Aduro Biotech Completes Enrollment in Phase 1b Clinical Trial of CRS-207 Immunotherapy for the Treatment of Mesothelioma

August 10, 2015

- Company plans to advance directly into a global, randomized Phase 3 registration trial based on compelling results from Phase 1b trial
- Phase 1b sites remain open for continued exploratory evaluation of CRS-207 administered with low-dose cyclophosphamide

BERKELEY, Calif., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (Nasdaq:ADRO) today announced that it has completed enrollment in the Phase 1b clinical trial of its novel immunotherapy, CRS-207, in combination with standard-of-care chemotherapy in patients with unresectable malignant pleural mesothelioma (MPM). The multi-center Phase 1b trial enrolled 38 patients who were chemotherapy-naïve, had unresectable MPM, had good performance status (ECOG 0 or 1), and adequate organ function. The company plans to advance directly to a Phase 3 clinical trial with CRS-207 in combination with standard-of-care chemotherapy in patients with unresectable MPM in the first half of 2016.

"Based on compelling data from the Phase 1b trial, as well as recent meetings with the U.S. Food and Drug Administration, Paul-Ehrlich-Institut and thought leaders in the field, we believe that we have strong rationale to advance the combination regimen with CRS-207 into a pivotal Phase 3 clinical trial in the front-line setting," said Dirk G. Brockstedt, Ph.D., senior vice president of research and development at Aduro. "We expect this approach may accelerate our ability to offer patients with mesothelioma, a particularly grievous and aggressive disease, an attractive therapeutic alternative. We are currently working with our key clinical advisors and regulatory authorities to finalize the design of a global Phase 3 pivotal study."

Thomas Dubensky, Ph.D., chief scientific officer at Aduro, added, "We are thrilled to advance our LADD technology into another late-stage program. We believe this platform offers significant promise in generating potent innate and tumor-specific adaptive immune responses and we look forward to continuing to explore its potential as a therapeutic alternative for patients."

In the Phase 1b trial, eligible patients received two prime vaccinations with CRS-207 two weeks apart, followed by up to six cycles of standard-of-care pemetrexed and cisplatin chemotherapy three weeks apart and two CRS-207 boost vaccinations three weeks apart. Clinically stable patients received CRS-207 maintenance vaccinations every eight weeks and were followed every eight weeks until disease progression. Objectives of the study were safety, immunogenicity, objective tumor responses and tumor marker kinetics.

Interim data presented at the 2015 American Society of Clinical Oncology Meeting (ASCO) indicate that the combination of CRS-207 with standard-of-care chemotherapy may elicit strong and durable responses in patients with unresectable MPM. Of the 32 evaluable patients enrolled at the time, disease control was observed in 94% (30/32), including 60% (19/32) with partial responses and 34% (11/32) experiencing stable disease following treatment with CRS-207 and chemotherapy.

The study sites will remain open to enroll an additional cohort of patients who will receive low-dose cyclophosphamide with CRS-207 and standard-of-care chemotherapy. Preclinical data indicate this combination may further enhance immune response, tumor-specific efficacy and overall survival.

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 estimated 13,000 cases a year worldwide. MPM is an aggressive disease with a poor prognosis. Most MPM patients are not candidates for surgical resection. Based on prior studies, expected median time to progression is 5.7 months and median overall survival is 12.1 months with combination pemetrexed and cisplatin chemotherapy. The tumor-associated antigen mesothelin is overexpressed on the majority of mesothelioma tumors.

About CRS-207

CRS-207 is one of a family of product candidates based on Aduro's live-attenuated, double-deleted (LADD) *Listeria monocytogenes* immuno-oncology platform that are designed to induce potent innate and adaptive immune responses. CRS-207 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 and gastric cancers.

About Aduro

Aduro Biotech, Inc. is a clinical-stage immuno-oncology company focused on the development of technology platforms to stimulate an immune response against cancer. Aduro's lead platform is based on proprietary strains of live-attenuated, double-deleted (LADD) *Listeria monocytogenes* that induce a potent innate immune response and have been engineered to express tumor-associated antigens to induce tumor-specific T cell-mediated immunity. Aduro has received Breakthrough Therapy designation from the FDA for its lead LADD regimen, CRS-207 in combination with GVAX Pancreas in pancreatic cancer. The company is evaluating the proprietary immuno-oncology combination in the ongoing Phase 2b ECLIPSE clinical trial and has additional ongoing clinical trials with its LADD platform in mesothelioma and glioblastoma. The company is also developing clinical candidates using cyclic dinucleotide (CDN) synthetic small molecule immune modulators that are designed to activate the intracellular STING receptor, a central mediator of the innate immune response. 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 CRS-207 in combination with standard-of-care chemotherapy, plans and timing of our Phase 3 clinical trial of CRS-207 in combination with standard-of-care chemotherapy and the potential for eventual regulatory approval, commercialization and launch of our product candidates. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "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 dependence on our lead product candidate, CRS-207, and GVAX Pancreas, 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 the most recent Form 10-Q which is on file with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. 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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