Aduro Announces First Patient Dosed in Phase 1 Study of ADU-S100 (MIW815) in Combination with YERVOY (ipilimumab) for the Treatment of Relapsed and Refractory Melanoma

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BERKELEY, Calif., Feb. 11, 2019 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (NASDAQ: ADRO) today announced that the first patient has been dosed in a Phase 1 trial of ADU-S100 (MIW815), a novel stimulator of interferon genes (STING) pathway activator, in combination with YERVOY® (ipilimumab), an approved anti-CTLA-4 antibody for the treatment of relapsed and refractory melanoma. The multicenter trial (see www.clinicaltrials.gov, identifier: NCT02675439), which is part of an ongoing research and development collaboration with Novartis, will enroll advanced melanoma patients who have relapsed after or are refractory to treatment with anti-PD-1 antibodies, nivolumab or pembrolizumab.

“We are pleased to initiate this study evaluating ADU-S100 with ipilimumab in a homogeneous patient population. Despite recent advancements in treating earlier stages of melanoma, the relapsed and refractory patient segment remains underserved due to a lack of therapeutic options. Based on their potential synergistic activity, ADU-S100 in combination with an anti-CTLA-4 antibody could generate a systemic adaptive immune response in patients with late-stage melanoma,” commented Stephen Isaacs, chairman, president and chief executive officer of Aduro Biotech. “As demonstrated leaders in the STING pathway, we are committed to build upon the growing body of data we’ve generated thus far, including encouraging clinical signals demonstrated by ADU-S100 as a single agent and in combination with spartalizumab, an investigational anti-PD-1 antibody.”

The protocol for investigation of ADU-S100 as a single agent was amended to include evaluation of ADU-S100 in combination with ipilimumab. During the ongoing dose escalation phase of the trial, ipilimumab will be administered at its approved dose and schedule, while the dose of ADU-S100 will be escalated. The dose expansion phase of the trial will evaluate the optimized dose of ADU-S100 in combination with ipilimumab in two expansion cohorts that will enroll patients with cutaneously and viscerally accessible melanoma.

As previously presented at the 2018 Society for Immunotherapy of Cancer Annual Meeting, target engagement of ADU-S100 and activation of the STING pathway was demonstrated in the ongoing Phase 1 dose escalation of ADU-S100 alone through increases in key systemic cytokines, IL-6, MCP-1 and IFN- β after administration. Partial responses were observed in 4.9 percent of patients (n=2/41), including one patient with parotid gland cancer who received prior anti-PD-1 therapy. Stable disease (SD) was achieved in 26.8 percent of patients (n=11/41), including five patients who had received prior checkpoint inhibitor therapy. In the ongoing study of ADU-S100 in combination with spartalizumab, clinical responses were observed in several tumor types, including two patients who had previously demonstrated responses to checkpoint inhibitor therapy alone.

In preclinical models, activation of the STING pathway has been shown to rapidly invoke an innate immune response, which subsequently leads to a systemic and sustained adaptive immune response through tumor-specific-CD8+ T cells. Ipilimumab may further augment such immunity, by blocking the activity of the checkpoint protein, CTLA-4, resulting in enhanced activity of T cells that attack melanoma cells in the body, supported by the demonstration of combined activity of ADU-S100 and anti-CTLA-4 in preclinical models.

About STING Pathway Activator Technology
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. Natural activation of STING is not always sufficient to prevent the growth and spread of cancer cells. In preclinical models, ADU-S100 directly activates STING to further amplify the natural anti-tumor response. 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.

Aduro’s lead molecule, ADU-S100, is the first therapeutic in development specifically targeting STING. In collaboration with Novartis, it is being tested in a Phase 1 clinical trial as a single agent and in combination with ipilimumab, and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody. These studies are enrolling patients with cutaneously accessible, advanced/metastatic solid tumors or lymphomas. The trials are evaluating the ability of ADU-S100 to activate the immune system and recruit specialized immune cells to attack the injected tumor, leading to a broad immune response that seeks out and kills distant metastases.

About Aduro
Aduro Biotech, Inc. is an immunotherapy company focused on the discovery, development and commercialization of therapies that are intended to transform the treatment of challenging diseases. Aduro's technologies, which are designed to harness the body's natural immune system, are being investigated in cancer indications, autoimmune diseases and have the potential to expand into infectious diseases. Aduro's STING pathway activator technology is designed to activate the STING receptor in immune cells, which may result in a potent tumor-specific immune response. ADU-S100 (MIW815) is the first STING pathway activator compound to enter the clinic and is currently being evaluated in a Phase 1 clinical trial as a single agent and in combination with ipilimumab and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody. Aduro’s B-select monoclonal antibody technology, including BION-1301, an anti-APRIL antibody, is comprised of a number of immune modulating assets in research and development. Aduro is collaborating with leading global pharmaceutical companies to expand its products and technologies. 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, the potential

for ADU-S100 for the treatment of cancer, the potential for ADU-S100 in combination with an anti-CTLA-4 antibody to generate a systemic adaptive immune response in patients with late-stage melanoma, the timing and volume of clinical data, our ability to continue as leaders in the STING pathway and our ability to advance our drug development programs on our own or with our collaborators. 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, early or preliminary clinical trial results may not be predictive of future results, 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 technologies 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. 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, 2018, 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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