Soleno Therapeutics Announces Financing Commitment for up to $60 Million

December 19, 2022

Funding from three leading healthcare investors, with Vivo Capital joining existing investors Nantahala Capital and Abingworth

$10 million capital infusion at closing and $15 million upon positive data to support NDA submission

Additional $35 million capital upon FDA approval to enable commercialization

REDWOOD CITY, Calif., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (“Soleno”) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced it has entered into a Securities Purchase Agreement with Nantahala Capital Management, LLC, Abingworth LLP and Vivo Capital, LLC for up to $60 million.

“This commitment from top-tier investors is a significant demonstration of confidence ahead of expected data from the randomized withdrawal period of Study C602 in mid-2023. It strengthens our balance sheet both near and longer term and supports continued preparation for our planned New Drug Application submission, as well as the acceleration of commercial readiness activities,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “In addition, we are pleased to report that the rate of enrollment in the study at our U.S. sites is progressing in line with our expectations. We anticipate initiating our U.K. sites shortly, which depends on the timing of local regulatory and ethics processes.”

Under the terms of the agreement, the investors have committed to pay $10 million in exchange for warrants to purchase common stock upon the Company’s announcement of enrollment completion in the randomized withdrawal period of Study C602, anticipated in Q1 2023. The warrants consist of two tranches. Tranche A warrants to purchase up to 8,598,870 shares of common stock at $1.75 for a total of approximately $15 million are required to be exercised within 30 days of announcement of positive top-line data from the randomized withdrawal period of Study C602. Tranche B warrants to purchase up to 14,000,000 shares of common stock at $2.50 for a total of $35 million expire upon the earlier of 3.5 years from the date of issuance and 30 days following receipt of U.S. Food and Drug Administration approval of DCCR for the treatment of PWS. The total possible proceeds raised under this agreement is $60 million for the issuance of 22.6 million shares at an average price of $2.65 per share, which represents a substantial premium over the December 16, 2022, closing price of $0.91.

The randomized withdrawal period of Study C602 is a multi-center, randomized, double-blind, placebo-controlled study of DCCR in approximately 80 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. The randomized withdrawal period consists only of patients currently enrolled in Study C602. Patients are randomized to receive either DCCR or placebo for a period of four months.

About PWS
The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. The hallmark symptom of this disorder is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients and their families. Additional characteristics of PWS include behavioral problems, cognitive disabilities, low muscle tone, short stature (when not treated with growth hormone), the accumulation of excess body fat, developmental delays, and incomplete sexual development. Hyperphagia can lead to significant morbidities (e.g., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, choking, accidental death due to food seeking behavior). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia and 92.9 % body composition as the most important or a very important symptom to be relieved by a new medicine. There are currently no approved therapies to treat the hyperphagia/appetite, metabolic, cognitive function, or behavioral aspects of the disorder. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and E.U., and Fast Track Designation in the U.S.

About DCCR (Diazoxide Choline) Extended-Release Tablets
DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and is administered once-daily. The parent molecule, diazoxide, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and adults, but has not been approved for use in PWS. Soleno conceived of and established extensive patent protection on the therapeutic use of diazoxide and DCCR in patients with PWS. The DCCR development program is supported by data from five completed Phase 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 3 study, DCCR showed promise in addressing hyperphagia, the hallmark symptom of PWS, as well as several other symptoms such as aggressive/destructive behaviors, fat mass and other metabolic parameters.

About Soleno Therapeutics, Inc.
Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company’s lead candidate, DCCR extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS), is currently being evaluated in a Phase 3 clinical development program. For more information, please visit www.soleno.life.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding timing closing of the offering, timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of PWS. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including the risks and uncertainties associated with market conditions, as well as risks and uncertainties inherent in Soleno’s business,

including those described in the company's prior press releases and in the periodic reports it files with the SEC. The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Corporate Contact:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

Source: Soleno Therapeutics