Ayala Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Business Update

November 17, 2020

- Presented New Positive Interim Data from 4mg Cohort of Phase 2 ACCURACY Study of AL101 for the Treatment of R/M ACC at European Society for Medical Oncology 2020 -

- Trial In Progress Poster of Phase 2 TENACITY Study of AL101 Monotherapy in Patients with Notch-activated Triple-Negative Breast Cancer Accepted for Presentation at San Antonio Breast Cancer Virtual Symposium -

REHOVOT, Israel and WILMINGTON, Del., Nov. 17, 2020 (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 third quarter ended September 30, 2020 and highlighted recent progress and upcoming milestones for its pipeline programs.

“Ayala has made important steps forward in just over a quarter since our IPO as we have laid a strong financial and clinical foundation to support several upcoming milestones throughout the remainder of 2020 and into 2021. Most importantly, we announced encouraging new interim data from our Phase 2 ACCURACY study of AL101 in an extremely difficult to treat population, R/M ACC, demonstrating that AL101 4mg monotherapy has the potential to be a safe and effective treatment for patients with Notch activating mutations. These data further support our rationale for evaluating the 6mg dose cohort of this study for which we remain on track with enrollment,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “Our broader pipeline focused on genetically defined cancers continues to advance and we look forward to commencing patient dosing of our Phase 2 TENACITY study of AL101 for the treatment of R/M TNBC by year-end 2020, as well as additional trial initiations for desmoid tumors in the first half of 2021 and T-ALL in the second half of 2021.”

Key Business and Clinical Highlights

- **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

- **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 in the first half of 2021.

- **Trial in Progress Poster of Phase 2 TENACITY Study of AL101 Monotherapy in Patients with Notch-Activated Triple-Negative Breast Cancer to be Presented at The 2020 Virtual San Antonio Breast Cancer Symposium (SABCS):** A trial in progress poster will be presented on December 9, 2020. Ayala expects to initiate patient dosing before year-end 2020.

- **On Track to Initiate Two Phase 2 Clinical Trials in 2021:**

  - **Phase 2 Study of AL102 for the Treatment of Desmoid Tumors:** Ayala expects to initiate a Phase 2 study of AL102, a potent, selective, oral gamma secretase inhibitor, in patients with desmoid tumors, rare, disfiguring and often debilitating soft tissue tumors, in the first half of 2021.

  - **Phase 2 Study of AL101 for the Treatment of Relapsed or Refractory T-cell Acute Lymphoblastic Leukemia:** Based on findings from Ayala’s Phase 1 study of AL101 and supporting data from its preclinical studies, Ayala expects to initiate a Phase 2 study of AL101 for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia (R/R T-ALL), an aggressive and rare form of T-cell specific leukemia, in the second half of 2021.

Third Quarter 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were $48.8 million as of September 30, 2020, as compared to $16.7 million as of December 31, 2019.

- **Collaboration Revenue:** Collaboration revenue was $0.7 million and $0.8 million for the third quarter of 2020 and 2019, respectively.

- **R&D Expenses:** Research and development expenses were $5.4 million for the third quarter of 2020, compared to $4.4 million for the same period in 2019. The increase was primarily driven by additional costs in connection with the advancement of AL101 clinical trials and other preclinical development.

- **G&A Expenses:** General and administrative expenses were $1.9 million for the third quarter of 2020, compared to $0.9 million for the same period in 2019. The increase was primarily related to higher costs in connection of becoming a public company and costs to support the growth of the company.

- **Net Loss:** Net loss was $7.4 million, or $0.59 loss per share, for the third quarter of 2020, compared to $5.0 million, or $1.01 loss per share, for the same period in 2019, mainly attributable to the advancement of clinical trials and other preclinical development.

Financial Guidance

Ayala expects its existing cash balance to fund operations through multiple potential key clinical and development milestones into the second half of 2022.

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. 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, 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 Quarterly Report on Form 10-Q for the three months ended September 30, 2020 filed with the U.S.

Securities and Exchange Commission (SEC) on November 13, 2020 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

(In thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
	(Unaudited)	
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 48,749	$ 16,725
Short-term Restricted Bank Deposits	84	83
Trade Receivables	589	469
Prepaid Expenses and other Current Assets	2,329	417
Total Current Assets	51,751	17,694
LONG-TERM ASSETS:		
Other Assets	$ 285	$ 283
Deferred Offering Costs	—	656
Property and Equipment, Net	1,357	1,421
Total Long-Term Assets	1,642	2,360
Total Assets	$ 53,393	**$ 20,054**
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS EQUITY (DEFICIT):		
CURRENT LIABILITIES:		
Trade Payables	$ 3,646	$ 2,922
Other Accounts Payables	2,353	2,380
Total Current Liabilities	5,999	5,302
LONG TERM LIABILITIES:		
Long-term Rent Liability	462	299
Total Long-Term Liabilities	$ 462	$ 299
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 and none on September 30, 2020 respectively; 3,679,778 issued and outstanding shares at December 31, 2019 and none on September 30, 2020; aggregate liquidation preference value of $23,919 and $0 at December 31, 2019 and September 30, 2020 respectively	$ —	$ 23,823
Series B Preferred Stock of $0.01 par value per share; 4,500,000 shares authorized at December 31, 2019 and none on September 30, 2020 respectively; 3,750,674 issued and outstanding shares at December 31, 2019 and none on September 30, 2020; aggregate liquidation preference value of $29,668 and $0 at December 31, 2019 and September 30, 2020 respectively	—	29,550
Total Convertible Preferred Stock	$ —	$ 53,373
STOCKHOLDERS' STOCKHOLDERS' DEFICIT:		
Common Stock of $0.01 par value per share; 20,000,000 shares authorized at December 31, 2019 and September 30, 2020; 5,064,722 and 12,781,909 shares issued at December 31, 2019 and September 30, 2020, respectively; 4,998,874 and 12,670,160 shares outstanding at December 31, 2019 and September 30, 2020, respectively	$ 127	$ 51
Additional Paid-in Capital	108,294	1,770
Accumulated Deficit	(61,489)	(40,741)
Total Stockholders' Equity (Deficit)	46,932	(38,920)
Total Liabilities, Convertible Preferred Stock, and Stockholders' Equity	$ 53,393	$ 20,054

AYALA PHARMACEUTICAL, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share & per share amounts)

For the Three Months ended September 30,		For the Nine Months ended September 30,	
2020	**2019**	**2020**	**2019**

Revenues from licensing agreement	$ 658	$ 845	$ 2,704	$ 1,962
Cost of services	658	485	2,704	910
Gross profit	—	360	—	1,052
Operating expenses:				
Research and development	5,421	4,372	15,616	10,563
General and administrative	1,862	945	4,719	2,814
Operating loss	(7,283)	(4,957)	(20,335)	(12,325)
Financial loss, net	(40)	(51)	(38)	183
Loss before income tax	(7,323)	(5,008)	(20,373)	(12,142)
Taxes on income	(115)	(39)	(375)	(227)
Net loss attributable to common stockholders	(7,438)	(5,047)	(20,748)	(12,369)
Net Loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (1.01)	$ (2.33)	$ (2.49)
Weighted average common shares outstanding, basic and diluted	**12,664,485**	**4,974,839**	**8,894,182**	**4,974,641**