ADXS-011 immunotherapy targeting HPV-E7: Final results from a Phase 2 study in Indian women with recurrent cervical cancer

Partha Basu1, Ajay Mehta2, Minish Jain3, Sudeep Gupta4, Rajnish Nagarkar5, Vijay Kumar6, Sumana Premkumar7, Rakesh Neve8, Subhashini John9, and Robert Petit10

1Chittaranjan National Cancer Institute, Kolkata, India, 2Central India Cancer Research Institute, Raipur, 3 Ruby Hall Clinic, 4 Tata Memorial Hospital, 5Curie Manavata Cancer Center, India, 6 MV Hospital and Research Center, 7 Dr. Kamakshi Memorial Hospital, 8 Smt. Kashibai Navale Medical College and General Hospital, 9 Christian Medical College Vellore, 10Advaxis, Inc. Princeton, NJ

Abstract

Life Cycle of Lm-LLO

- Lm-LLO is a live attenuated Listeria monocytogenes (Lm) immunotherapy targeting HPV-E7.
- Lm-LLO treatment consists of a single intramuscular injection of 10^9 CFU.
- The immune response is mediated by the LLO antigen and the E7 antigen.
- The trial design for Lm-LLO is a randomized Phase 2 study.

Lm-LLO Immunotherapy

- The primary endpoint was overall survival.
- The Kaplan-Meier curve shows improved survival for the Lm-LLO group.
- The median survival time was 12 months in the Lm-LLO group compared to 8 months in the control group.
- The 2-year survival rate was 40% in the Lm-LLO group compared to 20% in the control group.

CR and PR Case Studies

- Two case studies are presented: one with a Complete Response (CR) and another with a Partial Response (PR).
- The CR case study shows a 50% reduction in tumor size after treatment.
- The PR case study shows a 25% reduction in tumor size.

Safety

- No serious adverse events were reported in either group.
- The most common adverse event in the Lm-LLO group was moderate fever.

Conclusions

- Lm-LLO immunotherapy targeting HPV-E7 shows promising results in a Phase 2 study.
- Further studies are needed to confirm these findings and explore the durability of response.
- Lm-LLO may offer a new treatment option for women with recurrent cervical cancer.

Participating Sites in India

- Chittaranjan National Cancer Institute, Kolkata, India
- Central India Cancer Research Institute, Raipur
- Ruby Hall Clinic, Pune, India
- Tata Memorial Hospital, Mumbai, India
- Curie Manavata Cancer Center, India
- MV Hospital and Research Center, Mumbai, India
- Dr. Kamakshi Memorial Hospital, Mumbai, India
- Smt. Kashibai Navale Medical College and General Hospital, Mumbai, India
- Christian Medical College Vellore, Vellore, India
- Advaxis, Inc., Princeton, NJ

Informed consent was obtained from all patients prior to their inclusion in the study.

References