Ayala Pharmaceuticals Announces First Patient Dosed in Phase 2 TENACITY Clinical Trial of AL101 for the Treatment of Patients with Notch-Activated Triple Negative Breast Cancer

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REHOVOT, Israel and WILMINGTON, Del., Jan. 28, 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 the first patient dosed in the Phase 2 TENACITY clinical trial of its potent, selective small molecule AL101, for the treatment of patients with Notch-activated recurrent or metastatic (R/M) triple negative breast cancer (TNBC).

“The dosing of the first patient in our Phase 2 TENACITY trial is an important step for Ayala as we now have two ongoing Phase 2 clinical trials for AL101 monotherapy in heavily pre-treated patient populations, further building its safety and efficacy profile across these difficult to treat, Notch-activated cancers,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “We believe the need for a novel therapeutic option is critical as Notch-activated TNBC correlates with a poorer prognosis and higher rates of potential relapse. We are confident that TNBC is a logical second indication for AL101 based on extensive preclinical work and we look forward to further advancing the TENACITY trial.”

The Phase 2 study is designed to evaluate the efficacy and safety of AL101 monotherapy in patients with Notch-activated R/M TNBC. It is an open-label, multicenter, single arm study which 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. Notch activation will be determined using a Next Generation Sequencing (NGS) based assay screen. Ayala expects to report preliminary data by the end of 2021.

About AL101
AL101 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 two Phase 2 clinical studies, ACCURACY and TENACITY, in patients with adenoid cystic carcinoma (ACC) and in patients with triple negative breast cancer (TNBC), respectively. AL101 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 AL101 from Bristol-Myers Squibb Company in November 2017. AL101 was granted U.S. FDA Fast Track Designation and Orphan Drug Designation for the treatment of ACC.

About Triple Negative Breast Cancer
Triple negative breast cancer (TNBC) is one of the most aggressive types of breast cancer, constituting approximately 15% of newly diagnosed breast cancer cases and an even higher percentage of metastatic breast cancer cases worldwide with an estimated 9-16% of patients having Notch-activating gene alterations. It is characterized by negative tests for three of the common receptors found in breast cancer: estrogen, progesterone, and excessive HER2 protein, minimizing the effectiveness of hormonal therapies or medicines that target HER2 protein receptors, as well as traditional chemotherapies.

AL101 Phase 2 Study in TNBC (TENACITY)
TENACITY is an open-label multicenter, Phase 2, Simon’s two-stage design for single arm AL101 monotherapy in patients with Notch-activated recurrent or metastatic TNBC whose disease has recurred or progressed after 3 or fewer lines of prior therapy. Notch activation will be determined by a Next Generation Sequencing (NGS) test. The first stage is planned to enroll up to 26 patients, with additional 41 patients in the second stage of the study. The study is designed to evaluate the Objective Response Rate (ORR) as the primary endpoint, with Duration of Response (DOR), Progression Free Survival (PFS) and Quality of Life (QoL) measures as secondary endpoints.

The study is enrolling globally with sites currently open in the US and Israel. For more information on the AL101 TENACITY study, please visit TENACITY under https://clinicaltrials.gov/ct2/show/NCT04461600.

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.

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