Aduro Biotech Highlights Positive Clinical Results from Second Cohort of Phase 1b Mesothelioma Clinical Trial

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Data Presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting Continues to Show Clinical Activity of CRS-207

Two Additional Poster Presentations Detailing Promising Preclinical Results of STING and pLADD Programs

BERKELEY, Calif., Nov. 12, 2016 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (Nasdaq:ADRO) today announced highlights from a poster presentation at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC) being held in National Harbor, Maryland on the preliminary safety and efficacy of its novel immunotherapy, CRS-207, being evaluated in unresectable malignant pleural mesothelioma. These data were from the second cohort of patients in an ongoing Phase 1b clinical trial of CRS-207 in combination with standard of care chemotherapy and immune-modulating doses of cyclophosphamide (Cy) as a first-line treatment.

Preliminary results as of October 2016 from the 22 patients in the second cohort in the Phase 1b clinical study (Abstract #261) showed that 82 percent (18/22) of patients had disease control, with 55 percent (12/22) of patients achieving a partial response (PR) and 27 percent (6/22) with stable disease. Tumor shrinkage was observed in 77 percent (17/22) of patients. Of these patients, 36 percent (8/22) experienced tumor shrinkage after two doses of immunomodulatory doses of cyclophosphamide combined with CRS-207 (Cy/CRS-207), but prior to initiation of standard of care chemotherapy. Fourteen percent (3/22) of these patients achieved a partial response. No treatment-related serious adverse events or unexpected toxicities were observed. Median duration on study was 9.7 months at the time of data cutoff. Treatment continues, with immune response evaluations and survival follow up ongoing.

Of note, analysis of paired tumor biopsies obtained from two patients showed a marked infiltration of immune effector cells into the tumor microenvironment (TME) following two doses of Cy/CRS-207, as compared to baseline. Post-therapeutic changes included an increase in CD8+ cytotoxic T cells as well as an increase in other immune cell types that are thought to be essential for effective immunotherapy, including dendritic cells and natural killer cells. Together, these data suggest that the Cy/CRS-207 remodeling of the TME may be an important component of the clinical responses observed in this cohort of patients.

“The data from the second cohort, which is a patient population with more advanced disease compared to the first cohort, demonstrate that the addition of immunomodulatory doses of cyclophosphamide, which has been shown to inhibit negative regulatory T cell populations, to the combination of CRS-207 and chemotherapy results in encouraging disease control and tolerability for patients with mesothelioma,” said Dirk G. Brockstedt, Ph.D., executive vice president of research and development of Aduro. “Importantly, we believe these data, together with the results from the first cohort, support further investigation of CRS-207 in mesothelioma, and we intend to initiate a Phase 2 study of CRS-207 used in combination with an anti-PD-1 therapy as an immune-modulator in patients with mesothelioma who have failed at least one prior therapy.”

Additional Data on STING, pLADD Platform Technologies

A poster presentation highlighting preclinical data on the potential mechanism of action of ADU-S100 (also known as MIW315) therapy for treating cancer (Abstract #399) was given yesterday. The data showed that injection of ADU-S100 directly into the tumor microenvironment induces a systemic tumor-specific T cell response that leads to durable anti-tumor immunity. The data demonstrate that TNF-alpha and neutrophil recruitment mediate the primary tumor shrinkage following injection with ADU-S100, while CD8-alpha+ cells and natural killer cells mediate durable anti-tumor immunity. Anti-tumor efficacy was enhanced by combining ADU-S100 with anti-PD-1 or anti-CTLA4 checkpoint inhibitors. An ongoing Phase 1 clinical study is ongoing evaluating the safety and tolerability and possible anti-tumor effects of ADU-S100 in patients with cutaneously-accessible non UV-induced and UV-induced malignancies.

An additional poster presentation highlighting preclinical data on a personalized, live, attenuated double-deleted Listeria monocytogenes (pLADD) immunotherapy (Abstract #366) will be given today at 11:45 a.m. ET. pLADD is a patient-specific immunotherapy based on Aduro’s LADD platform. To design the individualized pLADD immunotherapy, tumor-specific mutations, called neoantigens, are identified through a comparison of tumor and normal tissue sequences. Aduro then constructs a LADD strain encoding patient-specific neoantigens that will be administered to the patient. Preclinical data included in the poster presentation demonstrate that a mouse tumor-specific pLADD induces a robust neoantigen-specific response and survival benefit in two mouse models of cancers when combined with anti-PD-1 checkpoint modulation.

About LADD and CRS-207
LADD is Aduro's proprietary platform of live, attenuated double-deleted *Listeria monocytogenes* strains that have been engineered to generate a potent innate immune response and to express tumor-associated antigens to induce tumor-specific T cell-mediated immunity.

CRS-207 is one of a family of product candidates based on Aduro's LADD immunotherapy platform that has been engineered to express the tumor-associated antigen mesothelin, which is over-expressed in many cancers including mesothelioma and pancreatic, non-small cell lung, ovarian, endometrial and gastric cancers.

About STING Pathway Activator Platform
The Aduro-proprietary STING Pathway Activator product candidates, including ADU-S100 (MIW815), are synthetic small molecule immune

modulators that are designed to target and activate human STING. STING is generally expressed at high levels in immune cells, including dendritic cells. Once activated, the STING receptor initiates a profound innate immune response through multiple pathways, inducing the expression of a broad profile of cytokines, including interferons and chemokines. This subsequently leads to the development of a systemic tumor antigen-specific T cell adaptive immune response.

About pLADD
Aduro's pLADD platform is a highly-personalized immunotherapy based on the live, attenuated double-deleted *Listeria monocytogenes* (LADD) platform. The pLADD approach leverages the immune activating activity of the Listeria bacterial vector in combination with patient-specific neoantigens, or an individual's own cancer mutations, derived from a patient's own tumor cells. Once administered, pLADD therapies are designed to mobilize the immune system through: 1.) an immediate recognition of the presence of Listeria as being foreign, and 2.) a specific and customized immune attack on cells containing the tumor neoantigens presented by pLADD. Aduro plans to initiate a Phase 1 clinical trial to evaluate the safety and immunogenicity of pLADD in patients with advanced gastrointestinal cancers in 2017.

About Aduro
Aduro Biotech, Inc. is an immunotherapy company focused on the discovery, development and commercialization of therapies that transform the treatment of challenging diseases. Aduro's three technology platforms, which are designed to harness the body's natural immune system, are being investigated in cancer indications and have the potential to expand into autoimmune and infectious diseases. Aduro's LADD technology platform is based on proprietary attenuated strains of Listeria that have been engineered to express tumor-associated antigens to induce specific and targeted immune responses. This platform is being developed as a treatment for multiple indications, including pancreatic, ovarian, lung and prostate cancers, mesothelioma and glioblastoma. Additionally, a personalized form of LADD, or pLADD, is being developed utilizing tumor antigens that are specific to an individual patient's tumor. Aduro's STING Pathway Activator platform is designed to activate the intracellular STING receptor, resulting in a potent tumor-specific immune response. ADU-S100 is the first STING Pathway Activator compound to enter the clinic and is currently being evaluated in a Phase 1 study in patients with cutaneously accessible metastatic solid tumors or lymphomas. Aduro's B-select monoclonal antibody platform includes a number of immune modulating assets in research and preclinical development. Aduro is collaborating with leading global pharmaceutical companies to expand its products and technology platforms. 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 intentions or current expectations concerning, among other things, development plans for our product candidates and the potential for our technology platforms and for the eventual regulatory approval of our product candidates. 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 inability 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. 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 September 30, 2016, which is on file with the Securities and Exchange Commission. 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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