June 13, 2017

Advaxis Details Registrational Trials, EU Regulatory and Commercial Plans at Annual Investor & Analyst Day

Updates Presented on Cervical, Prostate and Anal Cancer Clinical Programs

ADXS-NEO Ph 1 Trial, ADXS-HOT INDs Coming

PRINCETON, N.J.--(BUSINESS WIRE)-- Advaxis, Inc. (NASDAQ: ADXS), a late-stage biotechnology company developing cancer immunotherapies, held its annual Investor & Analyst Day this week with clinical investigators and company leaders providing updates and details on the company's *Lm* Technology™ and nine development programs.

ADXS-PSA: Prostate Cancer Program

Mark Stein, MD, of Rutgers Cancer Institute of New Jersey, discussed encouraging preliminary immunological data generated from Advaxis' prostate cancer program with ADXS-PSA in combination with *Keytruda*® (pembrolizumab). Dr. Stein reported that ADXS-PSA when used as monotherapy was shown to stabilize disease progression in ~30% (4/13) of patients in the dose escalation phase of the study. He also reported that ADXS-PSA was shown to be able to both activate and expand pre-existing T cell clones and was also responsible for generation of new clones of T cells in nearly all patients. He remarked that for patients who have stabilization of disease, high levels of the new T cell clones persist. However, in patients where the expanded T cell clones diminish, it leads to disease progression.

Early data on the first few patients treated with ADXS-PSA in combination with *Keytruda* suggested that the combination may lead to the emergence of a larger number of expanded and new T cell clones, especially over the first few treatments, thereby increasing the frequency of expanded T cells that can persist. This T cell clone expansion and persistence effect correlates with stabilization of disease. These findings and additional correlative immunologic data from this ongoing trial have been submitted for presentation at the CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in Frankfurt, Germany, in September. Dr. Stein also detailed plans to initiate an investigator sponsored trial of ADXS-PSA in patients with earlier stage prostate cancer.

Cervical Cancer Program Update: Axalimogene filolisbac

Axalimogene filolisbac has received Fast Track designation for adjuvant therapy for high-risk locally advanced cervical cancer (HRLACC) and a Special Protocol Assessment for the global, 450-patient phase 3 AIM2CERV trial in HRLACC patients. The immunotherapy has also received orphan drug designation in three clinical indications.

Sharad Ghamande, MD, of the Georgia Cancer Center at Augusta University, provided an update on axalimogene filolisbac, the company's lead cancer immunotherapy candidate which targets HPV-associated cancers, including cervical cancer, and presented a case study showing an ongoing and durable partial response seen in a patient with recurrent metastatic disease who was heavily pre-treated and received monotherapy with axalimogene filolisbac. "A sustained and durable partial response is very rare for this kind of tumor that is unresponsive to chemotherapy, and survival in these patients is often less than 10 months," said Dr. Ghamande.

Metastatic Cervical Cancer Combination Study with ADXS-DUAL

Dr. Ghamande previewed the upcoming registrational-quality study for patients with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC) with Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, *Opdivo*® (nivolumab), and ADXS-DUAL, Advaxis' next generation HPV-associated cancer immunotherapy candidate. "ADXS-DUAL, which contains antigens for both alpha 7 (HPV 18) and alpha 9 (HPV 16) families, has the potential to promote more potent T-cell responses for patients with metastatic cervical cancer where patients may have a greater disease burden," said Dr. Ghamande.

Focus on Patient Case Studies

The physicians in attendance shared their experiences with patients they have personally treated with axalimogene filolisbac, and the impact on the patients' lives. Dr. Ghamande also shared another case study during his presentation; a complete recovery from the company's GOG-0265 study. The patient was also had recurrent metastatic disease, was heavily pre-treated and received monotherapy with axalimogene filolisbac. Dr. Ghamande stated, "Putting it into perspective, women with this stage of disease rarely live more than a few months. To see these types of responses, and to have these women not just surviving, but living full lives, is truly stunning."

Brian Slomovitz, MD, Director Division of Gynecologic Oncology at the University of Miami Miller School of Medicine, shared a case study from the company's ongoing phase 2 study of axalimogene filolisbac in combination with the PD-L1 blocker *IMFIZI*™ (durvalumab) in metastatic cervical cancer and metastatic head and neck cancer. His 48-year-old patient, with heavily pre-treated, recurrent cervical cancer, was enrolled in the axalimogene filolisbac and durvalumab combination study. "She is currently 18 months out from when she started the trial and she has had a sustained, complete remission," said Slomovitz. "For those of us who see cervical cancer and treat this disease, this is truly a remarkable outcome. With only traditional therapy, it's unlikely this woman would be alive today."

Axalimogene filolisbac: Anal Cancer Program

Cathy Eng, MD, FACP, of the University of Texas MD Anderson Cancer Center, provided an update on the phase 2 FAWCETT study of axalimogene filolisbac as a monotherapy for metastatic anal cancer. The FAWCETT study is a multi-center, open-label, two-stage study designed to evaluate the efficacy and safety of axalimogene filolisbac as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for advanced disease. Dr. Eng, the principal

investigator of the study, reported that data from 29 of the planned 31 evaluable patients enrolled in Stage 1 met the predefined 6-month progression free survival rate, paving the way for stage 2 of the study. Dr. Eng also noted that one patient experienced a durable partial response lasting greater than 6 months (after progression on prior anti-PD-1 therapy). Stable disease was reported in 7 patients (24%) and a disease control rate of 28% was also reported. Treatment was well tolerated with mostly grade 1-2 infusion related AEs that resolved successfully with standard care; common (≥ 30%) treatment related AEs (TRAEs) included grade 1-2 chills/rigors, fever, hypotension and vomiting.

Advaxis is evaluating whether to continue to the second stage of the monotherapy trial, or initiate a registrational-quality study in combination with a checkpoint inhibitor in the same patient population later this year.

European Path Towards Commercialization

Advaxis reaffirmed plans to file a complete Marketing Authorization Application (MAA) for axalimogene filolisbac in Europe for the treatment of metastatic cervical cancer by the end of 2017. The European Medicines Agency (EMA) issued an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data following a thorough scientific evaluation over several months of the quality (CMC) data and non-clinical data by the EMA's Committee for Advanced Therapies (CAT).

As part of the company's overall strategy for the EU, Advaxis is working on a comprehensive commercialization plan that will minimize up-front costs and maximize value to shareholders. "With a significant unmet need for cervical cancer, low vaccination and screening rates and limited and toxic treatment options, a therapy with the potential of axalimogene filolisbac is gaining strong support from the European medical community," said Chris Duke, Advaxis Chief Operating Officer.

ADXS-HER2 Osteosarcoma Studies

Nicola Mason, PhD, BVetMed, an Associate Professor of Medicine and Pathobiology at the University of Pennsylvania School of Veterinary Medicine, discussed how the learnings from her work evaluating ADXS-HER2 in dogs with surgically treated osteosarcoma is informing the study design for a human study in pediatric osteosarcoma. Advaxis intends to initiate a phase 2, open-label, single-arm study of ADXS-HER2 in patients between the ages of 12 and 39 years old with HER2-expressing recurrent, completely resected osteosarcoma. This study is being conducted in collaboration with the Children's Oncology Group, the world's largest organization devoted exclusively to childhood and adolescent cancer research, with more than 9,000 experts in childhood cancer at more than 200 leading children's hospitals, universities, and cancer centers across North America, Australia, New Zealand, and Europe.

AXAL and Prognostic Indicators of Response

Advaxis has analyzed over 50 markers using pre- and post-treatment samples from patients in the GOG-0265 study in a search for potential biomarkers associated with survival benefit in axalimogene filolisbac treatment. Four markers were found to be highly correlated with statistical significance. Two clusters of patients associated with positive

and negative survival outcomes were identified respectively. Upon further analysis, the majority of the effect correlated with one particular marker, designated as “Marker #1.” This is an important finding because Marker #1 has not previously been associated with survival in cervical cancer, and appears to be consistent with the axalimogene filolisbac mechanism of action.

Marker #1 is undergoing extensive further evaluation as a prospective biomarker indicative of response to treatment with axalimogene filolisbac, reported Robert Petit, PhD, Advaxis Chief Scientific Officer. The 12-month survival rate in GOG-0265 patients with “low” levels of Marker #1 was 49%, compared to 0% in the patients who were Marker #1 high (N=10/50, 20%) with no differences in other prognostic factors. “If we excluded “Marker #1 high” patients and adjust the 12-month survival rate in the GOG-0265 patient population, then the 12-month survival rate would increase to almost 50 percent,” said Dr. Petit. “We look forward to further study of Marker #1 and anticipate prospectively stratifying patients in future studies to meet the regulatory standard to validate it as a biomarker.”

The company plans to present this data at the International Meeting of the European Society of Gynecological Oncology (ESGO) in Vienna, Austria, in November.

Emerging Opportunities: ADXS-NEO, ADXS-HOT and *Lm*-WT1

The company confirmed that it is on track to initiate clinical studies of ADXS-NEO later this year. ADXS-NEO is a personalized neoantigen-targeted approach to cancer immunotherapy that is being developed in collaboration with Amgen for the treatment of several metastatic tumor types. This approach also uses *Lm* technology, and the FDA accepted the ADXS-NEO IND in March 2017. This is an important milestone, as the NEO IND is one of the first INDs for a patient-specific neoantigen treatment. Once in clinic, the Advaxis turnaround time from biopsy to infusion is expected to take 6-8 weeks.

Building on the learnings from ADXS-NEO, the company confirmed plans to file two new Investigational New Drug applications with the U.S. Food and Drug Agency (FDA) in the second half of this year for ADXS-HOT. ADXS-HOT leverages Advaxis’ *Lm* Technology to target public or shared acquired mutations, so-called “hotspots,” in tumor driver genes. Advaxis has developed a library of constructs targeting hotspots that could be available to patients following a rapid diagnostic test that does not require sequencing.

Advaxis is collaborating with SELLAS Life Sciences to use *Lm* technology and SELLAS’ patented WT1 targeted heteroclitic peptide antigen. The WT1 antigen is highly expressed in most tumor types and considered the most important cancer antigen by the National Cancer Institute.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a late-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology. *Lm* Technology, using bioengineered live attenuated *Listeria monocytogenes* (*Lm*) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic

attack and contribute to tumor growth. Advaxis' lead *Lm* Technology™ immunotherapies axalimogene filolisbac and ADXS-DUAL target HPV-associated cancers and are in clinical trials for four potential indications, including phase 3 in invasive cervical cancer and metastatic cervical cancer in combination with nivolumab, phase 2 in head and neck cancer, and phase 2 in anal cancer. The FDA has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings, as well as Fast Track designation for adjuvant therapy for HRLACC patients and a SPA for the phase 3 AIM2CERV trial in HRLACC patients. Axalimogene filolisbac has also been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the EMA's CAT. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development. In addition, Advaxis and Amgen are developing ADXS-NEO, an investigational cancer immunotherapy treatment designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor, with plans to enter the clinic in 2017.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook, and YouTube.

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapies, axalimogene filolisbac and ADXS-DUAL. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2016, which is available at http://www.sec.gov.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law.

You are cautioned not to place undue reliance on any forward-looking statements.

View source version on businesswire.com:
http://www.businesswire.com/news/home/20170613006195/en/

Company:
Advaxis, Inc.
Noelle Heber, 609-250-7575
Sr. Director Corporate Communications and Government Affairs
heber@advaxis.com
or
Media Contact:
JPA Health Communications
David Connolly, 617-657-1301
dconnolly@jpa.com

Source: Advaxis, Inc.