difference between the CX-4945 and placebo groups ($P > 0.05$)
2.Secondary Endpoints:
(a)Within 29 days, hospitalization, emergency room visits, or death from any cause occurred in only one participant from each group: one in the CX-4945 group (COVID-19 subgroup) and one in the placebo group (influenza virus subgroup). There was no statistically significant difference between the groups ($P > 0.05$).
(b)In terms of improvement in pneumonia findings on chest X-ray, there was no statistically significant difference between the CX-4945 group and the placebo group in either the COVID-19 subgroup or the influenza virus subgroup.($P > 0.05$).
(c)Four participants in each group presented with fever at enrollment. The median time to resolution of fever was 1.8 days in the CX-4945 group and 1.6 days in the placebo group. There was no statistically significant difference between the groups ($P > 0.05$).
(d)There was no statistically significant difference in the SF ratio between the CX-4945 and placebo groups ($P > 0.05$).
(e)Based on the NIAID 8-point ordinal scale used by physicians to assess patient status, the proportion of subjects showing clinical improvement on Days 7 and 29 was higher in the CX-4945 group than in the placebo group, although the difference was not statistically significant ($P > 0.05$).
(f)In the COVID-19 subgroup, the proportion of participants with a negative RT-PCR test for SARS-CoV-2 on Day 7 did not differ significantly between the CX-4945 and placebo groups ($P > 0.05$).
(g)In the influenza virus subgroup, the proportion of participants with a negative RT-PCR test for influenza virus on Day 7 did not differ significantly between the CX-4945 and placebo groups ($P > 0.05$).

(h)In the COVID-19 subgroup, the median reduction in viral load in nasal secretions on Day 7 compared to baseline was -5.4 × 10^7 copies/mL (IQR: -1.16 × 10^8 to -5.04 × 10^6) in the CX-4945 group, and -1.24 × 10^7 copies/mL (IQR: -1.71 × 10^6 to -1.27 × 10^5) in the placebo group, with a statistically significant difference (P = 0.0021), suggesting that CX-4945 may accelerate viral clearance.
(i)In the COVID-19 subgroup, the mean change in Ct values from baseline, after adjustment, did not show a statistically significant difference between the CX-4945 and placebo groups (P > 0.05).
Secondary Objective: To evaluate the safety and tolerability of Silmitasertib (CX-4945).
(j)Treatment-related adverse events with an incidence greater than 10% (CX-4945:placebo) were: diarrhea (50.0% : 13.6%), nausea (27.3% : 4.5%), and dizziness (13.6% : 0%). These were consistent with known adverse events associated with CX-4945. No treatment-related serious adverse events were reported in either group.
3.Exploratory Endpoints:
In the exploratory biomarker analysis, we observed that CX-4945 exhibited potential regulatory effects on certain inflammatory markers. Overall, by Day 7, the adjusted mean reduction in CCL2 levels was similar between the CX-4945 and placebo groups (−56.5 vs −51.6 ng/L). Among COVID-19 patients, the CX-4945 group showed an additional decrease of approximately 54 ng/L by Day 15. Although this trend was noticeable, it did not reach statistical significance (P = 0.0601).
No significant differences were observed between the two groups in other serum inflammatory markers. However, these preliminary findings suggest that CX-4945 may have potential immunomodulatory effects under specific viral infection conditions, warranting further validation in larger sample sizes.
4.Conclusion:
Due to the early termination of the trial, and the widespread administration of national COVID-19 vaccines along with the effective use of oral antiviral combinations in reducing severe cases, there was no statistically significant difference between the treatment and control groups in the primary endpoint.
c.The results of a single clinical trial—including statistical P values and whether primary and secondary endpoints reach statistical significance—are not sufficient to fully determine the success or failure of future new drug development and approval. Investors should exercise careful judgment and invest cautiously.
(2)Once disapproved by competent authority or each of clinical trials (include interim analysis) results less than statistically significant sense, the risks & the associated measures the Company may occur: Not applicable
(3)After obtaining official approval or the results of statistically significant sense, the future strategy:
Due to strategic operational considerations, this study has been terminated ahead of schedule.
(4)Accumulated investment expenditure incurred: To protect the interests of the company and its investors, the information will not be disclosed.
6.Upcoming development plan:
Due to strategic operational considerations, it has been decided to terminate this study. The company will leverage the unique mechanism of Silmitasertib (CX-4945) to focus on more promising areas in the anti-infective field.
7.Market situation:
With the rising coverage of COVID-19 vaccination in Taiwan, 94% of the population has received at least one dose, 88% have completed two doses, and over 74% have received three or more doses, establishing a strong level of herd immunity by the end of 2023. On the other hand, oral antiviral agents such as Paxlovid and Molnupiravir have significantly improved treatment outcomes for high-risk patients, effectively reducing the risk of severe disease, hospitalization, and mortality. Additionally, Tamiflu remains the frontline oral treatment for influenza, demonstrating clinical benefits in symptom relief and the prevention of complications. In light of the availability of effective therapies for these infectious diseases, the company has decided to shift its development strategy toward exploring other indications with therapeutic potential via the mechanism of Silmitasertib (CX-4945), such as HIV.
8.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 8 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.
9.New drug development requires long process, vast investments and with no guarantee in success which may pose investment risks.The investors are advised to exercise caution and conduct thorough evaluation.: