ADXS11-001 immunotherapy targeting HPV-E7: Updated survival and safety data from a Phase 2 study in Indian women with recurrent cervical cancer

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Abstract

ADXS11-001 immunotherapy is a live attenuated Listeria monocytogenes (Lm) bioengineered to secrete a HPV-E7 fusion protein targeting HPV-16 infected cells. The Lm vector serves as its own adjuvant and effector antigen-presenting cells (APC) where it resides, stimulating MHC class I and II pathways resulting in specific T cell responses to HPV. Here we describe 30 month overall survival and safety data from 107 patients with recurrent cervical cancer treated with ADXS11-001 as a monotherapy or in combination with cisplatin at the Chittaranjan National Cancer Institute, Kolkata, India.

Safety

Safety Summary: Lm-LLO-E7-15

- 119 patients received 286 doses of ADXS11-001 at 10 mg q3w
- 40 patients received cisplatin at 75 mg q3w

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Safety: Frequency of SAEs in 110 patient Phase 2: ADXS11-001 vs. Chemotherapy

Trial Regimen

<table>
<thead>
<tr>
<th>Regimen</th>
<th>ADXS11-001</th>
<th>cisplatin q3w</th>
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</thead>
<tbody>
<tr>
<td>Overall Survival</td>
<td>105/110</td>
<td>98/110</td>
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<tr>
<td>Landmark Survival</td>
<td>70/110</td>
<td>62/110</td>
</tr>
<tr>
<td>Duration of Response (PFS)</td>
<td>60/110</td>
<td>54/110</td>
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Conclusions

The Kaplan Meier curve represents overall survival for all patients that completed at least 12 months of follow-up. The addition of cisplatin to ADXS11-001 did not significantly improve survival (p=0.41). Median overall survival was 395 days (6.5 months).

The 3 Kaplan Meier curves below represent relative overall survival by treatment arm and by prior therapy. 50% of patients were previously treated with combination radiation/chemotherapy. 40% of patients were treated with radiodcytotoxic therapy alone, and 10% of patients were treated with chemotherapy alone. No differences in overall survival were observed based on prior therapy.

Case Study: Patient 110-002

Resolution of long-term cervical lesions at cT1a at 6 months

Resolution of long-term cervical lesions at cT1a at 6 months

Resolution of persistent cervical lesions at cT1a at 6 months

Conclusion

Tumor reduction observed in patients infected with different high-risk HPV strains including HPV 16, 18, 31, 33 and 45.

The best overall response is shown for 66 patients. 18 patients expired prior to the 3 month evaluation and 27 patients withdrew consent or were lost to follow up over the same interval.

Using RECIST criteria 20 patients had a best overall response of progressive disease, 12 patients had objective responses (6 CR/PR). 35 patients had stable disease ≥ 3 months, for a disease control rate of 43% (47/110).

Similar tumor responses were observed in both treatment groups. Tumor responses were observed in all strains of high-risk HPV detected including HPV 16, 18, 31, 33 and 45.