Ayala Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Business Update

May 14, 2021

- First Patient Dosed in Phase 1 AL102 Combination Trial with Novartis' Anti-BCMA Agent for the Treatment of Multiple Myeloma -

- On Track to Initiate AL102 Phase 2/3 Pivotal Trial for the Treatment of Desmoid Tumors in 1H21-

- Multiple Near-Term Milestones Expected Across Clinical-Stage Pipeline -

REHOVOT, Israel and WILMINGTON, Del., May 14, 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 first quarter ended March 31, 2021 and highlighted recent progress and upcoming milestones for its pipeline programs.

"Continuing on the strong momentum set in 2020, we are pleased with our progress through the first quarter of 2021. With a strengthened balance sheet and extended cash runway into 2023, we are well positioned to further progress our innovative pipeline of assets targeting the inhibition of gamma secretase through key pathways implicated in rare and aggressive cancers, including adenoid cystic carcinoma, multiple myeloma, triple negative breast cancer and desmoid tumors," said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. "We have made great strides to advance our pipeline programs in 2021 with the first patients dosed in both the Phase 2 TENACITY trial in triple negative breast cancer and the Phase 1 combination trial with Novartis in multiple myeloma. We also remain on track to report additional data from the 6mg cohort of our Phase 2 ACCURACY trial of AL101 for the treatment of adenoid cystic carcinoma in the second half of this year."

Recent Business Highlights and Upcoming Milestones:

- **First Patient was dosed in Phase 1 Clinical Trial of AL102 in Combination with Novartis' BCMA Targeting Agent, WVT087 for the Treatment of Relapsed/Refractory Multiple Myeloma:** In April 2021, Ayala announced that the first patient was dosed in its Phase 1 combination trial of AL102 with Novartis' investigational anti-B-cell maturation antigen (BCMA) agent, WVT078, for the treatment of relapsed and/or refractory multiple myeloma (MM).

- **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.

- **Phase 2 TENACITY Clinical Trial Continues to Progress:** 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). Ayala expects to report preliminary data from this ongoing trial by the end of 2021.

- **Accelerated Development of AL102 for the Treatment of Desmoid Tumors with Pivotal Trial; First site opened in the US for the Phase 2/3 RINGSIDE 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. 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 of the study and dose selection by mid-2022 with part B of the study commencing immediately thereafter.
- **On Track to Report Additional ACCURACY Phase 2 Data; 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 recurrent/metastatic adenoid cystic carcinoma (R/M ACC), which will include up to 42 subjects. Further trial progress updates, including additional data, are expected in the second half of 2021.

First Quarter 2021 Financial Results

- **Cash Position:** Cash and cash equivalents totaled $56.0 million as of March 31, 2021.
- **Collaboration Revenue:** Collaboration revenue was $1.0 million for the first quarter of 2021 and 2020.
- **R&D Expenses:** Research and development expenses were $6.9 million for the first quarter of 2021, compared to $5.1 million for the same period in 2020. The increase was primarily driven by additional costs in connection with the

advancement of the Desmoids, TNBC and ACC clinical trials.

- **G&A Expenses:** General and administrative expenses were $2.3 million for the first quarter of 2021, compared to $1.3 million for the same period in 2020. This increase was primarily due to higher expenses in connection with becoming a public company, including director and officers insurance and stock-based compensation.
- **Net Loss:** Net loss was $9.6 million for the first quarter of 2021, resulting in a basic and diluted net loss per share of $0.74. Net loss was $6.6 million for the same period in 2020, resulting in a basic and diluted net loss per share of $1.32.

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). 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) 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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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.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	March 31, 2021	December 31 2020
	(Unaudited)	
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 56,030	$ 42,025
Short-term Restricted Bank Deposits	117	90
Trade Receivables	169	681
Prepaid Expenses and other Current Assets	1,534	1,444
Total Current Assets	57,850	44,240
LONG-TERM ASSETS:		
Other Assets	$ 264	$ 305
Property and Equipment, Net	1,119	1,283
Total Long-Term Assets	1,383	1,588
Total Assets	**$ 59,233**	**$ 45,828**
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade Payables	$ 3,004	$ 3,726
Other Accounts Payables	2,690	3,151
Total Current Liabilities	5,694	6,877
LONG TERM LIABILITIES:		
Long-term Rent Liability	505	553
Total Long-Term Liabilities	$ 505	$ 553
STOCKHOLDERS' DEFICIT:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 13,240,961 and 12,824,463 shares issued at March 31, 2021 and, respectively December 31, 2020; 13,072,213 and 12,728,446 shares outstanding at March 31, 2021 and December 31, 2020, respectively	$ 131	$ 128
Additional Paid-in Capital	133,358	109,157
Accumulated Deficit	(80,455)	(70,887)
Total Stockholders' Equity	53,034	38,398
Total Liabilities, Convertible Preferred Stock, and Stockholders' Equity	$ **59,233**	**$ 45,828**

AYALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share & per share amounts)

	For the Three Months Ended March 31,	
	2021	**2020**
Revenues from licensing agreement	$ 974	$ 1,001
Cost of Revenues	(974)	(1,001)
Gross profit	—	—
Operating expenses:		
Research and development	6,925	5,128
General and administrative	2,303	1,311
Operating loss	(9,228)	(6,439)
Financial loss, net	(92)	(38)
Loss before income tax	(9,320)	(6,477)
Taxes on income	(248)	(121)
Net loss attributable to common stockholders	(9,568)	(6,598)
Net Loss per share attributable to common stockholders, basic and diluted	$ (0.74)	$ (1.32)
Weighted average common shares outstanding, basic and diluted	**12,888,340**	**4,999,563**