Aduro Biotech and Novartis Present Results from Ongoing Phase 1b Study of STING Agonist ADU-S100 (MIW815) in Combination with Anti-PD-1 Monoclonal Antibody Spartalizumab (PDR001) in Patients with Advanced Solid Tumors or Lymphomas

June 2, 2019

- *ADU-S100 (MIW815) + spartalizumab combination data demonstrated antitumor activity in anti-PD-1-naïve triple-negative breast cancer (TNBC) and previously immunotherapy-treated melanoma*
- *As of the April 5, 2019 data cut-off, five patients treated in the weekly dosing schedule group achieved confirmed responses, one of which was a complete response (CR)*
- *Of the eight TNBC patients evaluable for efficacy, one anti-PD-1 naïve TNBC patient achieved a CR and two anti-PD-1 naïve TNBC patients achieved partial responses (PRs)*
- *Of the 25 melanoma patients radiologically evaluable for efficacy, two previously immunotherapy-treated melanoma patients achieved PRs*

BERKELEY, Calif., June 02, 2019 (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 data from an ongoing Phase 1b clinical trial in collaboration with Novartis. Aduro's ADU-S100 (MIW815), a novel STING pathway activator, is being evaluated in combination with Novartis' spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody, in patients with advanced solid tumors or lymphomas. The findings were presented as an oral abstract today by Dr. Funda Meric-Bernstam at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL (Abstract #2507).

"We are pleased with the clinical progress to date of ADU-S100 in combination with spartalizumab," said Stephen T. Isaacs, chairman, president and chief executive officer of Aduro. "The safety profile and preliminary anti-tumor activity demonstrated in patients with triple-negative breast cancer and other tumor types are encouraging. We look forward to completing dose escalation and evaluating with our partner Novartis the clinical and pharmacodynamic biomarker activity that may provide a basis for advancing this combination therapy toward dose expansion in tumor types where the potential to benefit patients is greatest."

Isaacs continued, "Our goal remains for ADU-S100 to be broadly explored as a combination agent, given our belief in the synergistic effects of STING agonism with checkpoint inhibitor therapy. Enrollment in our study of ADU-S100 and ipilimumab in relapsed/refractory melanoma is ongoing and we anticipate initiation of our study of ADU-S100 and pembrolizumab in first line head and neck cancer in the second half of 2019."

Study Design and Findings from Ongoing Phase 1b Trial of ADU-S100 (MIW815) + Spartalizumab (Data cut-off: April 5, 2019)

The Phase 1b multi-center, open-label, dose-escalation clinical trial (see www.clinicaltrials.gov, identifier NCT03172936) enrolled patients with advanced, metastatic treatment-relapsed/refractory solid tumors or lymphomas and evaluated two treatment schedules. All patients received a fixed dose of 400 mg of intravenous (IV) spartalizumab on day 1 and either an intratumoral (IT) injection of ADU-S100 (MIW815) on days 1, 8 and 15 in a 28-day cycle or an IT injection of ADU-S100 (MIW815) on day 1 of every 28-day cycle. Data presented were based on findings from 83 enrolled patients, with 53 patients in the weekly group and 30 patients in the monthly group.

No dose-limiting toxicities were reported during the first cycle in any of the 50 – 1,600 µg dose cohorts. The adverse events of the combination of ADU-S100 (MIW815) and spartalizumab reported were no more frequent or severe than those reported in either single agent trial. The most common (≥5 percent of patients) treatment-related adverse events (TRAEs) of any grade were injection site pain (13.3 percent), pyrexia (12.0 percent), diarrhea (9.6 percent) and rash (6.0 percent). Grade 3/4 TRAEs (in ≥2 pts) were increased lipase (3.6 percent), diarrhea, increased ALT and increased AST (all 2.4 percent). Treatment was discontinued in two patients due to adverse events (2.4 percent).

- Five patients enrolled in the weekly group achieved confirmed responses – one CR and two PRs in anti-PD-1-naïve TNBC, as well as two PRs in previously immunotherapy-treated melanoma.
- Eight of the 11 enrolled TNBC patients were evaluable for efficacy. Of the eight evaluable TNBC patients, the three patients with a CR/PR are continuing to receive treatment. Of the three unevaluable TNBC patients, one patient discontinued the study early due to toxicity (pneumonitis) and the two remaining patients are too early for assessment.
- Twenty-five of the 35 melanoma patients were radiologically evaluable for efficacy. Of the 25 evaluable melanoma patients, the two patients with a PR stayed on treatment for over five months and eight months, respectively. Nine melanoma

patients achieved stable disease (SD). Of the 10 unevaluable melanoma patients, seven patients were ongoing as of the data cut-off and were too early for assessments, two patients discontinued due to clinical progression and one patient chose to start another treatment.

- In the weekly group, 12 patients achieved SD, including five patients who maintained SD for five months or more. The SD patients had the following tumor types: sarcoma, melanoma (7), squamous cell carcinoma of the skin, breast, lymphoma and head and neck. Eight patients with SD received prior immunotherapy.

- In the monthly group, six patients achieved SD, including five patients who maintained SD for five months or more. The SD patients had the following tumor types: cutaneous melanoma, head and neck, ovarian (2), uveal melanoma and breast. Five patients with SD received prior immunotherapy.

- Among the five confirmed responders in the weekly group, the median was a 73 percent maximum reduction in the sum of the target lesion diameters.

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 (MIW815) 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 (MIW815), 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), Novartis' 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 (MIW815) 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 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) (MIW815), which potentially activates the intracellular STING receptor for a potent tumor-specific immune response, is being evaluated in patients with cutaneously accessible metastatic solid tumors or lymphomas. BION-1301, a fully blocking monoclonal antibody that blocks APRIL binding to both the BCMA and TACI receptors, is being evaluated for the treatment of 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 intentions or current expectations concerning, among other things, the potential for ADU-S100 (MIW815) alone or in combination, the completion of dose escalation, the continued evaluation of pharmacodynamic biomarker activity alone or together with Novartis, the advancement of ADU-S100 (MIW815) in combination with spartalizumab toward dose expansion in tumor types where the potential to benefit patients is greatest, the broad exploration of ADU-S100 as a combination agent, the synergistic effects of STING agonism with checkpoint inhibitor therapy, continued enrollment in our study of ADU-S100 and ipilimumab, the initiation of our study of ADU-S100 and pembrolizumab in first line head and neck cancer and the timing thereof, trends between IFN-β levels and systemic exposure of ADU-S100 (MIW815) and our ability to expand and drive our product pipeline alone or with 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 March 31, 2019, 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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