Ayala Pharmaceuticals Announces First Patient Dosed in Phase 1 Clinical Trial of AL102 in Combination with BCMA Targeting Agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma

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REHOVOT, Israel and WILMINGTON, Del., April 21, 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 dosing of the first patient in the ongoing Phase 1 clinical trial evaluating its potent investigational gamma secretase inhibitor (GSI), AL102, in combination with Novartis' investigational anti-B-cell maturation antigen (BCMA) agent, WVT078, for the treatment of patients with relapsed and/or refractory multiple myeloma (MM).

AL102 is an oral small molecule that inhibits gamma secretase. Inhibition of gamma secretase prevents the cleavage and shedding of BCMA, which are ubiquitously expressed on MM cells. Preclinical data have demonstrated that treatment with AL102 increases expression of membrane-bound BCMA on the surface of MM cells and could enhance activity of WVT078.

"The dosing of the first patient in this Phase 1 trial marks an important milestone in our collaboration with Novartis. We view this trial, not only as a significant opportunity to explore the clinical viability of enhancing BCMA-targeting agents with GSIs such as AL102, but also as an important step forward in bringing a novel treatment option to patients with MM," said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. "Despite numerous advances in the treatment landscape for MM, the disease remains incurable. BCMA is ubiquitously expressed on myeloma cells. Increasing BCMA expression on target cells and reducing the shedding in circulation is believed to potentially enhance therapies and increase responses. We look forward to further evaluating this potential as we bring this program into the clinic."

The Phase 1, open-label, multicenter trial of AL102 in combination with Novartis' WVT078 is currently enrolling patients with relapsed and/or refractory multiple myeloma who have received two or more standard of care lines of therapy including an IMID, a proteasome inhibitor, and an anti-CD38 agent. The first-in-human dose escalation trial is designed to assess the safety, tolerability and recommended dose regimen(s) of WVT078 alone and in combination with AL102. In addition, the trial will assess preliminary anti-MM response and characterize the pharmacokinetics and immunogenicity of WVT078 alone and in combination with AL102.

Under the terms of the option and license agreement established in December 2018, Novartis is responsible for the conduct and expenses of any trials of AL102 in combination with their BCMA-targeting agents, as well as potential commercialization, in multiple myeloma. Ayala retains worldwide license rights to AL102 in all other indications.

About AL102
AL102 is a potent, selective and oral gamma secretase inhibitor (GSI). AL102 is currently being developed for the treatment of desmoid tumors, as well as in combination with Novartis' BCMA-targeting agents for the treatment of multiple myeloma (MM).

About WVT078
WVT078 is a bispecific antibody that engages both BCMA and CD3, resulting in the recruitment of cytotoxic T cells that target BCMA-positive MM cells.

About Multiple Myeloma
Multiple myeloma is a rare and aggressive blood cancer that accounts for approximately one percent of all cancers. In the U.S., there are nearly 90,000 people living with, or in remission from, multiple myeloma. Approximately, 26,850 Americans are diagnosed with multiple myeloma each year and 11,240 patient deaths are reported on an annual basis.

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 trial for patients with desmoid tumors (RINGSIDE) and is being evaluated in a Phase 1 clinical trial in combination with Novartis' BMCA targeting agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma. For more information, visit www.ayalapharma.com.

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