Phase 1/2 study of ADXS11-001 or MEDI4736 (Durvalumab) immunotherapies alone and in combination, in patients with recurrent/metastatic cervical or human papillomavirus (HPV)-positive head and neck cancer

Ezra E.W. Cohen1, Kathleen N. Moore2, Brian M. Slomovitz3, Christine H. Chung4, Matthew L. Anderson5, Shannon R. Morris6, David Mauro7, Barbara Burt8

1University of California, San Diego, La Jolla, CA, USA; 2University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA; 3Sylvester Comprehensive Cancer Center, Miami, FL, USA; 4Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD, USA; 5Dan L. Duncan Cancer Center, Baylor College of Medicine, Houston, TX, USA; 6Medimmune, LLC, Gaithersburg, MD, USA; 7Advaxis Inc., Princeton, NJ, USA; 8Yale Medical Oncology, New Haven, CT, USA

INTRODUCTION

• The World Health Organization reported approximately 270,000 deaths from cervical cancer in 2012 worldwide.1
• The 5-year survival rate of patients with advanced cervical cancer is 15%.2 Patients with recurrent cancer are usually not candidates for standard treatment approaches.3
• HPV is the primary etiologic agent of cervical cancer. Of the 13 cervical-cancer types of HPV, types 16 and 18 are responsible for about 70% of recurrent cervical cancers.4
• Similarly, in HPV-positive oropharyngeal cancer, 10%-25% of patient progression occurs within 3 years of completing primary therapy and have a 2-year survival of approximately 54%.5,6 A retrospective analysis of specimens from the Surveillance, Epidemiology, and End Results Program's Fiscal Year 2004-2006 Cancer Registry screened 90% of the patients for whom data were available.7

OBJECTIVES

• The objectives of the study are outlined in Table 1.

STUDY DESIGN

• A 2-stage, 2-part phase I/II study of ADXS11-001 (1 × 10^9 TCID50) with or without durvalumab will evaluate the safety, tolerability, and antitumor activity of ADXS11-001 monotherapy or in combination in patients with recurrent cervical or recurrent/metastatic head and neck cancer.

METHODS

ENDPOINTS

• Safety
• Efficacy

STATISTICAL METHODS

• Statistical Analysis Software v9.2 or higher will be used for data analysis.

DISCLOSURES

• This study is supported by Advaxis Inc., Inc. and MedImmune, respectively.

REFERENCES


