Advaxis Announces Updated Survival Data in Phase 1/2 ADXS-PSA Trial at the ASCO Genitourinary Cancers Symposium

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Median overall survival of 16.4 months for advanced prostate cancer patients with visceral metastases treated with ADXS-PSA in combination with KEYTRUDA® compared to an estimated 11 months with Standard of Care

Median overall survival of 33.7 months in all patients treated with ADXS-PSA in combination with KEYTRUDA®

PRINCETON, N.J., Feb. 13, 2020 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced updated results from the combination arm of KEYNOTE-46 (Part B), the Company's ongoing Phase 1/2 study investigating ADXS-PSA with KEYTRUDA ® (pembrolizumab) in patients with metastatic, castrate-resistant prostate cancer (mCRPC) at the ASCO Genitourinary Cancers Symposium in San Francisco, California. The KEYNOTE-46 trial was conducted in conjunction with Merck (known as MSD outside the U.S. and Canada) and evaluated ADXS-PSA, one of Advaxis' *Listeria monocytogenes* (*Lm*)-based immunotherapies, alone and in combination with KEYTRUDA®, Merck's anti-PD-1 therapy.

"The presented survival data in patients with visceral metastases strengthens our confidence that ADXS-PSA in combination with KEYTRUDA ® has the potential to provide meaningful increases in median overall survival in patients with advanced, metastatic, castration-resistant prostate cancer," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "Importantly, these demonstrated impacts on survival have not been previously observed with immunotherapy in this advanced patient population leading us to actively assess next steps for the program with the hope of providing a much-needed new treatment for these patients with limited options."

Key findings presented by Mark N. Stein M.D., FACS, Associate Professor of Medical Oncology at Columbia University Medical Center and lead study investigator, titled, "KEYNOTE-046 (Part B): Effects of ADXS-PSA in combination with pembrolizumab on survival in metastatic, castration-resistant prostate cancer patients with or without prior exposure to docetaxel" include:

- Median overall survival (95% CI) of 33.7 months (15.4-NR) for patients treated with ADXS-PSA in combination with KEYTRUDA® (n=37)
- Median overall survival (95% CI) of 16.0 months (6.4-34.6) for patients with prior docetaxel (n=20)
- Median overall survival (95% CI) of 16.4 months (4.0-NR) for patients with prior visceral metastasis (n=11; 10 of who had prior docetaxel)
- 72.4% (21/29) of evaluable patients showed stable disease
- 38% of patients had PSA declines and 27% had >= 30% PSA decline from baseline
- The combination of ADXS-PSA and pembrolizumab appeared safe and tolerable in this heavily pretreated, unselected population of patients with MSI-High-negative mCRPC
- Treatment-related adverse events were mostly Grade 1-2, with no additive toxicity observed with combination therapy

Mark N. Stein M.D., FACS said, "These data are encouraging given the advanced nature of the patient population which includes those who have failed next generation hormonal agents and/or docetaxel, and now those with visceral metastasis." He added, "I am particularly enthusiastic to see increases in median overall survival to 16.4 months as compared to standard of care, which tends to be closer to 11 months in patients with measurable disease/visceral metastasis. This improvement, delivered with a generally safe and well-tolerated treatment regimen, warrants additional evaluation in larger studies and I look forward seeing the potential of a continued evaluation of ADXS-PSA in combination with KEYTRUDA®."

KEYNOTE-046 was an open-label, multicenter, dose-determining safety and tolerability Phase 1/2 trial of 50 heavily pretreated patients conducted in two parts (Part A and Part B), with a Phase 2 expansion cohort. The objective of the study was to evaluate ADXS-PSA alone (Part A) and in combination with KEYTRUDA® (Part B) for primary endpoints that include safety, tolerability and dosing. Secondary endpoints included anti-tumor activity, progression-free survival and overall survival, and exploratory endpoints that include associations between biomarkers of immunologic response (serum PSA) with clinical outcomes. Enrollment in the study has been completed and the database lock occurred on January 28, 2020. The majority of treatment-related adverse events consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and KEYTRUDA® has appeared to be well-tolerated, to date, with no additive toxicity observed.

About KEYNOTE-046
KEYNOTE-046 (NCT02325557) was a Phase 1/2 open-label, multicenter, dose-determination and expansion trial that evaluates the safety, tolerability and preliminary clinical activity of ADXS-PSA as monotherapy (Part A; n=14 [13 treated]), and in combination with KEYTRUDA® (Part B; n= 37) in heavily pretreated patients with progressive and refractory mCRPC.

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 and connect on Twitter, LinkedIn, Facebook and YouTube.

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 December 20, 2019, and its 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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