Aduro Biotech Announces Presentation of Results from First-in-Human Phase 1 Study of Anti-CD27 Agonist as Monotherapy and in Combination with Pembrolizumab in Patients with Advanced Solid Tumors at the Society for Immunotherapy of Cancer 34th Annual Meeting

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BERKELEY, Calif., Nov. 08, 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 that its license partner, Merck & Co., Inc. (known as MSD outside the United States and Canada), presented data from an ongoing Phase 1 clinical trial of MK-5890, an anti-CD27 agonist. MK-5890 is being evaluated as monotherapy and in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 antibody, in adults with advanced solid tumors. The findings were accepted as a late-breaking abstract and presented by Dr. Ronnie Shapira-Frommer as an oral presentation at the Society for Immunotherapy of Cancer 34th Annual Meeting (SITC 2019) in National Harbor, MD (Abstract #O83).

"We are pleased with the clinical progress Merck has made to date in the development of MK-5890, a candidate selected with the same proprietary B-select monoclonal antibody technology at Aduro that created BION-1301, an anti-APRIL antibody in development for IgA nephropathy," said Andrea van Elsas, Ph.D., chief scientific officer of Aduro. "We are encouraged by the early antitumor activity observed in patients with advanced solid tumors in both the MK-5890 monotherapy and combination therapy arms. We look forward to Merck's further exploration of MK-5890's potential in expansion cohorts, including an arm of MK-5890 administered with pembrolizumab, pemetrexed and carboplatin in patients with non-squamous non-small cell lung cancer."

Study Design and Findings for MK-5890 (Database cutoff date: May 30, 2019)

In this Phase 1, open-label, multi-arm, multicenter, dose-escalation clinical trial (see www.clinicaltrials.gov, identifier NCT03396445), MK-5890 was administered to patients with advanced solid tumors by intravenous (IV) infusion every three weeks. Dose escalations for MK-5890 were 2 – 700 mg and pembrolizumab was administered as an IV injection at a dose of 200 mg every three weeks. Patients receiving MK-5890 as monotherapy who progressed while on therapy were eligible for crossover to the MK-5890-pembrolizumab combination arm. Study objectives included evaluation of safety, tolerability, pharmacodynamics, pharmacokinetics and tumor responses evaluated using RECIST v1.1 criteria.

Interim data presented at SITC 2019 were based on findings from 25 patients enrolled in the MK-5890 monotherapy arm and 19 patients enrolled in the combination arm with pembrolizumab. Fourteen patients had crossed over from monotherapy to receive the combination regimen. In the monotherapy arm, one patient achieved a confirmed partial response with MK-5890. In the combination arm, one patient achieved a confirmed partial response with MK-5890 and pembrolizumab. In the crossover phase, two patients achieved confirmed complete responses and two patients achieved confirmed partial responses with MK-5890 and pembrolizumab. At the time of analysis, two of the confirmed partial responses that crossed over were ongoing and had lasted six months or longer.

In the initial phase, dose-limiting toxicities, all of which were associated with infusion-related adverse events, were reported in 12 percent (n=3/25) and 5.3 percent (n=1/19) of patients in monotherapy and combination arms, respectively. Maximum tolerated dose was defined as 200 mg every three weeks. Treatment with MK-5890, alone and in combination with pembrolizumab, demonstrated an acceptable safety profile. Grade 3 – 4 treatment-related adverse events (TRAEs) were reported in 24 percent (n=6/25) and 21.2 percent (n=4/19) of patients in monotherapy and combination arms, respectively. The most common TRAEs (occurring in ≥10% of patients) in both study arms included: fatigue, infusion-related reaction, nausea, pruritus, rash, myalgia and vomiting. In the combination arm, additional TRAEs occurring in ≥10% of patients included: chills, diarrhea, pyrexia, dry mouth, influenza-like illness and increased amylase.

About CD27 and MK-5890
CD27 signaling plays a role in cytotoxic T lymphocyte responses and the survival of activated T cells. CD27 triggering enhances the priming of cytotoxic T lymphocyte responses, thereby suggesting anti-CD27 is a promising immunotherapeutic approach for treatment of cancers. MK-5890 is a humanized agonist monoclonal antibody that binds to CD27 to provide a costimulatory signal that enhances T-cell-mediated responses. Preclinical data from syngeneic tumor studies with a human CD27 knock-in mouse model have demonstrated efficacy of MK-5890 as both monotherapy and in combination with anti-PD-1. MK-5890 is currently being evaluated in a Phase 1 clinical trial for the treatment of advanced solid tumors (see www.clinicaltrials.gov, identifier NCT03396445).

In 2014, Merck, through certain affiliates, entered into a worldwide license agreement with Aduro for the development and commercialization of anti-CD27 agonists, including MK-5890, which was identified with Aduro's proprietary B-select monoclonal antibody technology.

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 patients with cutaneously accessible metastatic solid tumors or lymphomas. BION-1301, a first-in-class humanized IgG4 monoclonal antibody that fully 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 intentions or current expectations concerning, among other things, the potential for MK-5890, an anti-CD27 agonist alone or in combination, the potential for our other therapies, our eligibility to receive additional milestone payments or royalties for MK-5890, Merck's further exploration of MK-5890's potential in expansion cohorts, including an arm of MK-5890 administered with pembrolizmab, pemetrexed and carboplatin in patients with non-squamous non-small cell lung cancer, the further progress of our and Merck's clinical programs 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 September 30, 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.

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

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