Senhwa Biosciences Presents Positive Cholangiocarcinoma Data.

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TAIPEI and SAN DIEGO, Jan. 15, 2021 /PRNewswire/ -- Senhwa Biosciences, Inc. (TPEx: 6492), a clinical-stage biopharmaceutical company focused on next generation DNA Damage Response (DDR) therapeutics for the treatment of cancer, today announces that promising clinical data from their global phase 1b/2 trial, evaluating the combination of Silmitasertib plus Gemcitabine and Cisplatin compared to Gemcitabine and Cisplatin alone in the frontline treatment of patients with Cholangiocarcinoma (CCA) will be presented at the 2021 ASCO GI Cancers Symposium in San Francisco.

The study met its primary endpoint during an interim analysis by demonstrating a statistically significant difference in the Silmitasertib plus Gemcitabine and Cisplatin Arm. These findings indicate a clinically meaningful improvement in progression-free survival (PFS) ($P<0.05$). Consequently, the trial was stopped early once superior efficacy was confirmed.

"We are encouraged by the preliminary efficacy evidence demonstrated by Silmitasertib in combination with Gemcitabine and Cisplatin in patients with locally advanced or metastatic CCA. The addition of Silmitasertib with Gemcitabine and Cisplatin fulfills an unmet need for the effective treatment for CCA and could change the standard of care, ultimately saving more lives," said Dr. John Soong, Chief Medical Officer of Senhwa Biosciences.

The 2021 ASCO GI Cancer poster titled "Silmitasertib (CX-4945) in Combination with Gemcitabine and Cisplatin as First-Line Treatment for Patients with Locally Advanced or Metastatic Cholangiocarcinoma, a Phase 1b/2 Study" is summarized here:

Key Study Population and Outcomes Definition:

A total of 88 patients were enrolled and define the intent-to-treat (ITT) population, of which 87 of these patients received Silmitasertib in the phase 1b (n=50) and phase 2 (n=37) portions of the study:

- All 87 patients were included in the safety population.
- 55 patients were able to complete at least one full cycle of therapy, without dosing interruption or dose reductions and form the modified intent-to-treat (mITT) population.
- The primary efficacy outcome measure was assessed with PFS.

Preliminary Efficacy Analysis:

The efficacy findings for Silmitasertib compare favorably with those reported in the literature for Gemcitabine and Cisplatin in the BT22 study (which included 6-weekly tumor scans, as in our study; the BT22 study looked at Gemcitabine alone verses Gemcitabine and Cisplatin in combination):

- Median PFS in the mITT population (11.2 months) is a clinically meaningful improvement when compared to the study's Phase II control group (5.8 months). PFS was approximately 5 months longer than in the BT22 study (5.8 months)
- Median OS (Overall Survival) in the mITT population (17.4 months) was approximately 6 months longer than in the BT22 study (11.2 months)
- The ORR (Overall Response Rate) in the mITT population (32.1%) was higher than in the BT22 study (19.5%).
- The DCR (Disease Control Rate in the mITT population (79.3%) was also higher than that in the BT22 study (68.3%).

Preliminary Safety Analysis:

- Almost all patients receiving Silmitasertib (99%) experienced at least 1 TEAE (Treatment-Emergent Adverse Events), although most were mild or moderate in severity.
- The most common Silmitasertib treatment-related TEAEs were diarrhea (66%), nausea (51%), vomiting (33%), and fatigue (31%).

Conclusions:

- This interim analysis shows that Silmitasertib in combination with Gemcitabine and Cisplatin shows promising preliminary efficacy evidence in patients with locally advanced or metastatic CCA.
- The TEAE profile of Silmitasertib compares favorably with that of Gemcitabine and Cisplatin in the BT22 study, with a lower incidence of hematological AEs (Adverse Events) of 21–39% versus 58.5–87.8%.
- 66% of patients had a reduction in their CA 19-9 levels.
- Based on these findings a randomized phase 3 trial is planned.

These findings will be presented at a virtual session of Poster Highlights at 2:30 PM-3:15 PM (PST) on Jan. 17, 2021 at the Annual ASCO GI Cancers Symposium (online, due to Covid-19).