OBJECTIVES

- Evaluate changes in the peripheral T cell repertoires of ADXS-patients undergoing treatment 
  with ADXS-PSA.
- Determine whether any changes in the peripheral T cell repertoires were associated with cli- 
  nical activity.

MATERIALS AND METHODS

- The KEYNOTE-046 trial (NCT02933367) is a phase 1/2 evaluation of ADXS-PSA shown (Part A), used in combination with KEYTRUDA® (pembrolizumab) (Part B), in the treatment of mCRPC. The study design is shown in Figure 1 (top).
- ADXS-patients treated with KEYTRUDA® (pembrolizumab) (Part A).
- The dose level in KEYNOTE-046 trial was determined by sequential monitoring of TCR repertoire 
  for 12 cycles of treatment.
- The study design is shown in Figure 1 (top).

RESULTS

- We measured the dynamis of the T cell repertoire on ADXS-patients by tracking the ab- 
  sorption of the top 100 TCR rearrangements over the 9-week time course, which included 3 
  reaction pairs for each patient (Part A) and 2 reaction pairs for each patient (Part B).
- Changes in TCR repertoire with treatment diversity may not be a predictive biomarker for clinical response to 
  ADXS-PSA treatment.

SUPPORTING INFORMATION

- All analytical methods, which are described in Table 1, were performed using Adaptive Bi- 
 otechnologies' ImmunoID™ technology.
- The dose level in KEYNOTE-046 trial was determined by sequential monitoring of TCR repertoire 
  for 12 cycles of treatment.

ACKNOWLEDGMENTS

- The patients and faculties who participated in Part A of the KEYNOTE-046 trial.
- The staff from the facilities who are involved in the KEYNOTE-046 trial.
- The research for this trial was funded by Adaptive, Inc.