Advaxis Announces Submission of IND Application for ADXS-HOT Drug Candidate for Prostate Cancer

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**Immune response data from its HOT Lung program expected early 2020**

PRINCETON, N,J.--(BUSINESS WIRE)--Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for the initiation of a Phase 1 clinical study of ADXS-504, the Company’s ADXS-HOT drug candidate for prostate cancer.

“We are pleased to announce continued clinical progress of our ADXS-HOT program,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. “Results from our ADXS-NEO program provided important proof-of-concept data demonstrating the generation of CD8+ T cells against hotspot mutations. Based on these encouraging results, and the convenient and broadly accessible off-the-shelf approach of our HOT therapies, we are focused on expanding the HOT program to additional cancer-specific trials through various, capital-efficient avenues. In addition, we look forward to reporting immune data from the monotherapy arm of our ongoing Phase 1/2 HOT clinical trial in non-small cell lung cancer (NSCLC) in early 2020.”

ADXS-504 is part of the company’s ADXS-HOT off-the-shelf immunotherapy platform which targets hotspot neoantigens, allowing for the development of multiple cancer-type specific clinical candidates. Advaxis has designed over ten ‘HOT’ drug candidates that are in various stages of development, with the company’s Phase 1/2 clinical trial for ADXS-503 in NSCLC currently enrolling patients at five centers. Advaxis anticipates reporting the immune data from the first dose level of ADXS-503, Part A, in monotherapy, and expects to dose the first patient in Part B, which is studying ADXS-503 in combination with the checkpoint inhibitor pembrolizumab, in early 2020.

**About ADXS-HOT**

ADXS-HOT is a program that leverages the Company’s proprietary Lm technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or “public” mutations in tumor driver genes along with other cancer-testes and oncoplastic tumor-associated antigens that also commonly occur in specific cancer types. ADXS-HOT drug candidates are an off-the-shelf treatment approach designed to potentially treat all patients with a specific cancer type, without the need for pretreatment biomarker testing, biopsy, DNA sequencing or diagnostic testing.

**About Advaxis, Inc.**

Advaxis, Inc. is a clinical-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 T cells to eliminate tumors.

To learn more about Advaxis, visit [www.advaxis.com](http://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 use of proceeds from the proposed offering. 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 January 11, 2019, and its periodic reports on Form 10-Q and Form 8-K, as well as the risks identified in the registration statement and the preliminary prospectus supplement relating to the offering. 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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