



Ayala Pharmaceuticals to Present Clinical Data from Ongoing Phase 2 ACCURACY Trial and New Preclinical Results from Combination Study of AL101 at the European Society for Medical Oncology (ESMO) Virtual Congress 2021

September 1, 2021

REHOVOT, Israel and WILMINGTON, Del., Sept. 01, 2021 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (NASDAQ: AYL), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, today announced upcoming ePoster presentations at the European Society for Medical Oncology (ESMO) Virtual Congress 2021, being held September 16-September 21, 2021. Ayala will present preliminary data from the 6mg cohort of the ongoing Phase 2 ACCURACY clinical trial of AL101 for the treatment of recurrent/metastatic (R/M) adenoid cystic carcinoma (ACC) harbouring Notch-activating mutations in addition to preclinical results from Ayala's new study of AL101 in combination with other drugs for dual targeting of Notch dysregulated tumors.

ePoster details:

Title: ACCURACY: a phase 2 trial of AL101, a selective gamma secretase inhibitor, in subjects with recurrent/metastatic (R/M) adenoid cystic carcinoma (ACC) harboring NOTCH-activating mutations (NOTCH^{mut}): results of 6-mg cohort

Presentation Number: 904P

Presenter: Alan L. Ho, M.D., Ph.D., Memorial Sloan Kettering Cancer Center

Title: The gamma secretase inhibitor AL101 combined with other drugs for dual targeting of Notch dysregulated tumor

Presentation Number: 1789P

Presenter: Renata Ferrarotto, M.D., MD Anderson Cancer Center

The two ePosters will be available to registrants of the ESMO Virtual Congress 2021 starting at 8:30 AM CEST (2:30 AM ET) on Thursday, September 16, 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 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' BMCA targeting agent, WV7078, in Patients with relapsed/refractory Multiple Myeloma. For more information, visit www.ayalapharma.com.

Investors:

Julie Seidel

Stern Investor Relations, Inc.

+1-212-362-1200

Julie.seidel@sternir.com

Ayala Pharmaceuticals:

+1-857-444-0553

info@ayalapharma.com