Ayala Pharmaceuticals Announces Key Business Objectives for 2022

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-- Data read-outs expected on AL102 in desmoid tumors and AL101 in ACC and TNBC --

REHOVOT, Israel and WILMINGTON, Del., Jan. 04, 2022 (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, primarily in genetically defined patient populations, today announced its key objectives for 2022.

“We believe that 2022 will be a pivotal year for Ayala as we continue to advance our unique clinical stage portfolio of gamma secretase inhibitors to treat rare and aggressive cancers with no approved therapies,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “We hope to build on the excellent progress we made in 2021 and look forward to multiple clinical milestones that have the potential to create significant value. Specifically, we expect data read-outs from AL102 in desmoid tumors and from our AL101 programs in adenoid cystic carcinoma and triple negative breast cancer. We plan to advance AL101 into the clinic in a Phase 2 trial in T-cell acute lymphoblastic leukemia. We are pleased, also, with our ongoing collaboration with Novartis to develop AL102 in combination with its anti-BCMA agent for multiple myeloma and hope to be able to share an update on this exciting program as well.”

2021 Key Achievements

- Initiated pivotal Phase 2/3 RINGSIDE study of AL102 in desmoid tumors
- Initiated Phase 2 TENACITY study of AL101 in Notch-activated TNBC
- Initiated Phase 1 trial of AL102 in combination with BCMA targeting agent WVT078 in relapsed/refractory MM (in collaboration with Novartis)
- Presented positive preliminary data from the 6 mg cohort of the ongoing Phase 2 ACCURACY study of AL101 in recurrent/metastatic ACC at ESMO 2021
- Published case studies highlighting clinical activity of AL101 with long-lasting responses in patients with desmoid tumors
- Completed $25 million strategic equity financing

Expected Milestones in 2022

Initial Interim Data from Pivotal Phase 2/3 RINGSIDE Trial in Desmoid Tumors (Mid-2022):

- Ayala expects to report an initial interim data read-out from Part A of the Phase 2/3 RINGSIDE trial of AL102 in desmoid tumors in mid-2022. Part A is open-label and is evaluating safety, tolerability, and tumor volume by MRI after 16 weeks.
- Part B of the study will start immediately after dose selection from Part A and will be a double-blind placebo-controlled study enrolling up to 156 patients with progressive disease, randomized 2:1 between AL102 or placebo.
- If successful RINGSIDE will be used as a registrational study.

Preliminary Data from Phase 2 TENACITY Trial of AL101 in Triple Negative Breast Cancer (H2-2022)

- Preliminary data from the Phase 2 TENACITY clinical trial of AL101, for the treatment of patients with Notch-activated recurrent or metastatic (R/M) triple negative breast cancer (TNBC) are expected in H2-2022.
- TENACITY is an open-label, multicenter, single arm study that is expected to initially enroll up to 26 patients with Notch-activated R/M TNBC whose disease has recurred or progressed after three or fewer lines of prior therapy.
- The primary endpoint is the objective response rate. Secondary endpoints include safety, duration of response, progression free survival, and relapse free survival.
- Ayala is currently the only company pursuing clinical development of a Notch inhibitor for TNBC.

Additional Data from Phase 2 ACCURACY Trial of AL101 in Adenoid Cystic Carcinoma (Mid-2022)

- The ongoing ACCURACY trial is an open-label, single-arm Phase 2 clinical trial evaluating AL101 as monotherapy for the treatment of R/M ACC for Notch-activated mutations patients.
- Part 1 of the trial included 45 subjects dosed at 4 mg of AL101 IV once weekly. Final data from the 4 mg and additional data from the 6 mg cohort which includes 42 subjects are expected to be announced during 2022.
- The primary endpoint is the objective response rate as measured by RECIST 1.1 criteria. Secondary endpoints include objective response rate by investigator review, duration of response and progression-free survival by an independent review committee and an investigator review, overall survival, safety and tolerability, and pharmacokinetics.

- AL101, if approved, could potentially be the first systemic therapy for ACC.

Initiate Phase 2 Clinical Trial Evaluating AL101 in T-cell Acute Lymphoblastic Leukemia (H2-2022)

- Ayala plans to begin a Phase 2 clinical trial evaluating AL101 in R/R T-ALL
- Notch is known to be a critical component of T-cell development and is inherently implicated as a tumorigenic driver in T-ALL. Approximately 65% of all T-ALL patients have Notch-activating mutations.

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, primarily in genetically defined patient populations. 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 in a Pivotal Phase 2/3 clinical trials for patients with desmoid tumors (RINGSIDE) and is being evaluated in a Phase 1 clinical trial in combination with Novartis' BCMA targeting agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma. For more information, visit www.ayalapharma.com..

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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 our development of AL101 and AL102, the promise and potential impact of our preclinical or clinical trial data, the timing of and plans to initiate additional clinical trials of AL101 and AL102, the timing and results of any clinical trials or readouts, the sufficiency of cash to fund operations, and the anticipated impact of COVID-19, on our business. 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: we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability; we will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of AL101 and AL102; we have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability; we are heavily dependent on the success of AL101 and AL102, our most advanced product candidates, which are still under clinical development, and if either AL101 or AL102 does not receive regulatory approval or is not successfully commercialized, our business may be harmed; due to our limited resources and access to capital, we must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business; the outbreak of COVID-19, may adversely affect our business, including our clinical trials; our ability to use our net operating loss carry forwards to offset future taxable income may be subject to certain limitations; our product candidates are designed for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to marketable products; we were not involved in the early development of our lead product candidates; therefore, we are dependent on third parties having accurately generated, collected and interpreted data from certain preclinical studies and clinical trials for our product candidates; enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control; if we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed; our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales; the market opportunities for AL101 and AL102, if approved, may be smaller than we anticipate; we may not be successful in developing, or collaborating with others to develop, diagnostic tests to identify patients with Notch-activating mutations; we have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates; even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential; we have been granted Orphan Drug Designation for AL101 for the treatment of ACC and may seek Orphan Drug Designation for other indications or product candidates, and we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, and may not receive Orphan Drug Designation for other indications or for our other product candidates; although we have received Fast Track designation for AL101, and may seek Fast Track designation for our other product candidates, such designations may not actually lead to a faster development timeline, regulatory review or approval process; we face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to

compete effectively; we are dependent on a small number of suppliers for some of the materials used to manufacture our product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of our product candidates; our existing collaboration with Novartis is, and any future collaborations will be, important to our business. If we are unable to maintain our existing collaboration or enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected; enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set; if we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our markets; we may engage in acquisitions or in-licensing transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources; and risks related to our operations in Israel could materially adversely impact our business, financial condition and results of operations.

These and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC) on March 24, 2021 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.