Ayala Pharmaceuticals Announces Abstracts on AL102 and AL101 Accepted for Presentation at ESMO Congress 2023

August 1, 2023

REHOVOT, Israel and MONMOUTH JUNCTION, N.J., Aug. 01, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a publicly-traded clinical-stage oncology company, today announced that it will present posters on its gamma secretase inhibitors AL102 and AL101 at the European Society for Molecular Oncology (ESMO) Congress 2023, to be held in Madrid, Spain 20-24 October 2023.

Poster Presentation Details

Title:	Phase 2 Results from the RINGSIDE Phase 2/3 Trial of AL102 for Treatment of Desmoid Tumors
Presenter	Prof. Robin Jones (The Institute of Cancer Research and Royal Marsden, UK)
Presentation #	1929P
Abstract #	4578

Title	AL101 therapy in patients with recurrent/metastatic (R/M) adenoid cystic carcinoma (ACC): Final ACCURACY trial results and meta-analysis of clinical outcomes
Presenter	Renata Ferrarotto MD (M.D. Anderson Cancer Center, Houston TX)
Presentation #	903P
Abstract #	4549

About AL102

AL102 is an investigational small molecule gamma secretase inhibitor (GSI) that is designed to potently and selectively inhibit Notch 1, 2, 3 and 4, and is currently being evaluated in the Phase 2/3 RINGSIDE clinical studies in patients with progressing desmoid tumors. AL102 is designed to inhibit the expression of Notch gene targets by blocking the final cleavage step by the gamma secretase required for Notch activation. Ayala obtained an exclusive, worldwide license to develop and commercialize AL102 from Bristol-Myers Squibb Company in November 2017. AL102 was granted U.S. Food and Drug Administration (FDA) Fast Track Designation for the potential treatment of desmoid tumors.

About AL101

AL101 is a novel, injectable, potent and selective small molecule gamma secretase inhibitor. It is currently being studied in the Phase 2 ACCURACY trial for the treatment of patients with recurrent/metastatic adenoid cystic carcinoma (R/M ACC).The FDA granted Orphan Drug Designation and Fast Track Designation for AL101 for the potential treatment of ACC.

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). On July 26, 2023 Ayala entered into a definitive merger agreement with Biosight Ltd., a privately-held pharmaceutical company developing innovative therapeutics for hematological malignancies and disorders, pursuant to which Ayala will combine with Biosight in an all-stock transaction. The transaction is expected to close prior to the end of the third quarter of 2023, subject to regulatory and other conditions including approval of Biosight stockholders. 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 risk that the conditions to the closing of the proposed transaction with Biosight are not satisfied, including the failure to timely or at all obtain the approval of the Biosight stockholders for the proposed transaction or the failure to timely or at all obtain any required regulatory clearances; uncertainties as to the timing of the consummation of the proposed transaction and the ability of each of Biosight and us to consummate the proposed transaction; the ability of Ayala and us to integrate our businesses successfully and to achieve anticipated synergies; the possibility that other anticipated benefits of the proposed transaction will not be realized, including without limitation, anticipated revenues, expenses, earnings and other financial results, and growth and expansion of the combined company’s operations, and the anticipated tax treatment of the combination; potential litigation relating to the proposed transaction that could be instituted against us, Biosight or our respective directors; possible disruptions from the proposed transaction that could harm our and/or Biosight’s respective businesses; the ability of us and Biosight to retain, attract and hire key personnel; potential adverse reactions or changes to relationships with customers, employees, suppliers or other parties resulting from the announcement or completion of the proposed transaction; potential business uncertainty, including changes to existing business relationships, during the pendency of the proposed transaction that could affect our or Biosight’s financial performance; certain restrictions during the pendency of the proposed transaction that may impact our or Biosight’s ability to pursue certain business opportunities or strategic transactions; the success and timing of clinical trials, including subject accrual, 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 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 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; 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.