Aduro Biotech Announces First Patient Dosed in Phase 2 Clinical Trial of CRS-207 in Combination with KEYTRUDA® (pembrolizumab) for the Treatment of Patients with Previously Treated Malignant Pleural Mesothelioma

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BERKELEY, Calif., June 28, 2017 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (Nasdaq:ADRO), a biopharmaceutical company with three distinct immunotherapy technologies, today announced that the first patient has been dosed in the company's Phase 2 clinical trial in malignant pleural mesothelioma (MPM). The trial, which will involve approximately 35 patients, will evaluate the tolerability, safety and efficacy of CRS-207, Aduro's LADD (live, attenuated double-deleted) based immunotherapy, in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck (known as MSD outside the United States and Canada), for the treatment of patients with MPM whose disease progressed following prior treatment.

"We are excited to initiate this Phase 2 trial to evaluate the combination of CRS-207 and pembrolizumab, an anti-PD-1 therapy, which we believe has the potential to be a synergistic combination therapy for patients with malignant pleural mesothelioma," said Natalie Sacks, M.D., chief medical officer at Aduro. "Mesothelioma is an aggressive cancer with a poor prognosis and limited treatment options; currently, there are no FDA-approved therapies indicated for second- or third-line treatment. We have received Orphan Drug Designation in the U.S. and E.U. for CRS-207 for this indication, and we are committed to doing all that we can to bring new treatment options to patients facing this difficult disease."

The multicenter, single-arm, open-label Phase 2 study is designed to evaluate the safety and efficacy of CRS-207 with pembrolizumab in adults with previously treated MPM. The trial will be conducted at up to 10 sites and will enroll approximately 35 patients who have failed one to two prior treatments. The primary efficacy endpoint is objective response rate, defined as the proportion of patients with either complete or partial responses. For additional information about the study, please visit www.clinicaltrials.gov (NCT03175172).

Earlier this year, Aduro announced a clinical collaboration with Merck, through a subsidiary, relating to the investigation of CRS-207 used in combination with pembrolizumab for the treatment of MPM. This is the second clinical collaboration formed this year between the two companies, with the first announced in January 2017 relating to the investigation of CRS-207 used in combination with pembrolizumab for the treatment of gastric cancer.

Previously Reported Clinical Data with CRS-207 in Malignant Pleural Mesothelioma
In June 2016, data from a Phase 1b study evaluating CRS-207 alone and in combination with standard chemotherapy in patients with newly-diagnosed MPM were presented at the American Society of Clinical Oncology. Data from this study demonstrated that CRS-207 induced encouraging anti-tumor responses. Following treatment with the combination of CRS-207 and standard chemotherapy, disease control was observed in 94 percent of the 36 patients evaluated, including 3 percent with a complete response, 56 percent with partial responses, and 36 percent experiencing stable disease. Prior to receiving chemotherapy, patients received two doses of CRS-207 alone. During this period, 31 percent of patients experienced some tumor shrinkage, supporting the clinical activity of single-agent CRS-207. Additionally, paired pre- and on-treatment tumor biopsies demonstrated CRS-207 induced important changes in the tumor microenvironment, including an increase in infiltrating CD8+ T cells and other immune cell types that are thought to be essential for immunotherapy, including dendritic cells and natural killer cells.

About Malignant Pleural Mesothelioma
Mesothelioma is a form of cancer that affects the smooth layer of mesothelial cells that surround the chest, lungs, heart and abdomen. Malignant pleural mesothelioma (MPM), which affects the thin balloon-shaped lining of the lungs, is the most common form of this disease and accounts for approximately 3,000 cases a year in the United States. MPM is an aggressive disease with a poor prognosis. Most MPM patients are not candidates for surgical resection. The tumor-associated antigen mesothelin is overexpressed on the majority of mesothelioma tumors. Currently, there is no U.S. Food and Drug Administration-approved therapy for second- or third-line treatment of MPM.

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 an innate immune response and to express tumor-associated antigens to induce tumor-specific T cell-mediated immunity. CRS-207, the company's lead LADD product candidate, 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 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 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 mesothelioma, ovarian, lung and prostate cancers. Additionally, a personalized form of LADD, or pLADD, is being developed utilizing tumor neoantigens that are specific to an individual patient's tumor. Aduro's STING Pathway Activator platform is designed to activate the STING receptor in immune cells, 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, the combination of CRS-207 with pembrolizumab for the potential treatment of mesothelioma and gastric cancer, our technology platforms, plans, and the potential for 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," "seek", "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. 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, 2017, 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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