POSTER PRESENTATION

Open Access

J Immunother Cancer: first published as 10.1186/2051-1426-3-S2-P155 on 4 November 2015. Downloaded from http://jitc.bmj.com/ on April 20, 2024 by guest. Protected by copyright

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 Crocenzi², Jennifer N Urum³, Eric R Lutz¹, Daniel A Laheru³, Elizabeth A Sugar⁴, Robert H Vonderheide⁵, George A Fisher⁶, Andrew H Ko⁷, Aimee L Murphy⁸, Katherine McDougall⁹, Sandy Ferber¹⁰, Dirk G Brockstedt¹¹, Elizabeth M Jaffee¹

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

¹The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA

Full list of author information is available at the end of the article

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

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

