Ayala Pharmaceuticals Reports Full Year 2020 Financial Results and Provides Business Update

March 25, 2021

- Completed $25 Million Strategic Financing; Extending Cash Runway into 2023

- Accelerated Development of AL102 Desmoid Tumor Program into Phase 2/3 Pivotal Trial

- On Track to Report Multiple Milestones in 2021 Across Clinical-Stage Pipeline

REHOVOT, Israel and WILMINGTON, Del., March 25, 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, primarily in genetically defined patient populations, today reported financial results for the full year ended December 31, 2020 and highlighted recent progress and upcoming milestones for its pipeline programs.

“We are pleased with all that we were able to accomplish in 2020 despite the ongoing challenges of the COVID-19 pandemic, keeping clinical execution and patient and employee safety at the forefront of our everyday work. In 2020, we announced encouraging new data from the Phase 2 ACCURACY study of AL101 in R/M ACC, demonstrating initial safety and efficacy for the 4mg monotherapy cohort and we look forward to reporting additional data, including new 6mg cohort results from this program later this year,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “With a strong foundation built in 2020, we have already achieved significant milestones across our broader pipeline in 2021 with the first patient dosing in our Phase 2 TENACITY trial in TNBC, accelerated development pathway and pivotal trial design for AL102 in desmoid tumors, as well as our $25 million strategic financing. We look forward to continuing this momentum with several key clinical milestones expected during the remainder of this year, including two new trial initiations and interim data readouts.”

Business and Clinical Highlights

- **Completed $25 million Strategic Financing:** In February 2021, Ayala announced a $25 million strategic financing with investors including Redmile Group and SIO Capital Management, extending its cash runway into 2023.

- **Dosed First Patient in Phase 2 TENACITY Clinical Trial of AL101 for the Treatment of Notch-Activated Triple Negative Breast Cancer:** In January 2021, Ayala announced the dosing of the first patient 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).

- **Accelerated Development of AL102 for the Treatment of Desmoid Tumors with Pivotal Trial:** In January 2021, Ayala announced that based on its end-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA) on AL102 for the treatment of desmoid tumors, and data from AL101 and AL102 Phase 1 studies including durable responses observed in patients with desmoid tumors, the FDA agreed to advance the program into a Phase 2/3 pivotal trial.

- **Presented Updated Positive Interim Data from Phase 2 ACCURACY Study of AL101 for the Treatment of Recurrent/Metastatic Adenoid Cystic Carcinoma at European Society for Medical Oncology (ESMO) Virtual Congress 2020:** In September 2020, Ayala presented updated interim data from the 4mg cohort of its ongoing Phase 2 ACCURACY study of AL101 for the treatment of recurrent/metastatic adenoid cystic carcinoma (R/M ACC) harboring Notch activating mutations, demonstrating meaningful clinical activity of AL101 4mg monotherapy with a 68% disease control rate across 40 evaluable patients. Partial responses were observed in six subjects (15%) and stable disease was observed in 21 subjects (53%).

Upcoming Milestones

- **On Track to Initiate Phase 2/3 Pivotal RINGSIDE Clinical Trial of AL102 for the Treatment of Desmoid Tumors:** Ayala expects to initiate the pivotal RINGSIDE clinical trial of AL102 in adult and adolescent patients with desmoid tumors in the first half of 2021. Ayala expects an initial interim data read-out from part A and dose selection by mid-2022 with part B of the study commencing immediately thereafter.
- **Patient Enrollment in 6mg Cohort of Phase 2 ACCURACY Study Ongoing:** Ayala continues to enroll patients in the 6mg cohort of the Phase 2 ACCURACY study of AL101 for the treatment of R/M ACC, which will contain up to 42 subjects. The Company expects to provide further trial progress updates, including additional data, in the second half of 2021.

- **TENACITY Preliminary Data to be Reported in 2021:** Ayala expects to report preliminary data from the recently initiated Phase 2 TENACITY clinical trial of AL101 for the treatment of R/M TNBC in the second half of 2021.

Full Year 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were $42.4 million as of December 31, 2020, as compared to $16.8 million as of December 31, 2019. The increase in cash and cash equivalents was primarily due to Ayala's initial public offering in May 2020.
- **Collaboration Revenue:** Collaboration revenue was $3.7 million for the full year of 2020, as compared to $2.3 million for the same period in 2019. The increase was primarily attributable to the advancement of Ayala's collaboration with Novartis in 2020.
- **R&D Expenses:** Research and development expenses were $22.4 million for the full year 2020, compared to $14.4 million for the same period in 2019. The increase was primarily driven by an increase in expenses in connection with the advancement of the clinical trials in ACC and TNBC.
- **G&A Expenses:** General and administrative expenses were $7.4 million for the full year 2020, compared to $4.3 million for the same period in 2019. The increase was primarily related to increased costs in connection with becoming a publicly traded company in 2020.
- **Net Loss:** Net loss was $30.1 million for the full year 2020, resulting in a basic net loss per share of $3.06 and a diluted net loss per share of $3.06. Net loss was $17.8 million for the same period in 2019, resulting in a basic net loss per share of $3.57 and a diluted net loss per share of $3.57.

Financial Guidance

Ayala expects its existing cash balance to fund operating expenses and capital expenditure requirements through multiple potential key clinical and development milestones into 2023.

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). Ayala's lead product candidate, 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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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, upcoming milestones, including without limitation the timing and results of any clinical trials or readouts, patient enrollment and the sufficiency of cash to fund operations. 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: the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our cash runway; our limited operating history and the prospects for our future viability; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our requirement to pay significant payments under product candidate licenses; the approach we are taking to discover and develop product candidates and whether it will lead to marketable products; the expense, time-consuming nature and uncertainty of

clinical trials; enrollment and retention of patients; potential side effects of our product candidates; our ability to develop or to collaborate with others to develop appropriate diagnostic tests; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us. 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.

AYALA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except share and per share data)

	December 31, 2019	December 31, 2020
Assets		
Current Assets:		
Cash and Cash Equivalents	$ 16,725	$ 42,025
Short-Term Restricted Bank Deposits	83	90
Trade Receivables	469	681
Prepaid Expenses and Other Current Assets	417	1,444
Total Current Assets	17,694	44,240
Long-Term Assets:		
Other Assets	283	305
Deferred Offering Costs	656	—
Property and Equipment, Net	1,421	1,283
Total Long-Term Assets	2,360	1,588
Total Assets	$ 20,054	$ 45,828
Liabilities, Convertible Preferred Stock, and Stockholders' (Deficit) Equity:		
Current Liabilities:		
Trade Payables	$ 2,922	$ 3,726
Other Accounts Payables	2,380	3,151
Total Current Liabilities	5,302	6,877
Long-Term Liabilities:		
Long-Term Rent Liability	299	$ 553
Total Long-Term Liabilities	$ 299	$ 553
Convertible Preferred Stock, $0.01 par value:		
Series A Preferred Stock of $0.01 par value per share; 3,700,000 shares authorized at December 31, 2019; 3,679,778 issued and outstanding shares at December 31, 2019; aggregate liquidation preference value of $23,919 at December 31, 2019	23,823	—
Series B Preferred Stock of $0.01 par value per share; 4,500,000 shares authorized at December 31, 2019; 3,750,674 issued and outstanding shares at December 31, 2019, respectively; aggregate liquidation preference value of $29,668 at December 31, 2019	29,550	—
Total Convertible Preferred Stock	53,373	—
Stockholders' (Deficit) Equity:		
Common Stock of $0.01 par value per share; 20,000,000 and 200,000,000 shares authorized at December 31, 2019 and 2020, respectively; shares issued at December 31, 2019 and 2020, respectively; 4,998,874 and 12,728,446 shares outstanding at December 31, 2019 and 2020, respectively	$ 51	$ 128
Additional Paid-in Capital	1,770	109,157
Accumulated Deficit	(40,741)	(70,887)
Total Stockholders' (Deficit) Equity	(38,920)	38,398
Total Liabilities, Convertible Preferred Stock, and Stockholders' (Deficit) Equity	$ 20,054	$ 45,828

AYALA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. dollars in thousands (except shares and per shares data)

	Year ended December 31, 2019	Year ended December 31, 2020
Revenue from License Agreement	$ 2,334	$ 3,708
Cost of Revenue	(1,285)	(3,708)
Gross Profit	1,049	—
Research and Development	$ 14,424	$ 22,406
General and Administrative	4,336	7,371
Operating Loss	(17,711)	(29,777)
Financial Income, Net	225	56
Loss before Income Tax	(17,486)	(29,721)
Taxes on Income	(306)	(425)
Net Loss attributable to Common Stockholders	$ (17,792)	$ (30,146)
Net Loss per Share attributable to Common Stockholders, Basic and Diluted	$ (3.57)	$ (3.06)
Weighted Average Shares Used to Compute Net Loss per Share, Basic and Diluted	4,979,606	9,860,610