Arvinas Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

February 27, 2024

– Enrollment continues globally in multiple clinical studies of vepdegestrant (ARV-471) in ER+/HER2- metastatic breast cancer, including the VERITAC-2 Phase 3 trial in the second-line setting and the study lead-in for the VERITAC-3 Phase 3 trial in the first-line setting –

– Pending further data and discussions with regulatory authorities, the expanded development plan for vepdegestrant will include a new Phase 3 trial in combination with CDK4/6 inhibitors in the second-line setting and a new Phase 3 trial of vepdegestrant plus Pfizer's novel CDK4 inhibitor in the first-line setting –

– Prioritized second-generation PROTAC® AR degrader ARV-766 after updated data showed robust efficacy in tumors with all AR LBD mutations in mCRPC –

– Received regulatory clearance to initiate first-in-human Phase 1 clinical trials for PROTAC® targeting BCL6 and the first neuroscience PROTAC® degrader targeting LRRK2 –

NEW HAVEN, Conn., Feb. 27, 2024 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

"Our focused execution in 2023 enabled us to progress multiple trials across our entire portfolio and we are well-positioned for a catalyst rich year ahead, including completing our first Phase 3 trial," said John Houston, Ph.D., president and chief executive officer at Arvinas. "Our collaboration with Pfizer remains strong and we are on track to report topline data from our first Phase 3 clinical trial with vepdegestrant, the only PROTAC® ER degrader in clinical development for patients with ER+/HER2- breast cancer. If successful, assuming regulatory approval, we have the opportunity to address an area of high unmet need and offer patients a new oral treatment option in the second-line metastatic breast cancer setting. And with the recent Phase 1 initiation with our LRRK2 PROTAC® degrader – our first neuroscience program – we continue making significant progress with our novel PROTAC® technology."

Recent Developments and Fourth Quarter Business Highlights

Vepdegestrant (ARV-471)

- Received U.S. Food and Drug Administration Fast Track designation for the investigation of vepdegestrant for monotherapy in the treatment of adults with estrogen receptor (ER) positive/human growth epidermal growth factor 2 (HER2) negative (ER+/HER2-) locally advanced or metastatic breast cancer previously treated with endocrine-based therapy.
- Presented interim results (data cutoff: June 6, 2023) from the Phase 1b vepdegestrant and palbociclib *(IBRANCE®)* combination cohort at the 2023 San Antonio Breast Cancer Symposium (SABCS), which demonstrated encouraging clinical activity in heavily pre-treated patients with locally advanced or metastatic ER+/HER2- breast cancer with a median of four lines of therapy across disease settings.
    - A clinical benefit rate (CBR, defined as the rate of confirmed complete response, partial response, or stable disease ≥ 24 weeks) of 63% (95% CI: 47.5–76.8), or 29/46 patients; at the recommended Phase 3 dose of 200 mg (n=21), the CBR was 67% (95% CI: 43.0 – 85.4), or 14/21 patients.
    - An objective response rate (ORR) in evaluable patients with measurable disease at baseline (n=31) of 42% (95% CI: 24.5–60.9), or 13/31 patients; at the RP3D of 200 mg (n=15), the ORR was 53% (95% CI: 26.6 – 78.7); the median duration of response was 10.2 months.
    - Median progression free survival (PFS) of 11.1 months (95% CI: 8.2 – NE); 22 of 46 patients across all doses had progression events by time of data cutoff.
        - Median PFS of 11.1 and 11.0 months in patients with ESR1 wild-type and ESR1 mutant tumors, respectively.
    - The safety profile of vepdegestrant plus palbociclib was manageable. The primary toxicity was neutropenia, which was managed with palbociclib dose modifications (reductions and/or interruptions) per protocol. There was no febrile neutropenia and 3 of 46 patients discontinued due to neutropenia.
- Initiated Phase 1b/2 with vepdegestrant plus Pfizer's novel CDK4 inhibitor (PF-07220060) (TACTIVE-K: ClinicalTrials.gov Identifier: NCT06206837).
- Initiated an additional arm of the Phase 1b/2 combination umbrella trial with the CDK7 inhibitor samuraciclib (TACTIVE-U: ClinicalTrials.gov Identifiers: NCT05548127, NCT05573555, and NCT06125522).
- Completed enrollment in the TACTIVE-N Phase 2 trial of vepdegestrant as a monotherapy in the neoadjuvant setting in patients with ER+/HER2- localized breast cancer (ClinicalTrials.gov Identifier: NCT05549505).

- Completed enrollment in the TACTIVE-E Phase 1 trial of vepdegestrant in combination with everolimus for the treatment of advanced or metastatic ER+/HER2- breast cancer (ClinicalTrials.gov Identifier: NCT05501769).

Androgen Receptor PROTAC® degraders

- Presented data from the Phase 1/2 clinical trial with bavdegalutamide (ARV-110) at the European Society for Medical Oncology (ESMO) Congress showing a median radiographic progression free survival (rPFS) of 11.1 months in patients with AR 878/875 tumor mutations, demonstrating the strong potential for a PROTAC® AR degrader in prostate cancer.
    - Manageable tolerability profile with no grade ≥4 treatment-related adverse events (TRAEs).
- Selected our second generation PROTAC® AR degrader, ARV-766, as the lead program in prostate cancer and prioritized the initiation of a Phase 3 trial with ARV-766 in metastatic castrate resistant prostate cancer (mCRPC).
    - New interim data from Phase 1/2 trial with ARV-766 showed a broader efficacy profile and superior tolerability versus bavdegalutamide in the clinical setting, with a potentially differentiated profile against other AR-directed therapies.
- Completed enrollment in the bavdegalutamide Phase 1b combination trial with abiraterone.

Pipeline

- Received authorization from the European Medicines Agency to initiate clinical trials with the Company's new PROTAC ® degrader, ARV-102, designed to target the LRRK2 protein.
- Initiated first-in-human Phase 1 clinical trial in healthy volunteers with LRRK2 targeting PROTAC® ARV-102.
- Received clearance from the U.S. Food and Drug Administration to initiate clinical trials with the Company's PROTAC ® degrader, ARV-393, designed to target the BCL6 protein.

Corporate

- Completed oversubscribed $350 million private placement co-led by EcoR1 Capital and RTW Investments LP, with participation by new and existing investors.
- Announced the resignation of Chief Financial Officer and Treasurer, Sean Cassidy, effective February 29, 2024.
- Announced the appointment of Randy Teel, Ph.D., Arvinas' current senior vice president of corporate and business development, to the role of interim chief financial officer and treasurer.
    - The Arvinas Board of Directors has launched a formal search process to identify Mr. Cassidy's permanent replacement.
- Appointed Jared Freedberg, J.D., as general counsel.
- Entered into a new collaboration with Pfizer to identify novel chemical matter for E3 ligases leveraging Pfizer's proprietary compound libraries and Arvinas' ligase ligand expertise.

Anticipated Upcoming Milestones and Expectations
Vepdegestrant (ARV-471)
As part of Arvinas' global collaboration with Pfizer, the companies plan to:

- Complete enrollment of the VERITAC-2 Phase 3 monotherapy trial (ClinicalTrials.gov Identifier: NCT05654623) in patients with metastatic breast cancer (2H 2024).
- Continue enrollment in the study lead-in for the VERITAC-3 Phase 3 trial of vepdegestrant and palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer.
- Continue enrollment of the ongoing Phase 1b/2 clinical trial with vepdegestrant plus Pfizer's novel CDK4 inhibitor (PF-07220060) (TACTIVE-K: ClinicalTrials.gov Identifier: NCT06206837).
- Continue enrollment of the ongoing Phase 1b combination umbrella trial evaluating combinations of vepdegestrant with abemaciclib, ribociclib, or samuraciclib (TACTIVE-U: ClinicalTrials.gov Identifiers: NCTC05548127, NCTC05573555, and NCT06125522).
- Initiate discussion with regulatory authorities on a second-line Phase 3 trial of vepdegestrant in combination with palbociclib and potentially other CDK4/6 inhibitors, and a new first-line Phase 3 trial of vepdegestrant plus Pfizer's novel CDK4 inhibitor (PF-07220060).

ARV-766

- Continue enrollment of Phase 2 dose expansion study with ARV-766, with progression free survival data anticipated in mid-2024.
- Continue enrollment of Phase 1b/2 dose escalation trial with ARV-766 in combination with abiraterone in patients who have not previously received novel hormonal agents.

- Initiate discussions with regulatory authorities for a planned Phase 3 clinical trial with ARV-766 in mCRPC (2Q 2024).

Pipeline

- Continue enrollment in Phase 1 clinical trial in healthy volunteers with LRRK2 targeting PROTAC® ARV-102 (2024)
- Initiate first-in-human Phase 1 clinical trial in B-cell lymphomas with BCL6 targeting PROTAC® ARV-393 (1H 2024)

Financial Guidance
Based on its current operating plan, Arvinas believes its cash, cash equivalents, restricted cash and marketable securities as of December 31, 2023, is sufficient to fund planned operating expenses and capital expenditure requirements into 2027.

Full Year and Fourth Quarter Financial Results

Cash, Cash Equivalents and Marketable Securities Position: As of December 31, 2023, cash, cash equivalents, restricted cash and marketable securities were $1,266.5 million, as compared with $1,210.8 million as of December 31, 2022. The increase in cash, cash equivalents, restricted cash and marketable securities of $55.7 million for the year was primarily related to net proceeds from our private placement and ATM offerings of $370.2 million, unrealized gains on marketable securities of $16.1 million and proceeds from the exercise of stock options and issuance of ESPP shares of $4.5 million, offset by cash used in operations of $331.3 million (net of $2.5 million received from two collaborators), purchases of lab equipment and leasehold improvements of $2.9 million and losses on the sale of securities of $0.9 million.

Research and Development Expenses: Research and development expenses were $379.7 million and $95.2 million for the year and quarter ended December 31, 2023, as compared with $315.0 million and $98.3 million for the year and quarter ended December 31, 2022. The increase in research and development expenses of $64.7 million for the year was primarily due to an increase in expenses associated with our platform and exploratory programs of $1.1 million, our AR program (which includes ARV-766 and bavdegalutamide (ARV-110)) of $22.0 million and our ER program of $41.6 million, which includes the cost sharing of vepdegestrant (ARV-471) under the Vepdegestrant (ARV-471) Collaboration Agreement. The decrease in research and development expenses of $3.1 million for the quarter was primarily due to a decrease in expenses associated with our platform and exploratory programs of $19.4 million, offset by increases in our AR program of $5.7 million and our ER program of $10.6 million.

General and Administrative Expenses: General and administrative expenses were $100.3 million and $27.0 million for the year and quarter ended December 31, 2023, as compared with $79.6 million and $15.1 million for the year and quarter ended December 31, 2022. The increase in general and administrative expenses of $20.7 million for the year was primarily due to an increase in personnel and infrastructure related costs of $11.5 million, an increase in professional fees of $6.3 million and increases related to establishing our commercial operations of $3.5 million, offset in part by reduced insurance costs of $1.0 million. The increase in general and administrative expenses of $11.9 million for the quarter was primarily due to an increase in personnel and infrastructure related costs of $8.4 million, an increase in professional fees of $1.8 million and increases related to establishing our commercial operations of $1.7 million.

Revenues: Revenue was $78.5 million and $(43.1) million for the year and quarter ended December 31, 2023 as compared with $131.4 million and $38.0 million for the year and quarter ended December 31, 2022. Revenue is related to the Vepdegestrant (ARV-471) Collaboration Agreement, the collaboration and license agreement with Bayer, the collaboration and license agreement with Pfizer, the amended and restated option, license and collaboration agreement with Genentech and revenue related to our Oerth Bio joint venture. The decrease of $52.9 million for the year was primarily due to adjustments to revenue from changes in contract estimates related to our Pfizer ARV-471 Collaboration Agreement, Pfizer Research Collaboration Agreement and Bayer Collaboration Agreement, net of current year revenues, totaling $39.7 million, a decrease of $8.1 million in previously constrained deferred revenue recognized in 2023 related to our Oerth Bio joint venture and a decrease in revenue recognized from our Genentech License Agreement of $5.1 million. The decrease of $81.1 million for the quarter was primarily due to an adjustment to revenue from a change in contract estimate related to our Pfizer ARV-471 Collaboration Agreement.

About bavdegalutamide (ARV-110) and ARV-766
Bavdegalutamide (ARV-110) and ARV-766 are investigational orally bioavailable PROTAC® protein degraders designed to selectively target and degrade the androgen receptor (AR). Bavdegalutamide and ARV-766 are being developed as potential treatments for men with prostate cancer. Preclinically, both investigational agents have demonstrated activity in models of wild type tumors in addition to tumors with AR mutation or amplification, both common mechanisms of resistance to currently available AR-targeted therapies.

About vepdegestrant (ARV-471)
Vepdegestrant is an investigational, orally bioavailable PROTAC® protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with early and locally advanced or metastatic ER positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. Use of vepdegestrant in the ongoing and planned clinical trials will continue to monitor and evaluate patient safety and anti-tumor activity.

In preclinical studies, vepdegestrant demonstrated up to 97% ER degradation in tumor cells, induced tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed increased anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in combination with a CDK4/6 inhibitor. In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits.

About Arvinas
Arvinas is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development, and commercialization of therapies that degrade disease-causing proteins. Arvinas uses its proprietary PROTAC® Discovery Engine platform to engineer proteolysis targeting chimeras, or PROTAC® targeted protein degraders, that are designed to harness the body's own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. In addition to its robust preclinical pipeline of PROTAC protein degraders against validated and "undruggable" targets, the company has four investigational clinical-stage programs: vepdegestrant (ARV-471) for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer; ARV-766 and bavdegalutamide for the treatment of men with metastatic castration-resistant prostate cancer; and ARV-102 for the treatment of patients with neurodegenerative disorders. For more information, visit **www.arvinas.com**.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding plans with respect to an expanded development plan for vepdegestrant including a new Phase 3 trial in combination with CDK4/6 inhibitors in the second-line setting and a new Phase 3 trial of vepdegestrant plus Pfizer's novel CDK4 inhibitor in the first-line setting, pending further data and discussions with regulatory authorities; the anticipated timing to complete Arvinas' first Phase 3 clinical trial with vepdegestrant; the potential, pending regulatory approval, for vepdegestrant to address an area of high unmet need and offer patients a new oral treatment option in the second-line metastatic breast cancer setting; Arvinas' and Pfizer's plans with respect to the timing of ongoing and planned clinical trials of vepdegestrant, as a monotherapy and in combination studies, and the initiation of discussions with regulatory authorities regarding new potential clinical trials; Arvinas' plans with respect to its clinical trials of ARV-766, the anticipated timing of progression free survival data for the Phase 2 dose expansion study of ARV-766 and the initiation of discussions with regulatory authorities for a planned Phase 3 clinical trials of ARV-766; Arvinas' plans with respect to its ARV-102 clinical trial and timing related to initiating the first-in-human Phase 1 clinical trial in B-cell lymphomas with BCL6 targeting PROTAC®; the potential advantages and therapeutic benefits of vepdegestrant (ARV-471), ARV-766, bavdegalutamide, and Arvinas' other discovery programs, including LRRK2 and BCL6; and the sufficiency of Arvinas' cash, cash equivalents, restricted cash and marketable securities resources to fund planned operating expenses and capital expenditure requirements. All statements, other than statements of historical facts, contained in this press release, including statements regarding Arvinas' strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Arvinas may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Arvinas makes as a result of various risks and uncertainties, including but not limited to: Arvinas' and Pfizer, Inc.'s ("Pfizer") performance of the respective obligations with respect to Arvinas' collaboration with Pfizer; whether Arvinas and Pfizer will be able to successfully conduct and complete clinical development for vepdegestrant (ARV-471); whether Arvinas will be able to successfully conduct and complete development for its other product candidates, including ARV-766, and including whether Arvinas initiates and completes clinical trials for its product candidates and receive results from its clinical trials on its expected timelines or at all; whether Arvinas and Pfizer, as appropriate, will be able to obtain marketing approval for and commercialize vepdegestrant (ARV-471), ARV-766 and other product candidates on current timelines or at all; Arvinas' ability to protect its intellectual property portfolio; whether Arvinas' cash and cash equivalent resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the "Risk Factors" section of Arvinas' Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent other reports on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Arvinas' current views with respect to future events, and Arvinas assumes no obligation to update any forward-looking statements, except as required by applicable law. These forward-looking statements should not be relied upon as representing Arvinas' views as of any date subsequent to the date of this release.

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ARVINAS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets (Unaudited)

(dollars and shares in millions, except per share amounts)	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 311.7	$ 81.3
Restricted cash	5.5	5.5
Marketable securities	949.3	1,124.0
Accounts receivable	—	1.0
Other receivables	7.2	7.0
Prepaid expenses and other current assets	6.5	21.4
Total current assets	1,280.2	1,240.2
Property, equipment and leasehold improvements, net	11.5	13.4
Operating lease right of use assets	2.5	4.4
Collaboration contract asset and other assets	10.4	10.8
Total assets	$ 1,304.6	$ 1,268.8
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 92.2	$ 74.7

Deferred revenue	163.0	218.6
Current portion of operating lease liability	1.9	1.8
Total current liabilities	257.1	295.1
Deferred revenue	386.2	405.1
Long term debt	0.8	1.0
Operating lease liability	0.5	2.7
Total liabilities	644.6	703.9
Stockholders' equity:		
Preferred stock, $0.001 par value, zero shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Common stock, $0.001 par value, 68.0 and 53.2 shares issued and outstanding as of December 31, 2023 and 2022, respectively	0.1	0.1
Accumulated deficit	(1,332.7)	(965.4)
Additional paid-in capital	1,995.7	1,549.4
Accumulated other comprehensive loss	(3.1)	(19.2)
Total stockholders' equity	660.0	564.9
Total liabilities and stockholders' equity	$ 1,304.6	$ 1,268.8

ARVINAS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
(dollars and shares in millions, except per share amounts)	**2023**	**2022**	**2023**	**2022**
Revenue	$ (43.1)	$ 38.0	$ 78.5	$ 131.4
Operating expenses:				
Research and development	95.2	98.3	379.7	315.0
General and administrative	27.0	15.1	100.3	79.6
Total operating expenses	122.2	113.4	480.0	394.6
Loss from operations	(165.3)	(75.4)	(401.5)	(263.2)
Interest and other income	12.1	6.3	37.6	12.2
Net loss before income taxes and loss from equity method investment	(153.2)	(69.1)	(363.9)	(251.0)
Income tax expense	(1.6)	(10.8)	(0.9)	(20.9)
Loss from equity method investment	—	(3.0)	(2.5)	(10.6)
Net loss	$ (154.8)	$ (82.9)	$ (367.3)	$ (282.5)
Net loss per common share - basic and diluted	$ (2.53)	$ (1.56)	$ (6.62)	$ (5.31)
Weighted average common shares outstanding - basic and diluted	61.1	53.2	55.5	53.2