INTRODUCTION

ADXS-PSA

ADXS-PSA is a prostate cancer (PCa) antigen-based immunotherapy in development for advanced, hormone-refractory prostate cancer (HRPC).

METHODS

Patients

Patients with mCRPC were enrolled in a phase 1/2, open-label, multicenter, dose-determining safety and tolerability study with ADXS-PSA monotherapy or ADXS-PSA + pembrolizumab, with ADXS-PSA + pembrolizumab as the expansion cohort. ADXS-PSA was administered by intravenous injection in a 2-week cycle for up to 24 months or until disease progression or discontinuation. Pembrolizumab was administered according to the approved dosing schedule.

RESULTS

In bone-predominant disease the disease control rate was 22% per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria (Table 1). Time to progression (TTP) for all patients treated with ADXS-PSA monotherapy or ADXS-PSA + pembrolizumab was 14.1 (10.8-17.6) months with a median overall survival (OS) of 21.1 months (range, 16.0-not reached) (Figure 2).

CONCLUSIONS

The combination of ADXS-PSA and pembrolizumab appeared safe and tolerable, with no unexpected adverse events of concern and no evidence of drug-drug interactions. The majority of TRAEs consisted of Grade 1-2 chills/rigors, fever, hypotension, nausea, and diarrhea. There was a trend toward improved T-cell responses in patients treated with the combination compared with ADXS-PSA monotherapy, but this was not statistically significant. Further studies evaluating the combination at higher doses are warranted.

REFERENCES


