Aduro Biotech Announces First Patient Dosed in Phase 1 Study of BION-1301 in IgA Nephropathy

June 24, 2020

BERKELEY, Calif., June 24, 2020 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (NASDAQ: ADRO), a clinical-stage biopharmaceutical company focused on developing therapies targeting the Stimulator of Interferon Genes (STING) and A Proliferation Inducing Ligand (APRIL) pathways for the treatment of cancer, autoimmune and inflammatory diseases, today announced that the first patient with IgA nephropathy has been dosed in a Phase 1 clinical trial of BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL binding to both the BCMA and TACI receptors.

"We are thrilled to have dosed the first patient with IgA nephropathy in the Phase 1 clinical study of our investigational anti-APRIL antibody, BION-1301," said Dimitry S.A. Nuyten, M.D., Ph.D., chief medical officer of Aduro. "The data Aduro recently presented from Parts 1 and 2 of this study in healthy volunteers at the 57th ERA-EDTA Virtual Congress indicated BION-1301 was well-tolerated, had a half-life of approximately 33 days, achieved over 90% target engagement with a single 450 mg dose of BION-1301 and demonstrated dose-dependent and durable reductions in IgA and IgM levels, and to a lesser extent, IgG levels. We look forward to hopefully replicating this effect in addition to exploring BION-1301's disease-modifying potential in patients with IgA nephropathy in Part 3 of the ongoing Phase 1 clinical study."

Part 3 of the Phase 1 multi-center trial (see www.clinicaltrials.gov, identifier NCT03945318) is evaluating the safety and tolerability of BION-1301 in two cohorts of 20 total adult subjects with IgA nephropathy in an open-label multiple dose design. Cohort 1 will receive a 450 mg intravenous (IV) dose of BION-1301 every two weeks. The dose and regimen for Cohort 2 will be determined after an assessment of the first five patients dosed in Cohort 1 and will be based on all available data, including safety, pharmacokinetic, free-APRIL and pharmacodynamic data.

Parts 1 and 2 of the Phase 1 trial evaluated the safety and tolerability of BION-1301 in 63 healthy volunteers in double-blinded, placebo-controlled single-ascending dose (SAD) and multiple-ascending dose (MAD) settings. Healthy volunteers in the SAD portion of the study received placebo or a single IV dose of BION-1301 ranging from 10 mg to 1350 mg on day 1. Healthy volunteers in the MAD portion of the study received placebo or IV doses of BION-1301 ranging from 50 mg to 450 mg on days 1, 15 and 29 (three doses total).

About Aduro
Aduro Biotech, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies that are designed to harness the body's natural immune system for the treatment of patients with challenging diseases. Aduro's product candidates in the Stimulator of Interferon Genes (STING) and A Proliferation Inducing Ligand (APRIL) pathways are being investigated in cancer, autoimmune and inflammatory diseases. ADU-S100 (MIW815), which potentially activates the intracellular STING receptor for a potent tumor-specific immune response, is being evaluated in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as a potential first-line treatment for patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL binding to both the BCMA and TACI receptors, is being evaluated in IgA nephropathy. Aduro is collaborating with a number of leading global pharmaceutical companies to help expand and drive its product pipeline. For more information, please visit www.aduro.com.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our current intentions or expectations concerning, among other things, the potential for BION 1301 for treatment of IgA nephropathy, replicating the results seen in healthy volunteers in patients, the determination of the dose and regimen for Cohort 2 based on safety, PK, free-APRIL and PD data, and collaborations with leading global pharmaceutical companies to help expand and drive our product pipeline. In some cases, you can identify these statements by forward-looking words such as "may," "will," "continue," "anticipate," "intend," "could," "project," "expect" or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, the risk that the proposed merger with Chinook Therapeutics, Inc. may not be completed in a timely manner or at all, which may adversely affect Aduro's business and the price of the common stock of Aduro; our history of net operating losses and uncertainty regarding our ability to achieve profitability, our ability to develop and commercialize our product candidates, our ability to use and expand our technology platforms to build a pipeline of product candidates, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do, our reliance on third parties, and our ability to obtain and adequately protect intellectual property rights for our product candidates; and the effects of COVID-19 on our clinical programs and business operations. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our quarterly report on Form 10-Q for the quarter ended March 31, 2020, filed with the Securities and Exchange Commission (SEC), and our other filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contact:
Noopur Liffick
510-809-2465
investors@aduro.com
press@aduro.com

Source: Aduro Biotech, Inc.