



Advaxis Reports Fiscal 2018 First Quarter Financial Results and Announces Clinical Hold in Axalimogene Filolisbac Phase 1/2 Combination Study with AstraZeneca's IMFINZI® (Durvalumab)

March 12, 2018

Conference call to be held today at 4:30 p.m. Eastern time

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 financial results for the three months ended January 31, 2018 and provides a business update.

Recent Key Accomplishments Include:

- Conditional Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) for the company's lead *Lm* Technology product candidate, axalimogene filolisbac, for the treatment of adult women who progress beyond first-line therapy of persistent, recurrent or metastatic carcinoma of the cervix (PRmCC);
- Acceptance of data for publication from a Phase 2 clinical study of axalimogene filolisbac as a treatment for PRmCC in the peer-reviewed *International Journal of Gynecological Cancer*;
- Three abstracts highlighting the company's *Listeria*-based immunotherapy in combination with antibody-based immunotherapies have been accepted for poster presentation at the upcoming 2018 Keystone Symposia on Cancer Immunotherapies: Combinations (C5);
- Publication of data from an investigator-initiated study of axalimogene filolisbac in combination with chemoradiation as a treatment for high-risk, locally advanced anal cancer in the *International Journal of Radiation Oncology*; and
- \$20.0 million in gross proceeds raised in a public offering of common stock.

"We are confident in the safety and efficacy profile of axalimogene filolisbac, to date, based on our experience in over 250 patients and over 700 doses across multiple trials in HPV-associated cancers."

Clinical Hold

In the evening of March 9, 2018, the company received notification from the U.S. Food and Drug Administration (FDA) that its Investigational New Drug (IND) application for its Phase 1/2 combination study of axalimogene filolisbac with IMFINZI (durvalumab) for the treatment of patients with advanced, recurrent or refractory human papillomavirus (HPV)-associated cervical cancer and HPV-associated head and neck cancer was placed on clinical hold. The clinical hold pertains to a recent submission of a safety report to the FDA regarding a Grade 5 Serious Adverse Event (patient death) on February 27, 2018 involving respiratory failure which occurred following the sixth combination cycle in the trial. Enrollment and further dosing are on hold in this trial while the company, its partner and the FDA work closely with the site investigator to review this event in detail and to resolve this clinical hold.

Enrollment and dosing in all other Advaxis clinical programs are unaffected at this time.

"We care deeply for our patients and for their safety as we work to research and develop new treatment options for advanced cancers. We believe in the potential of our *Lm* Technology to provide new advancements in the area of cancer care," stated Anthony Lombardo, interim Chief Executive Officer of Advaxis. "We are confident in the safety and efficacy profile of axalimogene filolisbac, to date, based on our experience in over 250 patients and over 700 doses across multiple trials in HPV-associated cancers."

Management Commentary

"We are pleased with the progress we made during the quarter across a number of important areas. In particular, we were delighted to file the MAA with the EMA for conditional approval of axalimogene filolisbac for the treatment of metastatic cervical cancer, a condition that causes approximately 24,000 deaths annually in Europe," stated Mr. Lombardo. "This is a significant milestone for Advaxis as it is our first marketing application for an *Lm* Technology product."

"Throughout the first quarter, we continued to advance our clinical programs and were pleased to announce the publication and presentation of data in support of the potential of our *Lm*-based antigen delivery platform to treat a variety of cancers in peer-reviewed journals and at premier medical and scientific meetings.

"Our goals for 2018 remain steadfast as we execute our plans to advance our robust clinical development programs across our four franchises: HPV-associated cancers, neoantigen therapy, hotspot/ cancer antigens and prostate cancer. Over the coming months, we expect to make meaningful progress with these programs and to achieve a number of important value-creating milestones," Mr. Lombardo concluded.

Balance Sheet Highlights

As of January 31, 2018, Advaxis had cash, cash equivalents and investments of \$59.4 million, which included \$4.5 million related to its previously announced participation in the New Jersey NOL program and the receipt of \$2.7 million in connection with its controlled equity offering sales agreement. The company used approximately \$12.7 million in cash to fund operations during the first quarter of fiscal year 2018, mainly attributed to

funding strategic development programs and related personnel and infrastructure to support the company's progress and growth.

Following the close of the first quarter, Advaxis completed an underwritten public offering of 10,000,000 shares of common stock at \$2.00 per share for gross proceeds of \$20.0 million before deducting the underwriting discounts and commissions and other estimated offering expenses.

Throughout fiscal year 2018, Advaxis plans to continue to invest in its core clinical programs and expects its current cash position will be sufficient to fund its business plan into the second calendar quarter of 2019.

Financial Highlights for First Quarter Fiscal Year 2018

The net loss for the first quarter ended January 31, 2018 was \$20.5 million or \$0.49 per share based on 41.4 million shares outstanding. This compares with a net loss for the first quarter of fiscal year 2017 of \$17.1 million or \$0.43 per share based on 40.1 million shares outstanding.

Research and development expenses for the first quarter of fiscal year 2018 were \$17.1 million, compared with \$13.6 million for the first quarter of fiscal year 2016. The increase was primarily due to continued investment in support of the company's preclinical and clinical development programs, including support of the AIM2CERV Phase 3 clinical trial and costs associated with the MAA filing, which are now expected to wind down, post-submission. The increase also reflects higher headcount versus the first quarter of fiscal 2017, to support research and development initiatives primarily for the neoantigen franchises.

General and administrative expenses for the first quarter of fiscal year 2018 were \$5.5 million, compared with \$7.3 million for the fiscal year 2017 first quarter. The decrease was largely attributable to non-cash stock-based compensation expense in the prior-year quarter.

Conference Call and Webcast Information

Advaxis' senior management will host a conference call to review financial results, provide a business update and answer questions. The conference call and live audio webcast will begin today at 4:30 p.m. Eastern time.

To access the conference call please dial (844) 348-6133 (domestic) or (631) 485-4564 (international) and refer to conference ID 2588455. A live and archived audio webcast of the call will be available on the company's website at ir.advaxis.com/events-presentations.

For those unable to participate in the live conference call or webcast, a recording will be available beginning two hours after the call ends. To access the recording, dial (855) 859-2056 or (404) 537-3406 and provide conference ID 2588455.

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/ cancer antigens 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, and on Form 10-Q for the quarter ended January 31, 2018, which are 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.

IMFINZI is a registered trademark of AstraZeneca AB Corporation.

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