Ayala Pharmaceuticals Granted U.S. FDA Fast Track Designation For AL101 For The Treatment Of Recurrent Or Metastatic Adenoid Cystic Carcinoma

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REHOVOT, Israel & WILMINGTON, Del., March 2, 2020 – (BUSINESS WIRE) – Ayala Pharmaceuticals, Inc., a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AL101 for the treatment of recurrent or metastatic adenoid cystic carcinoma (ACC). AL101, Ayala's lead product candidate, is a potent, selective, injectable small molecule gamma secretase inhibitor (GSI) and was granted Orphan Drug Designation in May 2019 for the treatment of ACC.

"Receiving Fast Track designation from the FDA underscores the urgent need for a targeted therapy to address the devastating nature of ACC, a rare disease for which no standard drug therapy currently exists," said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. "We are pleased with the initial data from our Phase 2 ACCURACY clinical trial, demonstrating that AL101 has been well tolerated and has shown encouraging preliminary signs of activity in this extremely difficult to treat patient population. We look forward to continuing discussions with the FDA in our effort to develop a novel treatment for patients in need."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The designation offers the opportunity for more frequent interactions with the FDA over the course of drug development and allows for rolling review of a New Drug Application (NDA) if relevant criteria are met.

About AL101
AL101 is an investigational small molecule GSI that is designed to potently and selectively inhibit Notch 1, 2, 3 and 4, and is currently being evaluated in the Phase 2 ACCURACY trial in patients with adenoid cystic carcinoma (ACC). 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.

About Ayala Pharmaceuticals
Ayala Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company dedicated to developing targeted cancer therapies for people living with genetically defined cancers. Ayala is broadly developing its product candidates, AL101 and AL102, best-in-class gamma secretase inhibitors, with clinical and preclinical studies underway in both solid tumors (AL101) and hematologic malignancies (AL102). Ayala's lead product candidate, AL101, is currently in phase 2 for adenoid cystic carcinoma patients with tumor bearing Notch activating mutations (ACCURACY).

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