September 22, 2010

India Approves Advaxis Trial in Cervix Cancer

NORTH BRUNSWICK, N.J.-- As part of approving the human testing of ADXS11-001-- the lead agent for the treatment of cervix cancer of Advaxis, Inc., (OTCBB: ADXS), the live, attenuated Listeria monocytogenes (Listeria) immunotherapy company -- the Drugs Controller General of India (DCGI) required that the agent be tested to assure its safety prior to use. Testing will be completed in ten days and patient dosing will begin.

Currently nine (9) centers have been enrolled and have begun to screen patients with advanced, metastatic cervix cancer for enrollment in this trial. These centers include Tata Memorial, Apollo Hospitals and other centers of medical research excellence in India. Full enrollment is anticipated in approximately three (3) months after the DCGI releases the drug for human use.

"This design advances the clinical development of ADXS 11-001 greatly in a number of ways," said Dr. John Rothman EVP of Science and Operations. "If we can duplicate the results of our phase I or improve upon them with three (3) doses of our agent compared to two(2) doses in Phase I, or find improved outcomes with chemotherapy, we would be able to show ADXS11-001 to be a safe and effective therapeutic agent where no alternatives exist."

About Advaxis Indian Phase II Trial of ADXS11-001

Because of the progressive and rapidly fatal nature of cervix cancer in women for whom cytotoxic treatment has failed, the design of this trial allows for a rapid appraisal of overall survival. Historically, when given the most effective regimen tested to date, these patients have a median survival of approximately 6 months and a 1 year survival of 5%, and so by assessing survival in real time it will be possible to assess the effect of ADXS11-001 on survival versus these historical values before the end of the trial. In phase 1 ADXS11-001 was associated with a median survival of 347 days and a one year survival of 53%, which was significantly greater than historical controls.

This trial differs from Advaxis phase I trial in this patient population in three significant ways. First, unlike phase I in which two (2) doses of ADXS11-001 was administered, this phase II will assess the more therapeutic regimen of three (3) doses. Second, this randomized trial compares ADXS11-001 alone to ADXS11-001 given in a combined regimen with platinum based chemotherapy. This is very important, as the scientific literature indicates that combined immuno- and chemo-therapy regimens may be more effective than single agent regimens, and Advaxis has generated some anecdotal data in support of this idea in the phase I trial. Third, the ADXS11-001 regimen has been reduced from a 30 minute 250 ml infusion followed by I.V. and oral antibiotics over an 11 day period to an 80 ml 15 minute infusion followed by a seven (7) day oral course of antibiotic, which

is easier to administer and thus more "clinic friendly".

Patients will be randomly assigned to receive either 3 administrations of ADXS11-001 or a single dose of the immunotherapy, followed by cisplatin treatment, followed by a three (3) course regimen of ADXS11-001. Various clinical and immunologic measures will be taken, and survival will be followed for the life of the patient.

About Advaxis Phase I Trial of ADXS11-001

ADXS11-001 is a live attenuated Listeria vaccine that targets the HPV oncoprotein E7. HPV is recognized as the cause of cervix cancer and E7 is one of the HPV proteins believed to be responsible. Doses of $1x10^9$, $3.3x10^9$ or $1x10^{10}$ cfu were administered to groups of 5 women who had failed prior therapy including radiation and chemotherapy. In such cases no therapy has been found to be effective and the median survival once disease progression resumes is typically 6 months or less, depending upon the treatment given. One-year survival for these patients historically is approximately 5%.

The phase I trial of ADXS11-001 was intended to assess safety, and like all phase I trials was not powered for efficacy, and so no conclusions can be made based upon the small number of patients treated. However, in this trial the median survival was 347 days and the 1 year survival was 53%.

About Advaxis, Inc.

Advaxis is a biotechnology company developing proprietary, live, attenuated Listeria monocytogenes (Listeria) vaccines that deliver engineered tumor antigens, which stimulate multiple, simultaneous immunological mechanisms to fight cancer. Today, the Company has nine (9) distinct, cancer-fighting constructs in various stages of development, directly and through strategic collaborations with such recognized sites of excellence as the City of Hope, the Roswell Park Cancer Institute, the National Cancer Institute, the University of Pittsburgh and Cancer Research - UK. Advaxis' technology was developed by Dr. Yvonne Paterson, professor of microbiology at the University of Pennsylvania and chairperson of Advaxis' scientific advisory board.

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Forward-Looking Statements

Certain statements contained in this press release are forward-looking statements that involve risks and uncertainties. The statements contained herein that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements deal with the Company's current plans, intentions, beliefs and expectations and statements of future economic performance. Forward-looking statements involve known and unknown risks and uncertainties that may cause the Company's actual results in future periods to differ materially from what is currently anticipated. Factors that could cause or contribute to such differences include those discussed from time to time in reports filed by the Company with the Securities and Exchange Commission. The Company cannot guarantee its future results, levels of

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Source: Advaxis, Inc.