



Aduro Biotech Presents Nonclinical and Phase 1 Healthy Volunteer Data for BION-1301 at the 57th ERA-EDTA Virtual Congress

June 2, 2020

- *BION-1301 was well-tolerated, with no serious adverse events (SAEs), treatment discontinuations or events meeting stopping criteria, across a wide range of doses*
- *Pharmacokinetics (PK) of BION-1301 were generally dose-proportional with an estimated half-life of 33 days, suggesting the potential for monthly dosing*
- *BION-1301 dose-dependently and durably reduced IgA and IgM, and to a lesser extent, IgG, providing a pharmacodynamic (PD) window to potentially exploit reductions in IgA while tempering reductions in IgG*
- *No tox findings were reported in nonclinical toxicology studies of BION-1301 evaluating intravenous (IV) administration for up to 6 months and subcutaneous (SC) administration for up to 1 month*

BERKELEY, Calif., June 02, 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 the presentation of healthy volunteer data from the ongoing Phase 1 study of BION-1301 for the treatment of IgA nephropathy as well as data from long-term nonclinical studies. The findings are being presented as posters at the 57th European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Fully Virtual Congress.

“Preclinical studies have demonstrated that the APRIL pathway represents a key regulator of IgA, IgM and to a lesser extent, IgG production, which we believe could be relevant in IgA nephropathy,” said Stephen T. Isaacs, chairman, president and chief executive officer of Aduro. “These comprehensive datasets indicate that the biology of APRIL and its blockade by BION-1301 translate well from nonclinical studies to human subjects. Together with our newly developed subcutaneous formulation, we believe Aduro can effectively evaluate whether BION-1301 demonstrates disease-modifying potential in IgA nephropathy patients.”

Study Design and Findings from Ongoing Phase 1 Trial of BION-1301

The data is being presented in a poster titled, “Results of a Phase 1 Trial to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of BION-1301 in Healthy Volunteers.” The phase 1 multi-center trial (see www.clinicaltrials.gov, identifier NCT03945318) 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).

Key highlights from the poster presentation include:

- BION-1301 was well-tolerated, with no SAEs, treatment discontinuations or events meeting stopping criteria, across a wide range of doses.
 - Non-neutralizing ADAs occurred in less than 10% of subjects with no correlation to dose.
- The PK profile of BION-1301 was well-behaved, generally dose proportional, and had a half-life of approximately 33 days, suggesting the potential for monthly dosing.
- BION-1301 demonstrated a dose-dependent increase in target engagement as measured by free APRIL levels in serum; over 90% target engagement was achieved with a single 450 mg dose.
- BION-1301 dose-dependently and durably reduced IgA and IgM levels, and to a lesser extent, IgG levels. At all doses tested, IgG levels remained in the normal lab range, thereby providing a PD window to potentially exploit reductions in IgA, while tempering reductions in IgG.

Work is ongoing to further characterize changes in exploratory biomarkers, including Gd-IgA1 and immunophenotyping of B-cell subsets. Part 3 of this ongoing Phase 1 study is currently open and enrolling adult patients with IgA nephropathy in an open-label setting.

Study Design and Findings from Long-Term Nonclinical Studies of BION-1301

The data is being presented in a poster titled, "BION-1301, a Fully Blocking Antibody Targeting APRIL for the Treatment of IgA Nephropathy: Assessment of Safety, Toxicokinetics and Pharmacodynamics in Long-Term Nonclinical Studies." The objectives of the nonclinical studies were to evaluate the toxicity and determine the toxicokinetics of BION-1301 upon repeat dosing via IV and SC routes of administration in cynomolgus monkeys.

Key highlights from the poster presentation include:

- BION-1301 was well-tolerated in sexually mature cynomolgus monkeys with biweekly IV dosing up to 100 mg/kg per dose for 26 weeks, and with weekly SC dosing up to 180 mg/kg per dose for up to 4 weeks.
- BION-1301 led to decreased free APRIL levels in serum after repeat dosing via IV and SC routes of administration.
- BION-1301 demonstrated marked and durable reduction in levels of IgA and IgM, and to a lesser extent, IgG.
- A strong dose-dependent PK-PD relationship was recorded for BION-1301 with free APRIL, IgA and IgM in serum.

Both poster presentations demonstrate PD data consistent with modulation of APRIL levels in the blood and are supportive of the clinical development of BION-1301 in patients with IgA Nephropathy.

Live Conference Call and Webcast

Aduro will host a live conference call and webcast on Monday, June 8, 2020 at 1:00 pm PDT to review the data in healthy volunteers from the ongoing Phase 1 study of BION-1301 for the treatment of IgA nephropathy as well as data from long-term nonclinical studies. Members of the Aduro executive team will be joined by Dr. Jonathan Barratt, the Mayer Professor of Renal Medicine at University of Leicester.

Conference Call and Details

To access the call, please dial (844) 309-0604 (domestic) or (574) 990-9932 (international) and provide the Conference ID 8568238 to the operator.

To access the live webcast and subsequent archived recording of this and other company presentations, please visit the investor section of Aduro's website at www.aduro.com. The archived webcast will remain available for replay on Aduro's website for 90 days.

To access a recording of the conference call, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and enter the Conference ID 8568238. The conference call recording will also be available for 90 days.

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, the potential for monthly and/or subcutaneous dosing of BION 1301, the outcome of our ongoing work to further characterize changes in exploratory biomarkers, continued advancement of our programs, timelines for our programs, including expected timing for presentations of clinical and non-clinical 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, 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.

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