Alar Announce Results from ALA-1000 Single Ascending Dose Study in Opioid Dependent Patients

TAICHUNG, November 10, 2021 / -- Alar Pharmaceuticals Inc. (6785.TWO) announced the positive results of single-ascending-dose study assessing safety, tolerability, and pharmacokinetics of ALA-1000 in opioid dependent patients.

A total of 59 patients were enrolled in the study conducted at a single clinical center in the US. 46 subjects met the completer criteria for the 27-week study period. All drug-related AEs were mild or moderate in severity and were consistent with what is to be expected for subjects experiencing opioid withdrawal and known pharmacology effects of buprenorphine. The most commonly reported adverse events deemed treatment-related were weight increased, constipation, and nausea. No significant safety findings were identified during the study. The injection site grading results in terms of injection pain, tenderness, erythema/redness, induration, and swelling were all scored as none (grade 0) or mild (grade 1) and mostly resolved within 1 hour post injection. The mean scores of injection site pain VAS (Visual Analogue Scale) were reported below 10 of 100 and resolved mostly within 1-hour post-injection. No subjects reported for any other injection site reactions, evidence/attempt at removal of study drug, or discontinued the study due to injection site reactions. Buprenorphine is consistently released with low fluctuation over a period of at least 3 months and without dose dumping, significant initial burst, following the single subcutaneous injection of ALA-1000.

Efficacy endpoints evaluated withdrawal signs and symptoms, urine toxicology test for opioids, and opioid craving VAS. The mean scores in withdrawal signs and symptoms (COWS) remained relatively low (<5) in all groups after a single subcutaneous injection of ALA-1000 and throughout the study. Following the single SC injection of ALA-1000 and through the end of study (Day 175), positive urine opioid toxicology results in the highest dose group were generally <20%; the mean opioid craving VAS scores in Cohort 6 were continued to decrease during treatment (generally <10) and constantly lower than Day 1 predose.

Overall, the study shows that long-acting buprenorphine injectable (ALA-1000) is well tolerated in all dose-escalation cohorts without significant safety concerns. Importantly, the current study demonstrated that ALA-1000 performs a sustained pharmacokinetic releasing profile and provides positive preliminary efficacy results. Alar is planning to advance towards Phase III pivotal study in the next stage, followed by a long-term safety study to support NDA submission.