

Aduro announces Phase 2 clinical trial results demonstrating statistically significant survival benefit in pancreatic cancer patients treated with its novel immunotherapies

January 14, 2014 5:21 PM ET

January 14, 2014 05:00 PM Eastern Standard Time

2014 ASCO Gastrointestinal Cancers Symposium

SAN FRANCISCO -- Aduro BioTech, Inc., a clinical stage biotechnology company, today announced the presentation of safety and efficacy data from a randomized Phase 2 clinical trial of its novel immunotherapy product candidates, CRS-207 and GVAX Pancreas, in metastatic pancreatic cancer patients. The trial was stopped early for meeting the primary efficacy endpoint at a pre-planned interim analysis. The data will be presented by Dung Le, M.D., Assistant Professor of Oncology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center and Principal Investigator of the study, in an oral presentation at the annual American Society of Clinical Oncology (ASCO) 2014 Gastrointestinal Cancers Symposium in San Francisco.

The randomized, controlled, multi-center study, which enrolled 93 pancreatic cancer patients, 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=0.54, one-sided p=0.011). One-year survival probability for patients in Arm A was 24% compared with 12% for patients in Arm B.

The trial enrolled advanced-stage metastatic pancreatic cancer patients, with most patients having received two or more prior therapies in the metastatic setting. Patients were randomized in a 2:1 ratio to receive 2 doses of low-dose cyclophosphamide and GVAX Pancreas (CY/GVAX Pancreas) vaccine followed by 4 doses of CRS-207 (Arm A) or to receive 6 doses of CY/GVAX Pancreas vaccine alone (Arm B). The vaccines were well-tolerated, with no treatment-related serious adverse events or unexpected toxicities observed.

In a pre-defined subset of patients who received at least 3 doses in either treatment group (2 CY/GVAX Pancreas followed by at least 1 CRS-207 dose in Arm A or at least 3 doses of CY/GVAX Pancreas in Arm B), the median overall survival was 9.7 months in Arm A compared to 4.6 months in Arm B (HR=0.53, one-sided p=0.017).

“The significant improvement in survival in patients treated with our combination therapy expands on building evidence that immunotherapy can be a promising approach in oncology, even in a difficult-to-treat disease such as pancreatic cancer,” said Stephen T. Isaacs, chairman and chief executive officer of Aduro. “We are thrilled to be at the forefront of innovation in the field and look forward to advancing our vaccines into additional clinical trials in pancreatic cancer and other indications.”

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. Aduro’s GVAX portfolio includes vaccines for pancreatic, prostate, colon and breast cancers as well as multiple myeloma.

About CRS-207

CRS-207 is one of a family of product candidates based on Aduro’s proprietary platform of attenuated *Listeria monocytogenes* strains that have been genetically modified to induce potent innate and T cell-mediated immunity, specific for tumor-associated antigens. CRS-207 has been engineered to express the tumor-associated antigen mesothelin, which is over-expressed in many cancers including pancreatic, non-small cell lung, ovarian and gastric cancers as well as mesothelioma.

About Aduro BioTech, Inc.

Aduro BioTech, Inc. is a clinical-stage biotechnology company focused on immunotherapy for cancer. Aduro has ongoing clinical development programs in pancreatic cancer, mesothelioma and glioblastoma. The company is also developing clinical candidates that utilize small molecules that activate STING (STimulator of INterferon Genes), a central mediator of the innate immune response. The company's pipeline also includes programs in non-small-cell lung cancer, ovarian cancer and prostate cancer. For more information, please visit www.adurobiotech.com.

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