Aduro Biotech Announces Clinical Trial Agreement to Evaluate Combination of Two Novel Cancer Immunotherapies for the Treatment of Ovarian Cancer

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BERKELEY, Calif., Sept. 9, 2015 (GLOBE NEWSWIRE) -- Aduro Biotech, Inc. (Nasdaq:ADRO) announced today that it has entered into a clinical trial agreement with Incyte Corporation (Nasdaq:INCY) to evaluate the safety, tolerability and preliminary efficacy of Aduro's lead LADD immunotherapy, CRS-207, in combination with Incyte's oral indoleamine dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), in patients with ovarian cancer.

The combination of both investigational immunotherapeutic agents, which have different but complementary mechanisms directed at enhancing the body's own immune defenses, may provide unique synergies in fighting cancer. Incyte's epacadostat has been shown *in vitro* and in preclinical tumor models to enhance activities of multiple types of immune cells by reducing the immune suppression characteristic of the tumor microenvironment. Aduro's CRS-207 has been shown to stimulate immune cell activity, with particular targeting mechanisms that seek and attack tumor cells that express mesothelin like those found in ovarian cancer.

"There's a growing body of evidence and enthusiasm in the field of oncology to combine therapeutic agents with different mechanisms that may result in very powerful approaches to treating tough cancers," said Stephen T. Isaacs, chairman, president and chief executive officer of Aduro. "Incyte is a leader in the field of cancer immunotherapy and we're pleased to join forces with them to study a novel approach to treating ovarian cancer."

Rich Levy, M.D., chief drug development officer of Incyte added, "This clinical trial collaboration with Aduro is an important opportunity to further investigate the therapeutic value of epacadostat in advanced ovarian cancer. Research partnerships like this one help us deliver on our goal of advancing innovative science to improve patients' lives."

The Phase 1/2 trial, which is being funded equally between the two companies, is designed to test combinations of CRS-207 with two dose levels of epacadostat in dose escalation and then will expand to a Phase 2 evaluating the combination at the optimal dose level compared to CRS-207 alone based on safety and tumor biomarkers. The study plans to enroll up to 40 patients in Phase 1 and up to 86 patients in Phase 2 with platinum-resistant ovarian, fallopian or peritoneal cancers. The trial is expected to begin enrolling patients in early 2016.

Under the terms of the collaboration, Aduro and Incyte will collaborate on a non-exclusive basis to evaluate the combination. Aduro will be responsible for conducting the study and the results will be used to determine whether further clinical development of this combination is warranted.

About Epacadostat

Indoleamine 2,3-dioxygenase 1 (IDO1) is an immunosuppressive enzyme that has been shown to induce regulatory T cell generation and activation, and allow tumors to escape immune surveillance. Epacadostat is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays and has demonstrated potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity. Epacadostat has shown proof-of-concept clinical data in patients with unresectable or metastatic melanoma in combination with the CTLA-4 inhibitor ipilimumab, and is currently in four proof-of-concept clinical trials with PD-1 and PD-L1 immune checkpoint inhibitors in a variety of cancer types.

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. (Nasdaq:ADRO) is a clinical-stage 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. Based on compelling clinical data in advanced cancers, this platform is being developed as a treatment for multiple indications, including pancreatic, lung and prostate cancers, mesothelioma and glioblastoma. Aduro's cyclic dinucleotide (CDN) platform is designed to activate the intracellular STING receptor, resulting in a potent tumor-specific immune response. 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 in combination with epacadostat 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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