# Advaxis Reports First Quarter Ended January 31, 2020 Financial Results and Provides a Pipeline Update

March 13, 2020

PRINCETON, N.J., March 13, 2020 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced an update on its clinical pipeline and financial results for the first quarter ended January 31, 2020.

Key recent corporate and clinical pipeline updates:

- Presented updated clinical data from the ongoing Phase 1/2 ADXS-503 trial at the I/O 360° Conference. Data presented showed that the first two patients treated in the combination arm, who previously progressed on KEYTRUDA®, achieved a partial response with substantial tumor shrinkage of nearly 60% and the other patient achieving stable disease with a 25% reduction in a target lesion.
- Presented updated survival data from the Phase 1/2 ADXS-PSA trial at the ASCO Genitourinary Cancers Symposium. Data highlights include reported median overall survival (95% CI) of 16.4 months (4.0-NR) (n=11) for advanced prostate cancer patients with visceral metastases treated with ADXS-PSA in combination with KEYTRUDA® compared to an estimated 11 months with current standard of care. In addition, median overall survival (95% CI) was 33.7 months (15.4-33.7) in all patients treated with ADXS-PSA in combination with KEYTRUDA® (n=37).
- Data presented in 2020 suggest that both ADXS-503 and ADXS-PSA may have the potential to enhance or restore sensitivity to checkpoint inhibitors such as KEYTRUDA®.
- Announced FDA allowance of its Investigational New Drug Application (IND) for ADXS-504 for the treatment of prostate cancer. ADXS-504 is the Company's second drug product candidate from its HOT off-the-shelf neoantigen clinical program targeting hotspot mutations and other tumor-associated antigens.
- Closing of a $10.5 million equity financing with two investors.
- Announced a research agreement with Personalis to deploy ImmunoID NeXT Platform in the ADXS-503 clinical program. Personalis will conduct comprehensive tumor immunogenic profiling to enable the identification of predictive composite biomarkers and/or signatures of response, as well as the broad evaluation of potential mechanisms of therapy resistance.

**Management Commentary**

"We have started our fiscal year with encouraging positive data presented in our ADXS-PSA and ADXS-503 clinical programs," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "Importantly, data from both studies suggest that *Lm* immunotherapies may have the ability to synergistically enhance or restore sensitivity to checkpoint inhibitors which could be a meaningful breakthrough in improving outcomes for advanced and refractory patients. We continue to execute on our HOT off-the-shelf program in NSCLC with enrollment continuing in the combination arm of the study, Part B, and a planned initiation of Part C which will move combination therapy to a first-line setting, later this year. We are also planning to move an additional HOT construct, ADXS-504, for prostate cancer, into the clinic later this year for which the IND was allowed earlier this year."

Mr. Berlin continued, "We are currently evaluating next steps for our ADXS-PSA program based on the promising increases in median overall survival observed in combination with KEYTRUDA®. With an anticipated cash runway into mid-2021, we are positioned to explore the early signals of activity in our ongoing trials while advancing additional programs that leverage these important findings."

**First Quarter Ended January 31, 2020 Financial Results**

During the quarter ended January 31, 2019, the Company recognized $19.4 million in revenue associated with the revenue recognition requirements surrounding the termination of the collaboration agreement with Amgen in 2019; no similar situation existed during the fiscal quarter ended January 31, 2020.

Research and development expenses for the first quarter of fiscal year 2020 were $4.9 million, compared with $6.7 million for the first quarter of fiscal year 2019. The decrease is largely attributable to the winding down of our Phase 3 AIM2CERV and Phase 1 ADXS-NEO studies as announced in June 2019 and October 2019, respectively.

General and administrative expenses for the three months ended January 31, 2020 were approximately $3.0 million compared to $2.7 million in the same three-month period in 2019 as a result of higher business development and legal fees.

As of January 31, 2020, the Company had approximately $34.2 million in cash and cash equivalents. The Company believes this is sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least mid-2021.

**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 Form 10-K/A on February 28, 2020, 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

**Advaxis, Inc.**
**Selected Balance Sheet Data**
**(In thousands)**

| | January 31, 2020 | October 31, 2019 |
|---|---|---|
| Cash and cash equivalents | $ 34,156 | $ 32,363 |
| Total assets | $ 51,348 | $ 45,257 |
| Total stockholders' equity | $ 41,548 | $ 39,531 |

**STATEMENTS OF OPERATIONS**
**(in thousands, except share and per share data)**

| | Three Months Ended January 31, | |
|---|---|---|
| | 2020 | 2019 |
| Revenue | $ 3 | $ 19,689 |
| Operating expenses* | | |
| Research and development expenses | 4,859 | 6,707 |
| General and administrative expenses | 3,030 | 2,666 |
| Total operating expenses | 7,889 | 9,373 |
| (Loss) income from operations | (7,886) | 10,316 |
| Net changes in fair value of derivative liabilities | (37) | 2,409 |
| Other income and taxes | 66 | 92 |
| Net (loss) income | $ (7,857) | $ 12,817 |
| Net (loss) income per common share, basic and diluted | $ (0.15) | $ 2.76 |
| Weighted average number of common shares outstanding, basic | 51,412,408 | 4,642,718 |
| Weighted average number of common shares outstanding, diluted | 51,412,408 | 4,642,817 |

| * Includes stock-based compensation as follows: | | | | |
|---|---|---|---|---|
| Research and development | $ | 91 | $ | 323 |
| General and administrative | | 151 | | 299 |
| | $ | 242 | $ | 622 |

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Source: Advaxis, Inc.