Drake et al. Journal for ImmunoTherapy of Cancer 2015, 3(Suppl 2):P145
http://www.immunotherapyofcancer.org/content/3/S2/P145

Journal for ImmunoTherapy of Cancer

POSTER PRESENTATION Open Access

Immune response from STRIDE, a randomized, Phase II, open-label study of sipuleucel-T (sip-T) with concurrent vs sequential enzalutamide (enz) administration in metastatic castration-resistant prostate cancer (mCRPC)

Charles G Drake[1], David Quinn[2], Robert Dreicer[3], Emmanuel Antonarakis[4], Neal Shore[5], John Corman[6], Raoul Concepcion[7], Christopher Pieczonka[8], Dwayne Campogan[9], Li-Qun Fan[9], Nancy Chang[9*], Nadeem Sheikh[9], Daniel Petrylak[10]

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

P12-2 (STRIDE; NCT01981122) is an ongoing, randomized, Phase II, open-label study evaluating concurrent vs sequential administration of the androgen receptor inhibitor, enz, with the autologous cellular immunotherapy, sip-T. The primary aim of this study is to determine if the order of sip-T and enz administration impacts immune responses to the immunizing antigen, PA2024, of sip-T.

Methods

Patients with asymptomatic or minimally symptomatic mCRPC were randomized 1:1 to receive 3 sip-T infusions with enz starting 2 weeks (wks) before (n=25, concurrent arm A) or 10 wks after (n=27, sequential arm B) sip-T initiation. Antigen-specific cellular and humoral immune responses were evaluated via interferon (IFN)-γ ELISPOT, cell proliferation, and antibody ELISA assays. In addition, the breadth of the humoral response to non-target antigens was also studied.

Results

T cell proliferative responses to PA2024 were significantly elevated at all post-baseline time points ($p < 0.001$) and were sustained through wk 26, including a >10-fold increase at wk 20 in both arms. Both arms showed a significant and sustained increase in IFN-γ ELISPOT response to PA2024 and humoral responses to PA2024 and PAP. Broadening of the humoral responses to non-target antigens PSA, LGALS3, LGALS8, KRAS, ERAS and KLK2 at all post-treatment time points was observed in both arms. Cytokines indicative of immune activation (including IFN-γ, interleukin-2, and tumor necrosis factor-α) were also elevated in both arms, at the 2nd and 3rd sip-T infusions. Adverse events were similar between arms.

Conclusions

Treatment of mCRPC subjects with enz administered concurrently with or subsequent to sip-T resulted in significant and sustained peripheral antigen-specific T cell and humoral immune responses through wk 26. Both treatment schedules led to similarly robust humoral antigen spread sustained through wk 26. These data suggest enz did not affect sip-T production, subsequent immune responses, or safety.

Trial registration

ClinicalTrials.gov identifier NCT01981122.

Authors' details

[1]Department of Oncology, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, Baltimore, MD, USA. [2]Norris Comprehensive Cancer Center, University of Southern California, Los Angeles, CA, USA. [3]University of Virginia Cancer Center, Charlottesville, VA, USA. [4]Johns Hopkins University School of Medicine, Baltimore, MD, USA. [5]Atlantic Urology Clinics, Myrtle

[9]Dendreon, Seattle, WA, USA

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

Beach, SC, USA. [6]Virginia Mason Cancer Institute, Seattle, WA, USA. [7]Urology Associates, Nashville, TN, USA. [8]Associated Medical Professionals of New York, Syracuse, NY, USA. [9]Dendreon, Seattle, WA, USA. [10]Yale Cancer Center, New Haven, CT, USA.

Published: 4 November 2015

doi:10.1186/2051-1426-3-S2-P145
Cite this article as: Drake *et al.*: Immune response from STRIDE, a randomized, Phase II, open-label study of sipuleucel-T (sip-T) with concurrent vs sequential enzalutamide (enz) administration in metastatic castration-resistant prostate cancer (mCRPC). *Journal for ImmunoTherapy of Cancer* 2015 **3**(Suppl 2):P145.