Advaxis to Present Updated Clinical and Immunogenicity Data from Ongoing Phase 1/2 Trial of ADXS-503 in Metastatic Non-Small-Cell Lung Cancer (NSCLC) and Study Design of ADXS-504 Trial in Early Prostate Cancer at the American Society of Clinical Oncology

May 26, 2022

Overall response rate of 14% and disease control rate of 36% in Part B of ADXS-503 trial with durable clinical benefit as an add-on therapy to patients with prior disease progression on KEYTRUDA® (pembrolizumab)

Updated data continue to show disease control rate of 67% in Part C, with ADXS-503 being dosed in combination with KEYTRUDA® in first line NSCLC

In depth-immune correlative analysis suggest a central role of NK, T cells and certain cytokines in patients with clinical benefit

The design of the Phase 1 investigator-sponsor trial with ADXS-504 in biochemically recurrent prostate cancer to be presented

MONMOUTH JUNCTION, N.J., May 26, 2022 (GLOBE NEWSWIRE) -- Advaxis, Inc. (OTCQX: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced the publication of updated results from the clinical trial of the lead asset from its ADXS-HOT off-the-shelf, cancer-type specific, immunotherapy program.

These results from the clinical study ADXS-503-101 evaluating the ADXS-503 construct, which is designed to target certain cancers' commonly occurring hotspot mutations and other tumor-associated antigens, will be presented at the ASCO Annual Meeting to be held on June 4-7, 2022, along with the trial design of the study of the second construct from the ADXS-HOT program, ADXS-504.

The goals of this Phase 1/2 open-label trial are to evaluate safety, tolerability, antitumor activity and immune-correlative data of ADXS-503 administered in combination with KEYTRUDA® in patients with metastatic NSCLC. In Part B of this study, ADXS-503 is added-on to KEYTRUDA® within 12 weeks of the first scan showing disease progression following treatment with KEYTRUDA®. In Part C, both drugs are administered to previously untreated patients. The study design of the Phase 1 investigator-sponsor study of ADXS-504 for patients with biochemically recurrent prostate cancer at Columbia University, Herbert Irving Comprehensive Cancer Center NYC, will also be presented.

Key presentation highlights:

Poster Title: "*A phase 2 study of an off-the-shelf, multi-neoantigen vector (ADXS-503) in patients with metastatic non-small-cell lung cancer either progressing on prior pembrolizumab or in the first-line setting*"
Presenter: Gregory J. Gerstner, M.D., Illinois Cancer Care
Session Type: Poster Session – Hall A
Session Title: "Lung Cancer—Non-Small Cell Metastatic"
Date and Time: June 6, 2022, 8-11 AM (CDT)

Key study characteristics and takeaways:

- Part B: 14 patients failing pembrolizumab as last therapy have been treated with ADXS-503 + pembrolizumab (Dose Level 1) with all patients evaluable for safety and efficacy
- Overall response rate (ORR) was 14% (2/14) and Disease Control Rate (DCR) was 36% (5/14)
    - Two durable partial responses (PR) sustained for over 9 months and 21 months, respectively
    - Three durable cases of stable disease (SD) lasting for over 3, 5 and 14 months, respectively
    - Patients who seem to achieve clinical benefit in Part B of the study include those with PD-L1 expression ≥ 50% and those with prior pembrolizumab monotherapy exposure ≥ 12 months and/or with DCR > 6 months
- Part C: 3 patients have received ADXS-503 + pembrolizumab in the 1st-line metastatic setting with all patients evaluable for safety and efficacy
- Data continue to show a DCR of 67% (2/3) in the first three evaluable patients in Part C

Poster Title: "*Immunogenicity and disease control induced by a multi-neoantigen vaccine (ADXS-503) in patients with metastatic non-small-cell lung cancer who have progressed on pembrolizumab"*

Presenter: Dr. Aaron E. Lisberg, M.D., UCLA
Session Type: Poster Session – Hall A
Session Title: "Lung Cancer—Non-Small Cell Metastatic"
Date and Time: June 6, 2022, 8-11 AM (CDT)

Key takeaways: Long-term follow up of immune correlative markers suggest that ADXS-503 leads to durable clinical benefit in select patients through:

- the production of cytokines with periodic pro-inflammatory and anti-tumoral effects supporting innate and adaptive immunity
- the activation of Natural Killer (NK) cells in tumor control
- the induction of proliferation and activation of previously exhausted CD8+ T-cells facilitating reaction to hotspot mutation antigens, tumor associated antigens (TAAs), and antigen spreading.
- The activation of various subsets of memory CD8+ T cells

Poster Title: "*A phase I study of ADXS-504, a cancer type specific immunotherapy, for patients with biochemically recurrent prostate cancer*"

Presenter: Karie Runcie, M.D., Columbia University
Session Type: Poster Session – Hall A
Session Title: "Trials in Progress"
Abstract Number: TPS5115
Date and Time: June 6, 2022, 1:15-4:15 CDT (CDT)

"The correlation of durable clinical benefit with long-term immunological surveillance data from Part B of the ADXS-503 study is extremely encouraging," said Ken Berlin, President and CEO of Advaxis. "We not only observe a competitive ORR by adding-on ADXS-503 in patients failing pembrolizumab, but we also now better understand how ADXS-503 may reverse the exhaustion or enhance the activity of pembrolizumab in these cases," he concluded. "The immunogenicity studies tend to demonstrate that ADXS-503 does more than just activate antigen-specific T cells as part of the adaptive response in Part B patients. The clinical benefit may also be derived from the serial elevation of certain serum cytokines throughout the course of therapy as well as from the activation of NK and induction of memory T cells. These pleotropic effects of *Lm* vectors, which had been documented in preclinical models and now shown in the ADXS-503 trial, help to differentiate ADXS-503 from other vaccine platforms," added Andres Gutierrez, EVP and Chief Medical Officer of Advaxis. "Importantly, those effects are induced safely and without the use of adjuvant agents," he concluded.

Enrollment in Part B will continue up to a total of 18 patients to further evaluate if ADXS-503 is able to achieve ORR of ≥20% in patients progressing on pembrolizumab therapy, while Part C may enroll up to 25 patients.

About Advaxis, Inc.
Advaxis, Inc. is a clinical-stage biotechnology company focused on the 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 T cells to eliminate tumors.

To learn more about Advaxis, visit www.advaxis.com.

Forward-Looking Statements
This press release contains forward-looking statements that are made pursuant to the safe harbor provisions 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 are any statements that express the current beliefs and expectations of management, including but not limited to statements related to the expected clinical development of the Company's drug product candidates. These and other risks are discussed in the Company's filings with the SEC, including, without limitation, its Annual Report on Form 10-K, filed on filed on January 22, 2022, and its subsequent periodic reports on Form 10-Q and Form 8-K. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date they were made. The Company undertakes no obligation to update or revise forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

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