Ayala Pharmaceuticals Announces Continuation of RINGSIDE Phase 2/3 Study in Desmoid Tumors Following Recommendation of Independent Data Monitoring Committee

March 3, 2023

Registration-enabling Phase 3 segment of RINGSIDE is enrolling patients globally

Updated data on AL102 Phase 2 segment of RINGSIDE are planned for presentation at a medical meeting in 2023

REHOVOT, Israel and MONMOUTH JUNCTION, N.J., March 03, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, today announced that the Independent Data Monitoring Committee (IDMC) for its Phase 2/3 RINGSIDE study evaluating investigational new drug AL102 in desmoid tumors conducted a prespecified periodic review of data from the study and recommended that the study continue without modifications.

“We thank the IDMC members for their work and guidance and are pleased with their recommendation to continue RINGSIDE with no changes,” said Ken Berlin, President and CEO of Ayala. “This recommendation was made based on the analysis of recently updated data from the Phase 2 segment of RINGSIDE. We have commenced enrollment in the Phase 3 segment of RINGSIDE on a worldwide basis. In addition, patients from Phase 2 have the opportunity to continue treatment in the open label extension in Phase 3. We believe that once-daily AL102 has best-in-class potential and are excited about its potential use in desmoid tumors. If approved, we believe it will be a valuable addition to the future therapeutic armamentarium in this underserved indication.”

Andres Gutierrez, M.D. Ph.D., EVP and Chief Medical Officer of Ayala, stated, “The IDMC is looking forward to reviewing the long term-safety profile of AL102 from the open label extension of Phase 2 and has also agreed to the proposed plans for analysis and reporting of results in the ongoing Phase 3 segment of the study. We plan to present these recently updated data from the Phase 2 segment of RINGSIDE at an upcoming medical meeting in 2023.”

Phase 3 of RINGSIDE is a double-blind, placebo-controlled, clinical trial enrolling up to 156 patients with progressive disease, comparing AL102 at 1.2 mg once-daily to placebo. The primary endpoint for Phase 3 is progression-free survival (PFS) with secondary endpoints including objective response rate (ORR), duration of response (DOR), tumor volume reduction, and patient-reported Quality of Life (QOL) measures. 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 Desmoid Tumors

Desmoid tumors, also called aggressive fibromatosis or desmoid-type fibromatosis, are rare connective tissue tumors that typically arise in the upper and lower extremities, abdominal wall, head and neck area, mesenteric root, and chest wall, or other parts of the body. Desmoid tumors do not metastasize, but often aggressively infiltrate neurovascular structures and vital organs. People living with desmoid tumors are often limited in their daily life due to chronic pain, functional deficits, general decrease in their quality of life and organ dysfunction. Desmoid tumors have an annual incidence of approximately 1,700 patients in the United States and typically occur in patients between the ages of 15 and 60 years. They are most commonly diagnosed in young adults between 30-40 years of age and are more prevalent in females. Today, surgery is no longer regarded as the cornerstone treatment of desmoid tumors due to surgical morbidity and a high rate of recurrence post-surgery. There are currently no FDA-approved systemic therapies for the treatment of unresectable, recurrent or progressive desmoid tumors.

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 and is also developing proprietary *Lm*-based antigen delivery products for patients suffering from more common cancers. The Company’s lead candidates under development are the oral gamma secretase inhibitor, AL102, for desmoid tumors; ADXS-504, a *Lm*-based therapy for early-stage prostate cancer; and the intravenous gamma secretase inhibitor, AL101, for adenoid cystic carcinoma. AL102 has received Fast Track Designation from the U.S. FDA and is currently in the Phase 3 segment of a pivotal study for patients with desmoid tumors (RINGSIDE). 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 within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, 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 our clinical trials, including subject accrual; our ability to avoid and quickly resolve any clinical holds; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; 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 available cash, including to support current and planned clinical activities; uncertainties as to our ability to obtain a listing of our common stock on Nasdaq; our ability to integrate our various business areas successfully and to achieve anticipated synergies following our recent merger and the possibility that other anticipated benefits of the transaction will not be realized; potential litigation relating to the transaction; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; 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; 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, 2021 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.