Ayala Pharmaceuticals Announces $25 Million Strategic Financing

February 19, 2021

Funding Extends Cash Runway through Multiple Expected Value Drivers Into 2023

Funds Expected to Support the Recently Announced Accelerated Development of AL102 for the Treatment of Desmoid Tumors into Pivotal Phase 2/3 Study

REHOVOT, Israel and WILMINGTON, Del., Feb. 19, 2021 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (NASDAQ: AYLA), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, today announced that it has entered into a definitive agreement for the sale of its equity securities in a private placement to institutional investors, including Redmile Group and SIO Capital Management.

"We are very excited to have obtained additional funding enabling us to execute on our strategic priorities and support business growth from high quality US healthcare dedicated funds, which we also expect will extend our cash runway into 2023," said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “Ayala is well capitalized as we approach several key milestones planned for the remainder of 2021. We look forward to initiating our pivotal Phase 2/3 study of AL102 for the treatment of desmoid tumors in the first half of this year and presenting data from our Phase 2 study of AL101 for the treatment of recurrent/metastatic adenoid cystic carcinoma and triple negative breast cancer later this year.”

The agreement provides for the sale of an aggregate of 1,666,666 units at a price of $15 per unit. Each unit consists of one share of Ayala’s common stock and a warrant to purchase 0.35 of a share of common stock at an exercise price of $18.10 (the “Warrant”). One institutional investor has elected to receive pre-funded warrants to purchase common stock in lieu of its common stock. The Warrants are exercisable at any time during the period beginning on the closing date of the private placement and ending on the third anniversary of the closing. The gross proceeds from the sales of common stock are expected to be approximately $25 million, before deducting placement agent fees and offering expenses. The private placement is expected to close on or about February 23, 2021, subject to the satisfaction of customary closing conditions.

Jefferies LLC is acting as the exclusive placement agent for the private placement.

Based on Ayala’s current plans, it believes that its existing cash and cash equivalents and short-term restricted bank deposits, with the expected net proceeds from the private placement, will be sufficient to fund its operating expenses and capital expenditure requirements through multiple expected catalysts into 2023.

The securities to be sold in the private placement have not been registered under the Securities Act of 1933, as amended (Securities Act), or any state or other applicable jurisdiction’s securities laws, and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions’ securities laws.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any offer, solicitation or sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

About Ayala Pharmaceuticals

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers. Ayala’s approach is focused on predicating, identifying and addressing tumorigenic drivers of cancer through a combination of its bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. The company has two product candidates under development, AL101 and AL102, targeting the aberrant activation of the Notch pathway with gamma secretase inhibitors to treat a variety of tumors including Adenoid Cystic Carcinoma, Triple Negative Breast Cancer (TNBC), T-cell Acute Lymphoblastic Leukemia (T-ALL), Desmoid Tumors and Multiple Myeloma (MM) (in collaboration with Novartis). AL101 has received Fast Track Designation and Orphan Drug Designation from the U.S. FDA and is currently in a Phase 2 clinical trial for patients with ACC (ACCURACY) bearing Notch activating mutations and in a Phase 2 clinical trial for patients with TNBC (TENACITY) bearing Notch activating mutations and other gene rearrangements. AL102 is currently being advanced to a Phase 2/3 clinical trials for patients with desmoid tumors (RINGSIDE). For more information, visit www.ayalapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements relating to the sufficiency of our cash, cash equivalents, restricted banks deposits and the net proceeds from the private placement to fund our operating expenses and capital expenditure requirements, the timing of clinical trials, the gross proceeds from the private placement, the closing of the private placement, and the use of proceeds from the private placement. These forward-looking statements are based on management’s current expectations. The words “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the

impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our expectations regarding our cash runway; our limited operating history and the prospects for our future viability; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our requirement to pay significant payments under product candidate licenses; the approach we are taking to discover and develop product candidates and whether it will lead to marketable products; the expense, time-consuming nature and uncertainty of clinical trials; enrollment and retention of patients; potential side effects of our product candidates; our ability to develop or to collaborate with others to develop appropriate diagnostic tests; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us. These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the three months ended September 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC) on November 16, 2020 and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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