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

November 15, 2021

- Presented Preliminary Clinical Data from 6mg Cohort of Phase 2 ACCURACY Trial of AL101 in R/M ACC Demonstrating 70% Disease Control Rate at ESMO 2021 –

- Presented Pre-Clinical Proof of Concept Data for Enhanced Activity of AL101 in Combination with Approved Cancer Therapies in ACC-

- Published Case Studies Highlighting Clinical Activity of AL101 with Long-Lasting Responses in Patients with Desmoid Tumors –

- Enrollment in All Ongoing Studies is on Track and Have Progressed as Planned –

- Multiple Milestones Across Clinical-Stage Pipeline Expected in 2022 -

REHOVOT, Israel & WILMINGTON, Del., Nov. 15, 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 period ended September 30, 2021 and highlighted recent progress and upcoming milestones for its pipeline programs.

“As we gear up for multiple important milestones in 2022 across all of our clinical-stage programs in various indications, including desmoid tumors, triple negative breast cancer, adenoid cystic carcinoma and potentially multiple myeloma, we remain steadfast in our approach to developing gamma secretase inhibitors to treat these genetically defined cancers,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “We are incredibly pleased with the safety and efficacy profile of AL101 for the treatment of recurrent/metastatic adenoid cystic carcinoma harboring Notch-activating mutations, as presented at ESMO in September, as well as the strong preclinical rationale for potential combination treatment in this indication and other tumor types. We also continued to progress our pivotal RINGSIDE trial evaluating AL102 for the treatment of desmoid tumors as enrollment continues across multiple sites globally and look forward to reporting preliminary results from this trial in mid-2022. In addition, we are very pleased with our ongoing collaboration with Novartis and the status of the study of our AL102 in combination with their anti BCMA agent for multiple myeloma.”

Recent Business Highlights and Upcoming Milestones:

- **Published Two Case Studies Highlighting Clinical Activity of AL101 in Desmoid Tumors in *Current Oncology*:** In September 2021, Ayala published two case studies of adult patients with desmoid tumors treated with AL101. Both patients experienced significant tumor burden and symptomatic and life-threatening disease due to disease bulk and location. With AL101 treatment, both subjects achieved long-lasting partial responses with a maximal decrease in tumor size from baseline of 41% after approximately 1 year (55 weeks) of treatment in Case One, and a maximal decrease in tumor size from baseline of 60% after about 1.6 years (82 weeks) of treatment in Case Two.

- **On Track to Report Initial Interim Data from Part A of the Pivotal Phase 2/3 RINGSIDE Trial for the Treatment of Desmoid Tumors in Mid-2022**: Enrollment continues to progress globally in the Phase 2/3 RINGSIDE Trial of AL102. Ayala expects to report an initial interim data read-out from part A of the trial in mid-2022, with part B of the study commencing thereafter.

- **Phase 1 Trial of AL102 in Combination with Novartis’ BCMA Targeting Agent, WVT087 for the Treatment of Relapsed/Refractory Multiple Myeloma Continues to Progress:** Enrollment progresses as planned in the 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 (R/R) multiple myeloma (MM).

- **Presented Preliminary Clinical Data from the Ongoing Phase 2 ACCURACY Trial and ACC at European Society for Medical Oncology (ESMO) Virtual Congress 2021**: In September 2021, Ayala presented updated interim data from the 6mg 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. The data demonstrated meaningful clinical activity of AL101 6mg monotherapy with a 70% disease control rate across 33 evaluable patients. Partial responses were observed in three subjects (9%) and stable disease was observed in 20 subjects (61%). The 6mg dose of AL101 was well tolerated with manageable side effects consistent with those observed in the 4mg cohort.

- **Presented Preclinical Proof of Concept Data of AL101 in Combination with Approved Cancer Therapies in ACC at ESMO:** In September 2021, Ayala also presented a preclinical study evaluating the potential of combination therapy of AL101 in PDX models of ACC, comparing the differential gene expression of ACC tumors versus normal matched tissue

regardless of Notch activation status. AL101 in combination demonstrated significant tumor growth inhibition, including regressions, compared to each drug alone, and the study indicated that crosstalk between signaling pathways may increase the efficacy of AL101 in R/M ACC regardless of Notch mutational status.

- **Phase 2 TENACITY Trial of AL101 for the Treatment of Triple Negative Breast Cancer Continues to Progress:** Ayala continues to enroll patients in the Phase 2 TENACITY clinical trial of AL101, for the treatment of patients with Notch-activated recurrent or metastatic (R/M) triple negative breast cancer (TNBC). The Company expects to report preliminary data from this ongoing trial in 2022.

Third Quarter 2021 Financial Results

- **Cash Position:** Cash and cash equivalents were $40.8 million as of September 30, 2021, as compared to $42.0 million as of December 31, 2020.
- **Collaboration Revenue:** Collaboration revenue was $0.6 million for the third quarter of 2021, as compared to $0.7 million for the same period in 2020.
- **R&D Expenses:** Research and development expenses were $7.4 million for the third quarter of 2021, compared to $5.4 million for the same period in 2020. The increase was primarily driven by the advancement in our clinical trials.
- **G&A Expenses:** General and administrative expenses were $2.2 million for the third quarter of 2021, compared to $1.9 million for the same period in 2020.
- **Net Loss:** Net loss was $9.8 million for the third quarter of 2021, resulting in a basic and diluted net loss per share of $0.68. Net loss was $7.4 million for the same period in 2020, resulting in a basic and diluted net loss per share of $0.59.

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 in a Pivotal 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.

Investors:
Julie Seidel
Stern Investor Relations, Inc.
+1-212-362-1200
Julie.seidel@sternir.com

Ayala Pharmaceuticals:
+1-857-444-0553
info@ayalapharma.com

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 patient enrollment. 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)

	September 30 2021	December 31 2020
	(Unaudited)	
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 40,840	$ 42,025
Short-term Restricted Bank Deposits	120	90
Trade Receivables	373	681
Prepaid Expenses and other Current Assets	2,991	1,444
Total Current Assets	44,324	44,240
LONG-TERM ASSETS:		
Other Assets	$ 272	$ 305
Property and Equipment, Net	1,148	1,283
Total Long-Term Assets	1,420	1,588
Total Assets	**$ 45,744**	**$ 45,828**
LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade Payables	$ 2,888	$ 3,726
Other Accounts Payables	2,979	3,151
Total Current Liabilities	5,867	6,877
LONG TERM LIABILITIES:		
Long-term Rent Liability	493	553
Total Long-Term Liabilities	$ 493	$ 553
STOCKHOLDERS' STOCKHOLDERS' EQUITY:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 13,685,554 and 12,824,463 shares issued at September 30, 2021 and, respectively December 31, 2020; 13,549,362 and 12,728,446 shares outstanding at September 30, 2021 and December 31, 2020, respectively	$ 135	$ 128
Additional Paid-in Capital	140,341	109,157
Accumulated Deficit	(101,092)	(70,887)
Total Stockholders' Equity	39,384	38,398
Total Liabilities and Stockholders' Equity	**$ 45,744**	**$ 45,828**

AYALA PHARMACEUTICALS, INC.
CONDENSED 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,	
	2021	2020	2021	2020
Revenues from licensing agreement	$ 625	$ 658	$ 2,360	$ 2,704
Cost of services	(625)	(658)	(2,360)	(2,704)
Gross profit	—	—	—	—

Operating expenses:				
Research and development	7,368	5,421	22,414	15,616
General and administrative	2,198	1,862	7,037	4,719
Operating loss	(9,566)	(7,283)	(29,451)	(20,335)
Financial Income (Loss), net	(63)	(40)	(177)	(38)
Loss before income tax	(9,629)	(7,323)	(29,628)	(20,373)
Taxes on income	(167)	(115)	(577)	(375)
Net loss attributable to common stockholders	(9,796)	(7,438)	(30,205)	(20,748)
Net Loss per share attributable to common stockholders, basic and diluted	$ (0.68)	$ (0.59)	$ (2.14)	$ (2.33)
Weighted average common shares outstanding, basic and diluted	**14,483,629**	**12,664,485**	**14,130,993**	**8,894,182**