Soleno Therapeutics Receives Orphan Drug Designation from FDA for Diazoxide Choline for the Treatment of Glycogen Storage Disease Type 1a

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REDWOOD CITY, Calif., June 02, 2021 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (“Soleno”) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted its investigational drug, DCCR (diazoxide choline) Extended-Release tablets, Orphan Drug Designation for the treatment of Glycogen Storage Disease Type 1a (GSD 1a), or von Gierke disease. DCCR previously received Orphan Drug Designation for the treatment of Prader-Willi syndrome.

“The granting of Orphan Drug Designation for our DCCR program in an additional indication, GSD 1a, represents a significant milestone for Soleno,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “GSD 1a is a type of glycogen storage disease marked by the body’s inability to metabolize glycogen into glucose, resulting in hypoglycemia, high levels of fat in the blood, and impaired growth, among other complications. We believe DCCR’s mechanism of action as an ATP-dependent potassium channel agonist, with the potential to regulate hypoglycemia and reduce fatty acid synthesis, could provide a meaningful treatment option for GSD 1a, a condition for which there are currently no approved therapies.”

The FDA's Office of Orphan Drug Products grants Orphan Drug Designation to support drug candidates in development for underserved patient populations or rare disorders that affect fewer than 200,000 people in the United States. Orphan Drug Designation qualifies a candidate for various development incentives, including tax credits for eligible clinical trials, waiver of application fees and market exclusivity for seven years upon FDA approval.

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, is currently being evaluated in a Phase 3 clinical development program for the treatment of Prader-Willi syndrome (PWS). No clinical development program is underway for GSD 1a. 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 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.

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Source: Soleno Therapeutics