Introduction

- Approximately 14% of men will be diagnosed with PC at some point during their lifetime.
- Serum levels of biomarkers such as PSA/PAP and other serum markers of PC, PSA doubling time, and computerized tomography (CT) criteria are used to determine the presence, extent, and progression of prostatic adenocarcinoma.
- APC, antigen-presenting cell; CTL, cytotoxic T lymphocyte; LLO, listeriolysin O.

Methods

- The study is divided into two parts. Part A (phase 1 design) and Part B (phase 1/2 design) (Figure 2).

Patient Eligibility

- Key patient eligibility criteria are described in Table 3.

Table 3. Key patient eligibility criteria

<table>
<thead>
<tr>
<th>Key inclusion criteria</th>
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<tr>
<td>Adult male patients (+18 years)</td>
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<tr>
<td>Progressive mCRPC on androgen deprivation therapy identified by either</td>
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<td>PSA progression of 25% increase over baseline</td>
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Endpoints

- Safety: Safety will be assessed by grading AE severity as per NCI CTCAE v3.0 for treatment and as per NCI CTCAE v4.0 for concurrent medications. Endpoints include vital signs, physical examination, laboratory parameters, and AEs.

Statistical Analysis

- Descriptive statistics will be used to summarize and evaluate the safety and tolerability of ADXS31-142 alone and in combination with pembrolizumab.

References

- N. Haas et al. 2015. Cancer Treatment, Research and End Results Program. 2015.