Journal for ImmunoTherapy of Cancer

POSTER PRESENTATION Open Access

Randomized Phase II study of the safety, efficacy and immune response of GVAX pancreas (with cyclophosphamide) and CRS-207 with or without nivolumab in patients with previously treated metastatic pancreatic adenocarcinoma (STELLAR)

Dung T Le[1*], Todd S Crocenzi[2], Jennifer N Urum[3], Eric R Lutz[1], Daniel A Laheru[3], Elizabeth A Sugar[4], Robert H Vonderheide[5], George A Fisher[6], Andrew H Ko[7], Aimee L Murphy[8], Katherine McDougall[9], Sandy Ferber[10], Dirk G Brockstedt[11], Elizabeth M Jaffee[1]

From 30th Annual Meeting and Associated Programs of the Society for Immunotherapy of Cancer (SITC 2015)
National Harbor, MD, USA. 4-8 November 2015

Background

A heterologous prime-boost vaccination strategy using GVAX pancreas vaccine and CRS-207 is showing promise in patients with pancreatic adenocarcinoma (PDA) (Le, JCO 2015). Furthermore, blockade of the immune checkpoint programmed death-1 (PD-1) is active in some cancers. Combinatorial strategies aimed at priming tumor antigen-specific T cells while simultaneously blocking negative checkpoints may be necessary to improve outcomes in PDA. GVAX is composed of allogeneic pancreatic cancer cells modified to express GM-CSF and induces a broad response against multiple tumor antigens. GVAX is given with low-dose cyclophosphamide (CY) to inhibit regulatory T cells. CRS-207 is live-attenuated *Listeria monocytogenes* engineered to express the tumor-associated antigen mesothelin. CRS-207 boosts responses against mesothelin and is unique in its capacity to stimulate both innate and adaptive immunity by activating T cells and NK cells. Nivolumab is an antibody against PD-1.

Methods

This is a Phase II study comparing CY/GVAX and CRS-207 with or without nivolumab in subjects with PDA who failed only one chemotherapy regimen for metastatic disease. Subjects are randomized in a 1:1 ratio to receive either 2 doses of CY/nivolumab/GVAX and 4 doses of nivolumab/CRS-207 (Arm A) or 2 doses of CY/GVAX and 4 doses of CRS-207 (Arm B). The primary objective is to compare OS between Arms A and B. Secondary/exploratory objectives include: assessment of safety and clinical responses (tumor assessments and CA19-9 levels) and correlation of *Lm*- and mesothelin-specific T cell and other immunological responses with OS, progression-free survival and best overall response.

Authors' details
[1]The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA. [2]Providence Cancer Center, Portland, OR, USA. [3]The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA. [4]Departments of Biostatistics and Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA. [5]University of Pennsylvania, Baltimore, MD, USA. [6]Stanford University School of Medicine, Stanford, CA, USA. [7]UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA. [8]Aduro BioTech, Inc., Berkeley, CA, USA. [9]Aduro Biotech, Berkeley, CA, USA. [10]Array Biostatistics LLC, Evanston, IL, USA. [11]Aduro Biotech, Inc., Berkeley, CA, USA.

Published: 4 November 2015

doi:10.1186/2051-1426-3-S2-P155
Cite this article as: Le *et al.*: Randomized Phase II study of the safety, efficacy and immune response of GVAX pancreas (with cyclophosphamide) and CRS-207 with or without nivolumab in patients with previously treated metastatic pancreatic adenocarcinoma (STELLAR). *Journal for ImmunoTherapy of Cancer* 2015 **3**(Suppl 2):P155.

[1]The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA
Full list of author information is available at the end of the article