Aduro receives breakthrough therapy designation from FDA for innovative pancreatic cancer combination immunotherapy

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FDA Breakthrough Designation Highlights Aduro's Immunotherapeutic Approach as Promising Treatment for Patients with Pancreatic Cancer

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BERKELEY, Calif. -- Aduro BioTech, Inc., a clinical-stage biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for its pancreatic cancer combination treatment that consists of its CRS-207 and GVAX Pancreas immunotherapies. According to the FDA, a breakthrough therapy designation is for a drug that treats a serious or life-threatening condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint over available therapies.

The designation was based on findings from a Phase 2 trial in metastatic pancreatic cancer patients, which were presented and featured earlier this year at the ASCO Gastrointestinal Cancers Symposium conference. The randomized, controlled, multi-center study, which enrolled 93 patients who failed or refused prior therapy, demonstrated a statistically significant survival benefit in patients receiving the combination of GVAX Pancreas and CRS-207 cancer vaccines (Arm A) compared to GVAX Pancreas vaccine alone (Arm B). The median overall survival of the patients receiving the combination was 6.1 months compared to 3.9 months for those receiving GVAX monotherapy (HR=0.59, one-sided p=0.0172).

"We are extremely pleased to receive Breakthrough Therapy Designation and the high degree of FDA collaboration toward advancement of our program that it confers," said Stephen T. Isaacs, chairman, president and chief executive officer of Aduro. "This designation underscores the potential of our combination immunotherapy approach to make a difference in the lives of patients with pancreatic cancer, which remains a very difficult cancer to treat. We are encouraged by our Phase 2 results and look forward to completing enrollment in our Phase 2b ECLIPSE trial by end of 2015."

A breakthrough therapy designation is one of four avenues provided by FDA to expedite drug development for therapies that treat serious or life-threatening conditions. Breakthrough includes all of the fast track program features and provides more intensive FDA guidance involving senior FDA staff. As with fast track, breakthrough provides eligibility for rolling review and priority review of the company's Biologics License Application when submitted.

Aduro is currently conducting a 240 patient Phase 2b clinical trial (ECLIPSE; www.clinicaltrials.gov identifier NCT02004262) in metastatic pancreatic cancer patients who have progressed after at least one line of therapy. The randomized, controlled 3-arm trial will involve over 20 clinical trial sites in the U.S. and Canada and will evaluate the safety, immune response and efficacy of the combination immunotherapy of GVAX Pancreas and CRS-207 compared to chemotherapy or to CRS-207 alone. The primary endpoint of the trial is overall survival. Patients interested in the ECLIPSE trial or other pancreatic cancer treatment options may contact the Pancreatic Cancer Action Network's Patient & Liaison Services (PALS) program that provides patients and families with information, including personalized clinical trial searches, at no cost. Patients can visit their website at: www.pancan.org, call 877-272-6226 or email pals@pancan.org for information.

About CRS-207

CRS-207 is one of a family of product candidates based on Aduro's live-attenuated, double-deleted (LADD) *Listeria monocytogenes* immunotherapy platform that induce a potent innate and T cell-mediated immune response. 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 GVAX Pancreas

GVAX Pancreas is one of a family of GVAX vaccines derived from human cancer cell lines that are genetically modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune-stimulatory cytokine. GVAX Pancreas also expresses mesothelin.

About Aduro BioTech, Inc.

Aduro BioTech, Inc. is a private, clinical-stage biotechnology company focused on immunotherapy for cancer. Aduro has ongoing clinical trials with its LADD platform in pancreatic cancer, mesothelioma and high-grade glioma and its immunotherapies are in development in non-small cell lung cancer, ovarian cancer and prostate cancer. The company is also developing clinical candidates using novel small molecules that activate the intracellular STING receptor, a central mediator of the innate immune response. For more information, please visit www.adurobiotech.com.

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