Aduro Biotech Presents Encouraging Anti-Tumor Response Data From Ongoing Phase 1b Study in Malignant Pleural Mesothelioma at ASCO

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BERKELEY, Calif., June 04, 2016 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (Nasdaq:ADRO) today announced the presentation of updated data from an ongoing Phase 1b clinical trial of its immunotherapy product candidate CRS-207 in combination with pemetrexed and cisplatin (standard of care chemotherapy) as front-line treatment for patients with unresectable malignant pleural mesothelioma (MPM). The results from the first of two cohorts were presented today in a poster presentation at the 2016 American Society of Clinical Oncology Meeting (ASCO) held in Chicago. Of the 36 evaluable patients, disease control was observed in 94% (34/36), including 3% (1/36) with a complete response, 56% (20/36) with partial responses and 36% (13/36) experiencing stable disease following treatment with CRS-207 and chemotherapy. Prior to receiving chemotherapy, 31% (11/36) of patients experienced some tumor shrinkage (range: -1% to -43%) after receiving CRS-207 alone. The estimated median overall survival was 16.4 months (95% CI: 11.0 – 20.6 months). CRS-207 was generally well-tolerated with no treatment-related serious adverse events or cumulative toxicities when administered with chemotherapy.

"The observed responses with the combination of CRS-207 and standard chemotherapy are unprecedented in mesothelioma," said Dean Fennell, Ph.D., F.R.C.P., professor of Thoracic Medical Oncology at the University of Leicester and president of the International Mesothelioma Interest Group (iMig). "Pleural mesothelioma is a devastating disease, and these data suggest that immunotherapy has the potential to advance treatment options for these patients."

Dirk G. Brockstedt, Ph.D., executive vice president of Research and Development at Aduro added, "These results demonstrate that CRS-207 induces anti-tumor activity in patients with malignant pleural mesothelioma. We are looking forward to the results from the study's second cohort, which is evaluating the addition of immune modulating doses of cyclophosphamide to the CRS-207 chemotherapy combination. Preclinical data suggest that the simultaneous inhibition of regulatory T-cells through the addition of a checkpoint inhibitor may amplify the tumor response and overall survival seen with CRS-207. As such, the combination of CRS-207 with a checkpoint inhibitor could be the regimen we advance in our mesothelioma program going forward."

The multi-center Phase 1b study enrolled chemotherapy-naïve patients with unresectable MPM and good performance status (ECOG 0 or 1) to receive two doses of CRS-207, followed by up to six cycles of chemotherapy and two additional CRS-207 doses. Clinically stable patients receive CRS-207 maintenance every eight weeks and are followed every eight weeks until disease progression. Objectives of the study are safety, immunogenicity, objective tumor responses and tumor marker kinetics.

A second cohort of 22 patients is receiving an immunomodulatory dose of cyclophosphamide one day prior to each CRS-207 administration in the same treatment regimen utilized in the first cohort. This cohort is fully enrolled and patient follow-up is ongoing.

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. 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.[i] The tumor-associated antigen mesothelin is overexpressed on the majority of mesothelioma tumors.

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 a potent innate immune response and to express tumor-associated antigens to induce tumor-specific T cell-mediated immunity.

CRS-207 is one of a family of product candidates based on Aduro's LADD immunotherapy platform that 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 pancreatic, ovarian, lung and prostate cancers, mesothelioma and glioblastoma. Aduro's STING Pathway Activator platform is designed to activate the intracellular STING receptor, resulting in a potent tumor-specific immune response. 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 potential for CRS-207 and immunotherapies generally, plans and results of the mesothelioma trial, 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 "may," "potential," "could," "plan," "expect," "suggest" 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, the uncertainty related to clinical trials and combinations of clinical trial candidates, our dependence on our lead product candidate, CRS-207, 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 our quarterly report on Form 10-Q for the quarter ended March 31, 2016, 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.

[i] Vogelzang, N.J., Rusthoven, J.J., Symanowski, J., et al. (2003). Phase III Study of Pemetrexed in Combination with Cisplatin Versus Cisplatin Alone in Patients with Malignant Pleural Mesothelioma. J Clin. Oncol. 21: 2636-2644.

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