

# Advaxis Updates Business Outlook for 2013

Company has made progress to advance ADXS-HPV to a Phase 3 registration program

Management is committed to further strengthening financial position to execute on strategic priorities

Company expects to continue to deliver on multiple clinical milestones throughout the year

PRINCETON, N.J.-- Advaxis, Inc. (OTCBB: ADXS and ADXSD) (the "Company") a leader in developing the next generation of immunotherapies for cancer and infectious diseases, announced an updated business outlook for 2013, which includes the development of its clinical strategy to advance its lead product candidate, ADXS-HPV, to registrational trials. The Company has also generated additional encouraging data and continues to strengthen its financial position.

Thomas A. Moore, Chairman and Chief Executive Officer of Advaxis, stated, "Earlier in the year, Advaxis stated that it would provide periodic updates to its business outlook and announced two overarching objectives for 2013: one, to advance our lead product candidate, ADXS-HPV, toward a registration development program and, two, to continue to significantly strengthen our financial position. We have outlined the progress the Company has made on these two goals, as well as anticipated 2013 milestone events."

# **Anticipated 2013 Milestone Events**

- A determination with respect to the Company's three applications for Orphan Drug Designations with the FDA for ADXS-HPV in three human papillomavirus (HPV)associated indications: invasive cervical cancer, anal cancer, and head and neck cancer:
- Initiate dialogue with the FDA to discuss ADXS-HPV clinical development plans for the treatment of cervical cancer:
- Complete the elements required to file an Investigational New Drug (IND) application with the FDA for ADXS-PSA for the treatment of prostate cancer in the first half of 2014:
- Advance the canine osteosarcoma study into Phase 2 and expand to additional collaborative academic centers; and
- File an initial listing application for the NASDAQ Capital Market or NYSE AMEX.

#### **2013 Clinical Program Update**

- Final 12-month survival data from the Phase 2 cervical cancer trial announced at the 2013 ASCO Annual Meeting in Chicago in June;
- GOG 0265 safety run-in completed and study opened to the GOG group-wide;

- 16 patients enrolled in REALISTIC head and neck cancer trial;
- 3 patients enrolled and dosed in BrUOG 276 anal cancer study; and
- Third dose cohort underway in the canine osteosarcoma study.

## Phase 2 Cervical Cancer Program

In June 2013, the Company submitted an Application for Orphan Drug Designation with the FDA Office of Orphan Products Development for ADXS-HPV for the treatment of human papillomavirus (HPV)-associated invasive cervical cancer.

In June 2013, the final 12-month survival and updated safety data from the ongoing Phase 2 study that is being conducted in India in 110 patients with recurrent cervical cancer were presented at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting. Preliminary efficacy data continue to show apparent prolonged survival, durable complete and partial tumor reductions, as well as stable disease with ADXS-HPV alone or in combination with cisplatin. 41% (45/110) of patients experienced 104 mild-moderate Grade 1-2 adverse events. 2% (2/110) of patients experienced a Grade 3 serious adverse event, compared to a rate of 130% or more in published studies of active chemotherapy regimens in this disease setting.

The Company has made substantial progress in analyzing the Phase 2 data and is planning a study to determine the best dose and dosing regimen to enhance efficacy without compromising the encouraging preliminary safety profile already observed.

In July, the Company's clinical team met with global thought leaders in cervical cancer and, under their advisement, are developing the regulatory strategy for the Phase 3 registration approval most clinically relevant to the use of ADXS-HPV and how it can best fit among the treatment options for women with cervical cancer.

The Gynecologic Oncology Group (GOG) of the National Cancer Institute (NCI) continues to conduct a single arm Phase 2 study of ADXS-HPV in 67 patients with recurrent/refractory cervical cancer. As of July 2013, 10 patients have been enrolled in the safety run-in portion of the study.

#### Head and Neck Cancer Program

In June 2013, the Company submitted an Application for Orphan Drug Designation with the FDA Office of Orphan Products Development for ADXS-HPV for the treatment of human papillomavirus (HPV)-associated head and neck cancer.

Cancer Research UK (CRUK) is funding a Phase 1/2 to evaluate the use of ADXS-HPV for the treatment of 27 patients with HPV positive head and neck cancer. This trial is being conducted at the Aintree Hospital at the University of Liverpool, the Royal Marsden Hospital at the University of London, and the Cardiff Hospital at the University of Wales. As of July 2013, 16 patients have been enrolled in the study.

## Anal Cancer Program

In June 2013, the Company submitted an Application for Orphan Drug Designation with

the FDA Office of Orphan Products Development for ADXS-HPV for the treatment of human papillomavirus (HPV)-associated anal cancer.

The Brown University Oncology Group (BrUOG) is funding and coordinating a Phase 1/2 study of ADXS-HPV in 25 patients with HPV-associated anal cancer. The trial is being conducted at the Rhode Island Hospital and The Miriam Hospital (the main teaching hospitals of The Warren Alpert Medical School of Brown University). As of July 2013, 3 patients have been enrolled in the study. Multiple institutions will collaborate.

# **Prostate Cancer Program**

The Company expects to file an IND with the FDA for ADXS-PSA in the treatment of prostate cancer in the first half of 2014. In June 2011, the Company conducted a pre-IND meeting with the FDA to discuss the CMC, pharmacology, toxicology, and clinical plans for ADXS-PSA. The required toxicology studies have been completed and data analyses are ongoing.

## Canine Osteosarcoma Program

The Company recently announced preliminary data from a Phase 1/2 study that is being conducted at the University of Pennsylvania School of Veterinary Medicine evaluating ADXS-cHER2 for the treatment of dogs with osteosarcoma. Canine osteosarcoma is a leading killer of large breed dogs that causes tumors to form on long leg bones. The standard of care (SOC) is immediate limb amputation followed by chemotherapy and sometimes radiation, however, the cancer typically metastasizes to the lungs, causing death in 6-12 months. In this trial, dogs that have undergone SOC for osteosarcoma, and over-express HER-2/neu in their tumors, are treated with ADXS-cHER2.

Updated preliminary data show a significant survival advantage for 9 dogs that received SOC plus ADXS-cHER2 compared to 11 dogs, whose owners elected not to participate in the trial, but who were followed for survival (p=0.04). At this point in the study, 8 of 9 dogs treated with ADXS-cHER2 are alive (mean survival undefined), compared with 5 of 11 dogs in the control group (mean survival 265 days).

Plans are to expand the study into Phase 2 and to open the study to additional collaborative academic centers.

# **Regulatory Outlook**

The Company has assembled and met with an advisory board of key thought leaders in cervical cancer and is in the process of developing the regulatory strategy and Phase 3 clinical protocols necessary to support a request for an FDA meeting to discuss the clinical development plan for ADXS-HPV.

The Company is compiling the elements required to file an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for ADXS-PSA for the treatment of prostate cancer in the first half of 2014.

#### **Corporate Development Update**

In July 2013, David Sidransky, MD, was appointed to the Board of Directors of the Company. Dr. Sidransky has a very strong background in both the business and science of oncology, with a specialty in head and neck cancer. Dr. Sidransky is the Director of the Head and Neck Cancer Research Division and Professor of Oncology, Otolaryngology, Genetics, and Pathology at Johns Hopkins University School of Medicine and has served on the board of directors and as an employee of numerous biotechnology companies.

# **Business Development Outlook**

Advaxis has entered into several confidentiality agreements with biopharmaceutical companies for the license of ADXS-HPV in the U.S., Asia, and India. So far, these discussions have resulted in one memorandum of understanding and a proposed non-binding term sheet with major regional pharmaceutical companies for Asia and India. These preliminary terms establish the commercial parameters of a potential licensing deal. The Company plans to pursue these negotiations to closure in the coming months.

Advaxis has also entered into a confidentiality agreement with the animal health division of a major pharmaceutical company for the license of ADXS-cHER2. The Company plans to pursue discussions with the goal of entering into a licensing agreement. Discussions with other companies are ongoing.

## **Corporate Outlook**

At the annual meeting of stockholders in June, stockholders approved the effect of a reverse stock split and a decrease in authorized shares of the Company at the discretion of the Board of Directors. In July, Advaxis executed the reverse stock split at a ratio of 1-for-125 and decreased the number of authorized shares from 1,000,000,000 to 25,000,000.

The Company intends to seek an uplisting to a national exchange in the near term. We have explained in our recent SEC filings why uplisting to a national market is important to our overall business strategy and financial viability. The Company strongly believes that the combination of completing the reverse stock split and the contemplated uplisting could heighten the interest of the financial community in Advaxis, as well as potentially broaden the pool of investors that may consider investing in the Company, while strengthening its financial health.

#### About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing the next generation of immunotherapies for cancer and infectious diseases. Advaxis immunotherapies are based on a novel platform technology using live, attenuated bacteria that are bio-engineered to secrete an antigen/adjuvant fusion protein(s) that is designed to redirect the powerful immune response all human beings have to the bacterium to the cancer itself.

ADXS-HPV is currently being evaluated in four clinical trials for human papillomavirus (HPV)-associated cancers: recurrent/refractory cervical cancer (India), locally advanced cervical cancer (GOG/NCI U.S. study, Clinical Trials.gov Identifier NCT01266460), head & neck cancer (CRUK study, Clinical Trials.gov Identifier NCT01598792), and anal cancer

(BrUOG study, Clinical Trials.gov Identifier NCT01671488). Advaxis has over 15 distinct immunotherapies in various stages of development, developed directly by Advaxis and through strategic collaborations with recognized centers of excellence such as: the National Cancer Institute, Cancer Research – UK, the Wistar Institute, the University of Pennsylvania, the University of British Columbia, the Karolinska Institutet, and others.

For more information please visit: <a href="www.advaxis.com">www.advaxis.com</a>

## Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements as to the anticipated timing of clinical studies and other business developments, statements as to the development of new constructs, expectations as to the adequacy of our cash balances to support our operations for specified periods of time and as to the nature and level of cash expenditures, expectations as to market opportunities, our ability to take advantage of those opportunities, and 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, 2012, which is available at <a href="https://www.sec.gov">www.sec.gov</a>. The Company undertakes no obligation to publicly release the result of any revision to these forward-looking statements which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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