Nile Therapeutics Completes Dosing of Phase II Study

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SAN FRANCISCO, July 7 /PRNewswire-FirstCall/ -- Nile Therapeutics, Inc. (Nasdaq: NLTX [1]), a biopharmaceutical company focused on the development of novel therapeutics for cardiovascular disease, today announced that it has completed the dosing of the last patient in NIL-CDNP-CT005, an open-label, single-blind, placebo-controlled Phase II study of CD-NP in patients with acute decompensated heart failure, or ADHF. The study was designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in patients with ADHF and mild to moderate renal insufficiency. Additional endpoints included assessments of symptom relief and effects on biomarkers of heart failure and renal function.

"We are very pleased with the progress of this trial and look forward to reviewing the final clinical data. We are also very proud and impressed with the hard work of the clinical sites and investigators. Nile looks forward to building upon these relationships and the experience gained from this trial to optimally design and execute our future studies," said Hsiao D. Lieu, M.D. VP of Clinical Research for Nile.

In total, 77 patients were randomized into six cohorts at one of four doses of CD-NP (1.25, 2.5, 3.75 and 5 ng/kg/min) or placebo. Two cohorts were enrolled at each of the 1.25 and 2.5 ng/kg/min dose levels, which preliminary data suggest are the doses with the most attractive clinical profile to investigate in future ADHF studies. Over 35% of patients were enrolled in the U.S., with the remaining patients enrolled in Israel and Germany. Nile expects the last
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