

POSTER PRESENTATION

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# 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)

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## 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)- $\gamma$  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- $\gamma$

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- $\gamma$ , interleukin-2, and tumor necrosis factor- $\alpha$ ) were also elevated in both arms, at the 2<sup>nd</sup> and 3<sup>rd</sup> 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.

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