**ADXS11-001 immunotherapy in squamous or non-squamous persistent/recurrent metastatic cervical cancer: Results from stage 1 [and stage 2] of the phase II GOG-NRG-0265 study**

Authors: Wamer Hu, MD, Don Dizon, MD, Matthew A. Powell, MD, Charles A. Leath III, MD, Lisa M. Landrum, MD, Edward Tamer, MD, Robert Higgins, MD, Stefania Ueda, MD, Michael McHale, MD, Bradley J. Monk, MD, Carol Aghaiyan, MD

Affiliations: University of Alabama at Birmingham, Obstetrics and Gynecology; Birmingham, AL; Massachusetts General Hospital Cancer Center, Gynecologic Oncology, Boston, MA; Washington University School of Medicine, Obstetrics/Gynecology, St. Louis, MO; University of California, San Francisco, CA; UCSF School of Medicine, Obstetrics, Gynecology and Reproductive Sciences, Division of Gynecologic Oncology, San Francisco, CA; UC San Diego-Mother Cancer Center, Gynecologic Oncology, San Diego, CA; University of Arizona Cancer Center at Diamond Head St. Joseph’s Hospital and Medical Center, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Phoenix, AZ; Memorial Sloan-Kettering Cancer Center, Gynecologic Medical Oncology Service, New York, NY

Presented at the American Society of Clinical Oncology, Chicago, IL, June 7–9, 2016

**INTRODUCTION**

Cervical cancer is a leading public health problem in South America. For women in the United States and Europe, cervical cancer is the sixth leading cause of cancer death. Although HPV vaccination has had a substantial impact on cervical cancer incidence, many women with cervical cancer present at advanced stages and have a poor prognosis. ADXS11-001 is an immunotherapeutic vaccine against HPV that is currently being studied in phase II trials for the treatment of recurrent/metastatic cervical cancer (R/M CIN). This study demonstrates the phase II results of ADXS11-001 in patients with persistent/recurrent metastatic cervical cancer (PRmCC) whose disease has progressed on prior standard of care therapy.

**RATIONALE FOR ADXS11-001 IN CERVICAL CANCER**

ADXS11-001 is a live-attenuated Listeria monocytogenes (Lm) bacterial vaccine that expresses HPV E7 antigen. The Lm vector is replication-defective, enabling safety; it is tumour-specific and elicits immune responses against HPV E7 antigen. In this study, patients with R/M CIN received ADXS11-001 subcutaneously on Days 0 and 21 to induce HPV-specific immunity and reduce HPV-mediated cancer cell death. The dose, schedule, and key eligibility criteria are depicted in Figure 3.

**SAFETY/TOLERABILITY**

The study population included 26 patients with persistent/recurrent cervical cancer (PRmCC). A total of 30 patients were enrolled in stage 1 of the study at 11 sites, and 26 of those patients received at least 1 dose of ADXS11-001. The 4 patients who did not receive ADXS11-001 were eligible for treatment, but did not receive it for various reasons (see Figure 3). Of the 26 patients who received at least 1 dose of ADXS11-001, 18 (69%) received the maximum 3 doses with an interval of 21 days, and 69% (n = 18) received the maximum 3 doses.

**RESULTS**

**Primary endpoint:**

- **12-month survival rate:** 42% (n = 10/24). Median survival was 12 months, and 20% of patients survived >12 months. (Figure 4A)

**Secondary endpoints:**

- **20% response rate:** 10% (3/30) (95% Cl 0.03-0.26). (Table 1)

**Exploratory analysis:**

- **Survival rates:**
  - 12-month survival rate: 42% (n = 10/24). Median survival: 12 months. 20% of patients survived >12 months. (Figure 4A)
  - 24-month survival rate: 30% (n = 9/30). Median survival: 18 months. 10% of patients survived >24 months. (Figure 4B)

**Adverse events:**

- **Most common adverse events:**
  - Grade 1-2: Hypotension, chills
  - Grade 3-4: Hypotension, chills
  - Grade 5: None

**DISCUSSION**

The study was designed to proceed to stage 2 enrollment if conditional power at stage 1 was met. Although preliminary, findings from stage 2 reinforce the need to further study ADXS11-001 in R/M CIN.