Advaxis' Immunotherapy in Combination with Chemoradiation Highlighted as Potential Treatment for Anal Cancer in International Journal of Radiation Oncology

January 25, 2018

All patients who completed treatment had complete clinical response

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announces that data from the investigator-initiated study evaluating the Company's proprietary *Lm*-based antigen delivery product, axalimogene filolisbac (ADXS11-001), in combination with chemoradiation as a treatment for high-risk, locally advanced anal cancer were published in the *International Journal of Radiation Oncology* in an article titled, "Tolerability of ADXS11-001 *Lm*-LLO Listeria Based Immunotherapy With Mitomycin, Fluorouracil and Radiation for Anal Cancer."[1] The abstract is available on-line here.

"We are delighted to have these promising data highlighted in this prestigious, peer-reviewed journal. The complete clinical response demonstrated in patients who completed the combination treatment is very encouraging, particularly as there are limited treatment options or therapies under development for patients suffering with anal cancer"

The Phase 1 study, led by Dr. Howard Safran at Brown University, evaluated the safety and preliminary efficacy of the combination of ADXS11-001 with mitomycin, FU and intensity modulated radiation therapy in 10 patients with locally advanced, non-metastatic squamous cell anal cancer. Results showed that 9 patients achieved a complete response, and 8 patients (89%) remained disease free at a median follow-up of 42 months. One patient progressed, approximately 6 months post completion of study treatment and subsequently died from progressive disease, and one patient expired early in the study unrelated to study treatment.

Treatment-related adverse events were consistent with the observed safety profile of ADXS11-001, and consisted of mostly grade 1-2 cytokine-release related events such as chills, headache and fever. Two patients experienced grade 3 treatment-related toxicities. There were no grade 4 events and ADXS11-001 did not cause any additive chemoradiation related toxicities. All adverse events occurred within 24 hours of treatment and resolved with standard care.

These data show that ADXS11-001 can be safely administered with standard chemoradiation for patients with locally advanced, non-metastatic anal cancer.

"We are delighted to have these promising data highlighted in this prestigious, peer-reviewed journal. The complete clinical response demonstrated in patients who completed the combination treatment is very encouraging, particularly as there are limited treatment options or therapies under development for patients suffering with anal cancer," said Anthony Lombardo, interim Chief Executive Officer of Advaxis. "We look forward to advancing this promising therapy for anal cancer through investigator-led studies."

About Advaxis, Inc.

Advaxis, Inc. is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated Listeria monocytogenes (*Lm*) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T-cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T-cells to eliminate tumors. Advaxis has four franchises in various stages of clinical and preclinical development: HPV-associated cancers, neoantigen therapy, hotspot mutation therapy and prostate cancer.

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 and commercialize the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapies. 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, 2017, which is available at 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.

CONTACT:

Company:
Advaxis, Inc.

Noelle Heber, 609-250-7575
Sr. Director Corporate Communications and Government Affairs
Heber@advaxis.com
or
Media:
Stern Strategy Group
Brian Hyland, 908-325-3891
Bhyland@sternstrategy.com
or
Rachel Auerbach, 908-325-3898
Rauerbach@sternstrategy.com
or
Investors:
LHA Investor Relations
Anne Marie Fields, 212-838-3777
afields@lhai.com