Ayala Pharmaceuticals Announces Completion of Enrollment in Phase 3 RINGSIDE Study Evaluating AL102 in Desmoid Tumors

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REHOVOT, Israel and MONMOUTH JUNCTION, N.J., Feb. 20, 2024 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, today announced that patient enrollment has been completed in the Phase 3 RINGSIDE study evaluating AL102 in desmoid tumors. A total of 156 patients were enrolled.

”Completion of enrollment in RINGSIDE represents a significant milestone in the development of AL102,” said Kenneth Berlin, President and Chief Executive Officer of Ayala. “There has been a high-level of enthusiasm from clinical trial investigators, support staff, and patients during the enrollment of RINGSIDE. We are extremely grateful to the patients and their families, clinical investigators, operational partners and the Ayala team who have helped us achieve this important milestone several months ahead of schedule. Completing enrollment is an important step toward our goal of providing patients and physicians with a once-daily treatment option for desmoid tumors. We believe that AL102 has the potential to be a best-in-class gamma secretase inhibitor for this disease.”

The Phase 3 segment of the RINGSIDE study is a double-blind, multi-center trial enrolling patients with progressive disease, randomized between AL102 1.2 mg dosed once daily or placebo. The primary endpoint is progression-free survival (PFS) with secondary endpoints including objective response rate (ORR), duration of response (DOR), and patient-reported Quality of Life (QOL) measures. RINGSIDE has been designed as a registration study to support a New Drug Application (NDA) in desmoid tumors.

About RINGSIDE

The RINGSIDE pivotal Phase 2/3 study is a randomized global multi-center trial, with a seamless design, which allowed Ayala to continue to Phase 3 without concluding the Phase 2 segment. The Phase 2 segment of the study (Part A) evaluated the efficacy, safety, tolerability, and tumor volume by MRI after 16 weeks of AL102 in patients with desmoid tumors. It enrolled 42 patients and evaluated 3 doses of AL102. Phase 3 of RINGSIDE (Part B) is a double-blind, placebo-controlled, clinical trial enrolled a total of 156 patients with progressive disease, comparing AL102 at 1.2 mg once-daily to placebo. For more information on the RINGSIDE Phase 2/3 study of AL102 for the treatment of desmoid tumors, please visit ClinicalTrials.gov and reference Identifier NCT04871282 (RINGSIDE).

About Ayala Pharmaceuticals, Inc.
Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company primarily focused on developing and commercializing small molecule therapeutics for people living with rare tumors and aggressive cancers. The Company’s lead candidates under development are the oral gamma secretase inhibitor, AL102, for desmoid tumors, and aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML). AL102 has received Fast Track Designation and Orphan Drug Designation from the U.S. FDA, and is currently in the Phase 3 segment of a pivotal study for patients with desmoid tumors (RINGSIDE). On February 6 2024, Ayala announced that it had entered into a definitive agreement with Immunome (Nasdaq:IMNM) whereby Immunome will acquire certain assets and liabilities relating to AL102 and related drug candidate AL101, constituting substantially all of Ayala’s assets.

For more information, visit www.ayalapharma.com.

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Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this filing may be considered forward-looking statements that involve a number of risks and uncertainties, including statements regarding the future conduct of our studies and the potential efficacy and success of product candidates. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “anticipate,” “plan,” “likely,” “believe,” “estimate,” “project,” “intend,” and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the success and timing of clinical trials regarding AL102, the ability to avoid and quickly resolve any clinical holds and the ability to obtain and maintain regulatory approval and/or reimbursement of product candidates for marketing; the ability to obtain the appropriate labeling of products under any regulatory approval; plans to develop and commercialize

our products; our ability to continue as a going concern; our levels of available cash and our need to raise additional capital, including to support current and future planned clinical activities; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain our existing collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; legislative, regulatory and economic developments; unpredictability and severity of catastrophic events, including, but not limited to, acts of terrorism or outbreak of war or hostilities, as well as management's response to any of the aforementioned factors; the completion of the planned transaction with Immunome; and such other factors as are set forth in our periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in the Form 10-K for the fiscal year ended December 31, 2022 of Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) and the Form 10-K for the fiscal year ended October 31, 2022 of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.) ("Ayala" or "we," "us" or "our"), and such entities' periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in Ayala's Form 10-K for the fiscal year ended October 31, 2022. Except as required by applicable law, we undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.