

## **Aduro Biotech Collaborates with Leaders in Cancer Research on Investigator-Sponsored Phase 2 Trial Combining Aduro's Innovative Immunotherapies with Anti-PD-1 Technology to Treat Patients with Advanced Pancreatic Cancer**

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BERKELEY, Calif.—(BUSINESS WIRE)—Aduro Biotech, Inc. today announced the initiation of an investigator-sponsored Phase 2 clinical trial of the company's immuno-oncology product candidates GVAX Pancreas and CRS-207 in combination with Bristol-Myers Squibb's Opdivo (nivolumab), a monoclonal antibody against programmed death-1 receptor (PD-1). The first patient has been enrolled in the trial that will be conducted at up to five U.S. clinical trial sites.

GVAX Pancreas and CRS-207 are designed to stimulate an immune response against a tumor, and nivolumab is designed to remove an immuno-suppressive mechanism that cancer cells have developed against the immune system. Aduro believes the combination of CRS-207 and GVAX Pancreas with nivolumab may improve clinical outcomes because of their complementary mechanisms of action.

The randomized, controlled STELLAR trial (Safety and Therapeutic Efficacy of Live-attenuated Listeria/GVAX with Anti-PD1 Regimen) will enroll approximately 88 adults with metastatic pancreatic cancer who have had one prior chemotherapy regimen for metastatic disease. The trial will include two arms: Arm A with CRS-207/GVAX Pancreas vaccine and nivolumab and Arm B with CRS-207/GVAX Pancreas vaccine. The primary objective of this study is to compare the overall survival (OS) of patients in Arm A and Arm B. Secondary endpoints include evaluation of clinical and immune response and safety. For more information, please visit [ClinicalTrials.gov](http://ClinicalTrials.gov) (Identifier: NCT02243371).

The trial is supported by Stand up to Cancer (SU2C)-Lustgarten Foundation Pancreatic Cancer Convergence Dream Team Translational Research; Pancreatic Cancer Action Network – AACR Research Acceleration Network Grant, supported by Fredman Family Foundation; and Bristol-Myers Squibb. SU2C is a program of the Entertainment Industry Foundation.

"For some time, we have recognized and embraced the power of combination strategies for immuno-oncology and this trial will evaluate expanding our lead combination to include Opdivo, the first-in-class anti-PD-1," said Stephen T. Isaacs, chairman, president and chief executive officer of Aduro. "While we continue our efforts to evaluate GVAX Pancreas and CRS-207 in our Phase 2b ECLIPSE trial as an effective treatment for pancreatic cancer, we look forward to generating data in yet another combination for potential future applications of our technologies."

"The Pancreatic Cancer Action Network is thrilled to have provided initial funding that has been leveraged for this important program," said Julie Fleshman, president and CEO of the Pancreatic Cancer Action Network. "In an effort to double pancreatic cancer survival by 2020, we are investing in projects that have the potential to improve the treatment landscape of pancreatic cancer and ultimately increase survival."

"Stand Up To Cancer is excited not only that this immunotherapy clinical trial has begun patient enrollment, one of the 120 clinical trials we have launched or completed," stated SU2C President and CEO Sung Poblete, R.N, Ph.D., "but that it involves collaboration by two distinct biotechnology firms to study the combination of two proprietary immunotherapies. Stand Up To Cancer is proud to have facilitated this level of multi-institutional and corporate collaboration, which is at the core of SU2C's research model and its mission to benefit cancer patients faster."

Last year, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for Aduro's pancreatic cancer combination treatment consisting of CRS-207 and GVAX Pancreas. According to the FDA, a Breakthrough Therapy designation is for a drug candidate that treats a serious or life-threatening condition and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint over available therapies.

Separately, Aduro is currently conducting a 240 patient Phase 2b clinical trial (ECLIPSE; [www.clinicaltrials.gov](http://www.clinicaltrials.gov) identifier NCT02004262) in metastatic pancreatic cancer patients who have received at least one line of therapy. The randomized, controlled 3-arm trial will involve approximately 20 clinical trial sites in the United States and Canada and will evaluate the safety, immune response and efficacy of the combination immunotherapy of GVAX Pancreas in combination with CRS-207 compared to chemotherapy or to CRS-207 as a monotherapy. The primary endpoint of the trial is overall survival.

#### **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 GVAX Pancreas**

GVAX Pancreas is one of a family of GVAX vaccines derived from human cancer cell lines that are genetically modified to express granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune system-stimulating cytokine. GVAX Pancreas is derived from human pancreatic cancer cell lines and is designed to activate specific T cell immunity to pancreatic cancer antigens, including mesothelin.

#### **About the Stand Up To Cancer Initiative**

Stand Up To Cancer (SU2C) raises funds to accelerate the pace of research to get new therapies to patients quickly and save lives now. SU2C, a program of the Entertainment Industry Foundation (EIF), a 501(c)(3) charitable organization, was established in 2008 by film and media leaders who utilize the industry's resources to engage the public in supporting a new, collaborative model of cancer research, and to increase awareness about cancer prevention as well as progress being made in the fight against the disease. As SU2C's scientific partner, the American Association for Cancer Research (AACR) and a Scientific Advisory Committee led by Nobel Laureate Phillip A. Sharp, PhD, conduct rigorous, competitive review processes to identify the best research proposals to recommend for funding, oversee grants administration, and provide expert review of research progress.

#### **About the Pancreatic Cancer Action Network**

The Pancreatic Cancer Action Network is the national organization creating hope in a comprehensive way through research, patient support, community outreach and advocacy for a cure. The organization is leading the way to increase survival for people diagnosed with this devastating disease through a bold initiative — The Vision of Progress: Double Pancreatic Cancer Survival by 2020. Together, we can Wage Hope in the fight against pancreatic cancer by intensifying our efforts to heighten awareness, raise funds for comprehensive private research, and advocate for dedicated federal research to advance early diagnostics and better treatments and increase chances of survival. For more information, go to [www.pancan.org](http://www.pancan.org).

#### **About Aduro**

Aduro Biotech, Inc. is a private, 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 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](http://www.aduro.com).