Advaxis Reports Second Quarter Ended April 30, 2020 Financial Results and Provides a Business Update

June 11, 2020

Expanding Phase 1/2 Study of ADXS-503 in NSCLC based on sustained and durable clinical responses in first two patients from Part B combination arm with KEYTRUDA®

Increasing patient enrollment in Part B and initiating Part C to move into first-line regimen with KEYTRUDA® in patients ineligible for standard of care platinum-based chemotherapy

Conference call scheduled for 11am ET today

PRINCETON, N.J., June 11, 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 second quarter ended April 30, 2020.

Key recent corporate and clinical pipeline updates:

- Presented updated clinical and preliminary biomarker data from the ongoing Phase 1/2 trial of ADXS-503 in non-small cell lung cancer (NSCLC) demonstrating clinical benefit in two patients with immediate prior progression on KEYTRUDA® including one durable response out to 25 weeks and another sustained response out to out least 16 weeks with both patients remaining on treatment in Part B, the combination arm with KEYTRUDA®
    - One sustained partial response with 60% reduction in site lesions at 16 weeks and one durable response of stable disease with 25% reduction in target lesion at 25 weeks confirmed by radiographic scans
    - Clinical benefit achieved after immediate prior progression on KEYTRUDA® with previous best responses of stable disease suggest ADXS-503 may re-sensitize or enhance response to KEYTRUDA®
- Part A monotherapy has been completed with three of six evaluable patients achieving responses of stable disease
- As monotherapy, as well as in combination with KEYTRUDA®, ADXS-503 appeared safe and well tolerated with no dose-limiting toxicities
- Preliminary biomarker data from seven patients in Part A monotherapy demonstrated activation of cytotoxic and memory CD8+ and CD4+ T cells in 100% of patients and antigen spreading in five of seven evaluable patients, including the first patient in combination therapy
- Presented updated survival data from the Phase 1/2 trial with ADXS-PSA in combination with KEYTRUDA® 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 prior docetaxel therapy and 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)
- Announced a research agreement with Personalis to deploy ImmunoID NeXT Platform in the ADXS-503 clinical program. Personalis will conduct comprehensive tumor genomic 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 continued our momentum throughout the second quarter with updated clinical data which support the prioritization of our off-the-shelf neoantigen HOT program,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. “These updated data from our ongoing Phase 1/2 study of ADXS-503 in NSCLC increase our confidence that ADXS-503 may synergistically enhance and/or restore sensitivity to checkpoint inhibitors and we are particularly encouraged by the sustained clinical benefit observed, now out to 16 and 25 weeks, in two patients who had immediate prior progression on KEYTRUDA®. Our results are further supported by preliminary biomarker data which provide insight into the on-mechanism immune stimulation which we believe are driving these responses.”

Mr. Berlin continued, “Based on these results, we are expanding Part B, dose level 1, to enroll up to an additional 15 patients who have progressed on KEYTRUDA® to further characterize the clinical activity of ADXS-503 in combination with KEYTRUDA® as previously observed in the first two evaluable patients in this part of our study. In addition, we have opened enrollment in Part C to evaluate ADXS-503 in combination with KEYTRUDA® as a first line treatment for patients with metastatic NSCLC that either have a high PD-L1 expression score and can receive KEYTRUDA® alone or for patients who are ineligible to receive the standard of care regimen of KEYTRUDA® in combination with platinum based-chemotherapy.” He added, “The safety, tolerability and clinical activity observed so far supports the initiation of Part C for advanced patients in a first-line setting as well as the expansion of Part B in later treatment settings. Based on the clinical and immune correlative results to date, we are hopeful for enhanced responses to KEYTRUDA® in patients in both of these settings who have limited treatment options and poor prognoses. We look forward to continued execution

and the expansion of our HOT program to new indications including our planned Phase 1 study of ADXS-504 in prostate cancer patients with biochemical recurrence which we expect to enter the clinic by the end of this year."

Second Quarter Ended April 30, 2020 Financial Results

Research and development expenses for the second quarter of fiscal year 2020 were $3.9 million, compared with $6.0 million for the second 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 April 30, 2020 were approximately $2.6 million compared to $3.1 million in the same three-month period in 2019. The decrease in expenses is mainly attributable to lower legal fees, and reduced employee and business development costs.

As of April 30, 2020, the Company had approximately $28.2 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 August 2021.

The company will host a conference call today at 11:00am ET to provide a business update. The call-in information is below and accessible on the Company's investor relations section of its website:
Webcast: http://public.viavid.com/index.php?id=140132
Domestic: 877-407-0789
International: 201-689-8562
Conference ID: 13704683

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)

	April 30, 2020 (Unaudited)	October 31, 2019
Cash and cash equivalents	$ 28,217	$ 32,363
Total assets	$ 45,210	$ 45,257
Total stockholders' equity	$ 35,437	$ 39,531

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

	Three Months Ended April 30,		Six Months Ended April 30,	
	2020	2019	2020	2019
Revenue	$ 250	$ 1,188	$ 253	$ 20,877

Operating expenses *				
Research and development expenses	3,922	5,969	8,781	12,675
General and administrative expenses	2,649	3,092	5,679	5,759
Total operating expenses	6,571	9,061	14,460	18,434
(Loss) income from operations	(6,321)	(7,873)	(14,207)	2,443
Other income (expense)	48	(1,510)	97	1,041
Net (loss) income before benefit for income taxes	(6,273)	(9,383)	(14,130)	3,484
Income tax expense	50	-	50	50
Net (loss) income	$ (6,323)	$ (9,383)	$ (14,180)	$ 3,434
Net (loss) income per common share, diluted				
Basic	$ (0.10)	$ (1.59)	$ (0.25)	$ 0.65
Diluted	$ (0.10)	$ (1.59)	$ (0.25)	$ 0.20
Weighted average number of common shares outstanding				
Basic	60,572,632	5,900,449	56,107,657	5,259,677
Diluted	60,572,632	5,900,449	56,107,657	5,282,772
* Includes stock-based compensation as follows:				
Research and development	$ 62	$ 258	$ 153	$ 581
General and administrative	148	221	299	520
	$ 210	$ 479	$ 452	$ 1,101

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Source: Advaxis, Inc.