UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 22, 2022

Arvinas, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38672**	**47-2566120**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5 Science Park **395 Winchester Ave.** **New Haven, Connecticut**	**06511**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (203) 535-1456

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**ARVN**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On November 22, 2022, Arvinas, Inc. (the "Company") will present clinical program updates for its novel investigational PROTAC® estrogen receptor protein degrader, ARV-471, on a conference call and webcast. A copy of the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Company Presentation, dated November 22, 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARVINAS, INC.

Date: November 22, 2022

By: /s/ Sean Cassidy

Sean Cassidy
Chief Financial Officer

Exhibit 99.1

ARVINAS

ARV-471: Phase 2 VERITAC Trial Results

November 22, 2022

Safe harbor and forward-looking statements

This presentation 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 the including statements regarding the potential for ARV-471 to become a a best-in-class estrogen receptor targeting therapy and the timing of expected future trials of our ARV-471, including any combination studies. 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.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of various risks and uncertainties, including but not limited to: whether we and Pfizer will be able to successfully conduct clinical development for ARV-471 and receive results from our clinical trials on our expected timelines, or at all, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of our quarterly and annual reports on file with the Securities and Exchange Commission. The forward-looking statements contained in this presentation reflect our current views as of the date of this presentation with respect to future events, and we assume 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 our views as of any date subsequent to the date of this presentation.

The Arvinas name and logo are our trademarks. We also own the service mark and the registered U.S. trademark for PROTAC®. The trademarks, trade names and service marks appearing in this presentation are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks named in this presentation.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

This presentation is intended for the investor community only. It is not intended to promote the products referenced herein or otherwise influence healthcare prescribing decisions. Cross-trial comparisons are not based on head-to head studies and no direct comparisons can be made.

Agenda

Topic	Participant	
Introduction	John G. Houston, Ph.D.	*President and Chief Executive Officer, Arvinas*
ARV-471: VERITAC Clinical Data Update	Ron Peck, M.D.	*Chief Medical Officer, Arvinas*
Conclusions	John G. Houston, Ph.D.	*President and Chief Executive Officer, Arvinas*
Q&A	*Includes:* Chris Boshoff, M.D., Ph.D.	*Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development*

ARV-471: Potential best-in-class estrogen receptor-targeting therapy

Continued signals of efficacy across the Phase 1/2 trial in a patient population with **100% pretreatment with CDK4/6 inhibitors**

- To our knowledge, this is the **most heavily pre-treated patient population evaluated** with an ER-targeted therapy to date, and is expected to have highly ER-independent disease
- In VERITAC: 100% prior CDK4/6i, 79% prior fulvestrant, and 73% prior chemo (45% in the metastatic setting)

	Clinical Benefit Rate (n)[a]
December 2020 (Phase 1 dose escalation)	42% (5 of 12)
December 2021 (Phase 1 dose escalation)	40% (19 of 47)
December 2022 (Phase 2 cohort expansion [VERITAC])	38% (71 of 71)

In VERITAC, favorable tolerability at both 200 mg qd and 500 mg qd

- No single TRAE in more than ~20% of patients
- In 35 patients treated at 200mg (RP3D), no dose reductions and only 1 discontinuation
- In this expansion cohort, no signal for bradycardia or visual disturbance

Expect to begin two Ph 3 pivotal studies and in multiple ongoing combination and monotherapy studies with the potential position ARV-471 as the ER therapy of choice across ER+/HER2- breast cancer

- 2L monotherapy Ph 3 to test patients with both ESR1-mutant tumors and all-comers (4Q 2022)
- 1L combination Ph3 with palbociclib in patients without prior CDK4/6i (1Q 2023)

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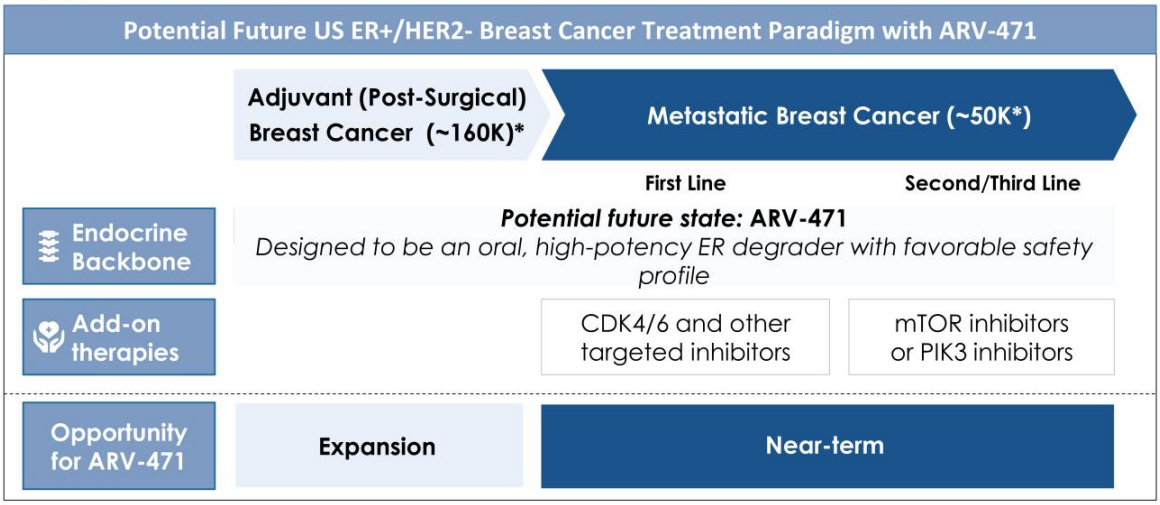
[a]Rate of confirmed complete response or partial response or stable disease ≥24 weeks
CBR=clinical benefit rate; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; PFS=progression-free survival; TRAE, treatment-related adverse events; RP3D, recommended Phase 3 dose; CDK, cyclin-dependent kinase

ARV-471: Potential to be the endocrine backbone of choice for ER+/HER2- breast cancer treatment



*U.S. incident population per year from SEER database
CDK: cyclin-dependent kinases, Pi3K: phosphoinositide 3-kinase; mTOR: mammalian target of rapamycin

Studies with SERDs or ARV-471 Include a Wide Range of Prior Therapies

VERITAC has most prior therapies among key studies

		CDK4/6 inhibitor	Fulvestrant	Chemotherapy in advanced / metastatic setting
PALOMA-3[1]	**Phase 3 study of palbociclib plus fulvestrant vs placebo plus fulvestrant (N=521)**	0	0	34%‡
acelERA[2]	**Phase 2 study of giredestrant vs SOC† (N=303)**	42%*	19%*	32%
SERENA-2[3]	**Phase 2 study of camizestrant vs fulvestrant (N=240)**	50%	0	19%
AMEERA-3[2]	**Phase 2 study of amcenestrant vs SOC† (N=290)**	79%*,‡	10%*,‡	11%‡
VERONICA[4]	**Phase 2 study of venetoclax plus fulvestrant vs fulvestrant (N=103)**	**100%**	**0**	**0**
EMERALD[5]	**Phase 3 study of elacestrant vs SOC† (N=477)**	**100%**	**30%**	**22%**
VERITAC	**Phase 2 expansion cohorts of ARV-471 (N=71)**	**100%**	**79%**	**45%**

Expected Efficacy

Expected Resistance

[1]Lancet Oncol 2016. [2]ESMO 2022. [3]San Antonio Breast Cancer Symposium 2022. [4]Clin Cancer Res 2022..[5]J Clin Oncol 2022.
*Advanced/metastatic setting. †Physician's choice of fulvestrant or an aromatase inhibitor; tamoxifen also permitted in AMEERA-3. SOC=standard of care
‡Published data, manually calculated for overall population

ARV-471: VERITAC Phase 2 Detailed Results

Ron Peck, M.D.

Chief Medical Officer, Arvinas

Phase 2 (VERITAC) Cohort Expansion Design

Phase 2 cohort expansion (Part B; VERITAC)

Key eligibility criteria

- Histologically or cytologically confirmed ER+ and HER2- advanced breast cancer
- Measurable or non-measurable disease per RECIST criteria v1.1
- ≥1 prior endocrine regimen (≥1 regimen for ≥6 months in the locally advanced or metastatic setting)
- ≥1 prior CDK4/6 inhibitor
- ≤1 prior chemotherapy regimen in the locally advanced or metastatic setting

ARV-471 200 mg orally QD[a] (n=35)

ARV-471 500 mg orally QD[a] (n=36)

Primary endpoint

- CBR (rate of confirmed CR or PR or SD ≥24 weeks)[b]

Secondary endpoints

- ORR, DOR, PFS, and OS
- AEs and laboratory abnormalities
- PK parameters

Exploratory endpoints

- *ESR1* mutational status
- ER protein levels

Data cutoff date for this analysis

- June 6, 2022

[a]Enrollment in the 200-mg QD cohort began before enrollment in the 500-mg QD cohort, [b]Analyzed in patients enrolled ≥24 weeks prior to the data cutoff
AE=adverse event; CBR=clinical benefit rate; CDK=cyclin-dependent kinase; CR=complete response; DOR=duration of response; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; HER2=human epidermal growth factor receptor 2; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PK=pharmacokinetic; PR=partial response; QD=once daily; RECIST=Response Evaluation Criteria in Solid Tumors; SD=stable disease

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Patient Baseline Characteristics (VERITAC)

Characteristic	Total (N=71)
Sex, n (%)	
Female	69 (97.2)
Median age, y (range)	60 (41–86)
ECOG PS, n (%)[a]	
0	47 (66.2)
1	23 (32.4)
Visceral disease, n (%)	39 (54.9)
Sites of metastasis, n (%)	
Bone	49 (69.0)
Liver	32 (45.1)
Lung	17 (23.9)
Other	5 (7.0)

Characteristic	Total (N=71)
Baseline *ESR1* status, n (%)[b]	
Mutant	41 (57.7)
Wild-type	25 (35.2)
Median no. of prior regimens (range)	
Any setting	4 (1–10)
Metastatic setting	3 (0–7)
Type of prior therapy, n (%)	
CDK4/6 inhibitor	71 (100)
Aromatase inhibitor	64 (90.1)
Fulvestrant	56 (78.9)
Chemotherapy	
Any setting	52 (73.2)
Metastatic setting	32 (45.1)

[a]Baseline ECOG PS status was unknown in 1 patient. [b]Baseline *ESR1* status was unknown or missing in 5 patients; CDK=cyclin-dependent kinase; ECOG PS=Eastern Cooperative Oncology Group performance status; *ESR1*=estrogen receptor 1 gene

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Primary Endpoint: Clinical Benefit Rate[a] (VERITAC)

	200 mg QD (n=35)	500 mg QD (n=36)	Total (N=71)
CBR, % (95% CI)	37.1 (21.5–55.1)	38.9 (23.1–56.5)	38.0 (26.8–50.3)
Patients with mutant *ESR1*	(n=19)	(n=22)	(n=41)
CBR, % (95% CI)	47.4 (24.4–71.1)	54.5 (32.2–75.6)	51.2 (35.1–67.1)

- CBR consistent with Phase 1 dose escalation data
  - Phase 1: 40% in all patients, 50% in patients with *ESR1*-mutant tumors
- Patients with WT ESR1 (n=25) exhibited CBR rate of 20%

[a]Rate of confirmed complete response or partial response or stable disease ≥24 weeks
CBR=clinical benefit rate; *ESR1*=estrogen receptor 1 gene; QD=once daily

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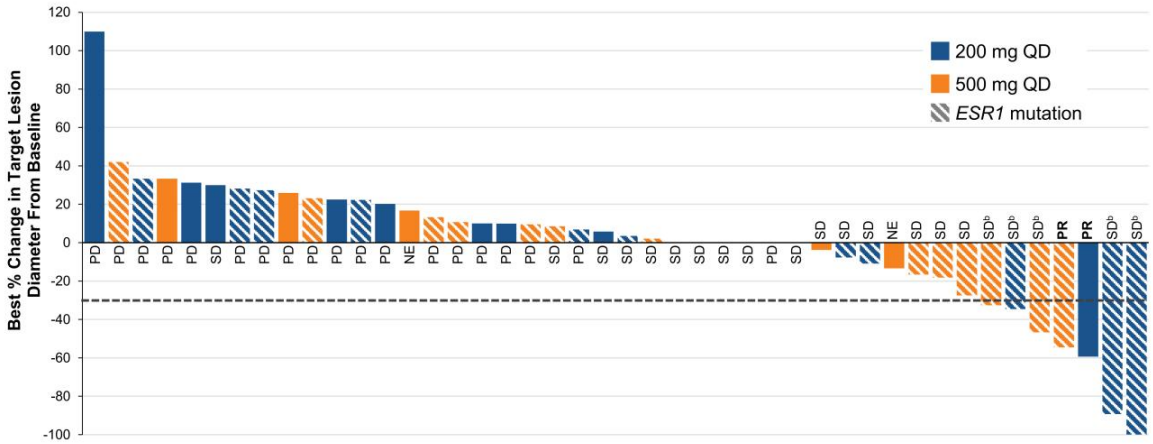
Tumor Response[a] (VERITAC)



[a]Includes patients with measurable disease (n=44); 1 patient with measurable disease at baseline and PD as best overall response was excluded due to lack of complete set of target lesion measurements on-study
[b]Patient had an unconfirmed partial response
ESR1=estrogen receptor 1 gene; NE=not evaluable due to missing data for best overall response; PD=progressive disease; PR=confirmed partial response; QD=once daily; SD=stable disease

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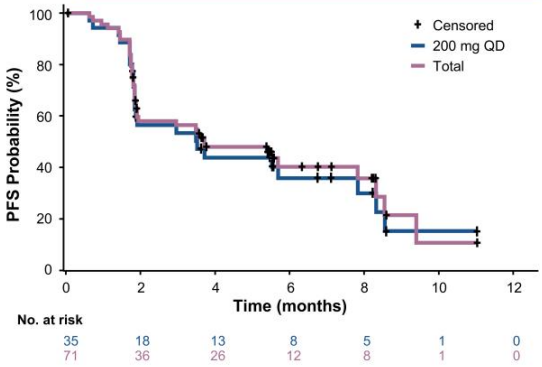
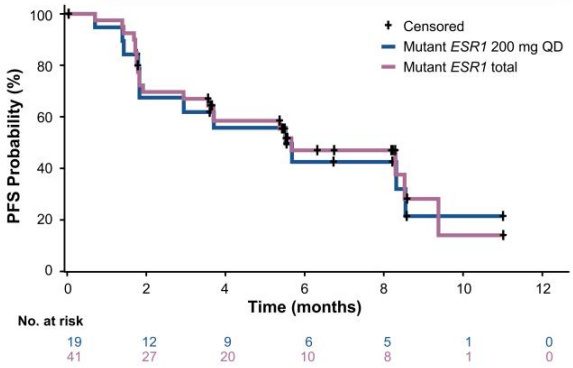
Progression-Free Survival[a] (VERITAC)

	All Patients	
	200 mg QD (n=35)	Total (N=71)
Events, n (%)	24 (68.6)	41 (57.7)
mPFS, mo (95% CI)	3.5 (1.8–7.8)	3.7 (1.9–8.3)



	Mutant *ESR1*	
	200 mg QD (n=19)	Total (n=41)
Events, n (%)	12 (63.2)	22 (53.7)
mPFS, mo (95% CI)	5.5 (1.8–8.5)	5.7 (3.6–9.4)



[a]Limited follow-up in 500-mg QD cohort led to ≥50% of patients censored for PFS (curve not shown)
ESR1=estrogen receptor 1 gene; mPFS=median progression-free survival; PFS=progression-free survival; QD=once daily

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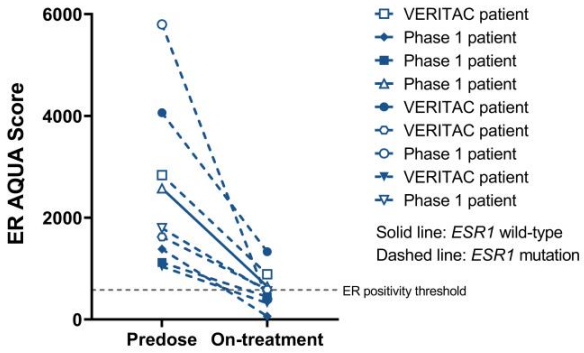
ER Degradation[a] With 200 mg QD ARV-471 (Phase 1/VERITAC)



- Median ER degradation was 69% (range: 28%–95%)
- Mean ER degradation was 71%

[a]ER immunoreactivity analyzed by QIF using the AQUA method, and ER positivity threshold derived by examining AQUA scores and visually inspecting all samples in the dataset to determine a cut point for ER positivity; *ESR1* mutation status determined from tumor biopsy (n=1) or circulating tumor DNA (n=8)
AQUA=automated quantitative analysis; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; QD=once daily; QIF=quantitative immunofluorescence

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Treatment-Emergent Adverse Event Summary (VERITAC)

n (%)	200 mg QD (n=35)	500 mg QD (n=36)	Total (N=71)
TEAEs			
Any grade	32 (91)	30 (83)	62 (87)
Grade 3/4	9 (26)	6 (17)	15 (21)
Grade 5[a]	1 (3)	0	1 (1)
Leading to discontinuation	1 (3)	2 (6)	3 (4)
Leading to dose reduction	0	3 (8)	3 (4)

[a]Acute respiratory failure in the setting of disease progression and unrelated to ARV-471 treatment
[b]Patient had QT prolongation at baseline, received a concomitant QT-prolonging drug during ARV-471 treatment, and had hypokalemia
[c]Patient had ECG T-wave abnormality at baseline
ALT=alanine aminotransferase; ECG=electrocardiogram; QD=once daily; TEAE=treatment-emergent adverse event

- Dose reductions due to TEAEs
  - 500-mg QD cohort (to 400 mg QD)
    - ALT increased (n=1)
    - Neutropenia (n=1)
    - Fatigue (n=1)
- Discontinuations due to TEAEs
  - 200-mg QD cohort
    - QT prolongation (n=1)[b]
  - 500-mg QD cohort
    - ECG T-wave abnormality (n=1)[c]
    - Back pain/spinal cord compression (n=1)

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TRAEs Reported in ≥10% of Patients Overall (VERITAC)

	200 mg QD (n=35)			500 mg QD (n=36)			Total (N=71)		
n (%)	Grade 1	Grade 2	Grade 3/4[a]	Grade 1	Grade 2	Grade 3/4[b]	Grade 1	Grade 2	Grade 3/4
Any TRAE	13 (37)	13 (37)	2 (6)	11 (31)	9 (25)	3 (8)	24 (34)	22 (31)	5 (7)
Fatigue	8 (23)	6 (17)	0	7 (19)	2 (6)	1 (3)	15 (21)	8 (11)	1 (1)
Nausea	2 (6)	3 (9)	0	6 (17)	1 (3)	0	8 (11)	4 (6)	0
Arthralgia	4 (11)	0	0	5 (14)	0	0	9 (13)	0	0
Hot flush	6 (17)	0	0	1 (3)	0	0	7 (10)	0	0
AST increased	3 (9)	1 (3)	0	2 (6)	1 (3)	0	5 (7)	2 (3)	0

[a]Grade 3/4 TRAEs in the 200-mg QD cohort were grade 3 QT prolonged (n=1; same TEAE that led to discontinuation as shown in the prior slide) and grade 3 thrombocytopenia and grade 4 hyperbilirubinemia (n=1)
[b]Grade 3/4 TRAEs in the 500-mg QD cohort were grade 3 fatigue, decreased appetite, and neutropenia (n=1 each)
AST=aspartate aminotransferase; QD=once daily; TEAE=treatment-emergent adverse event; TRAE=treatment-related adverse event

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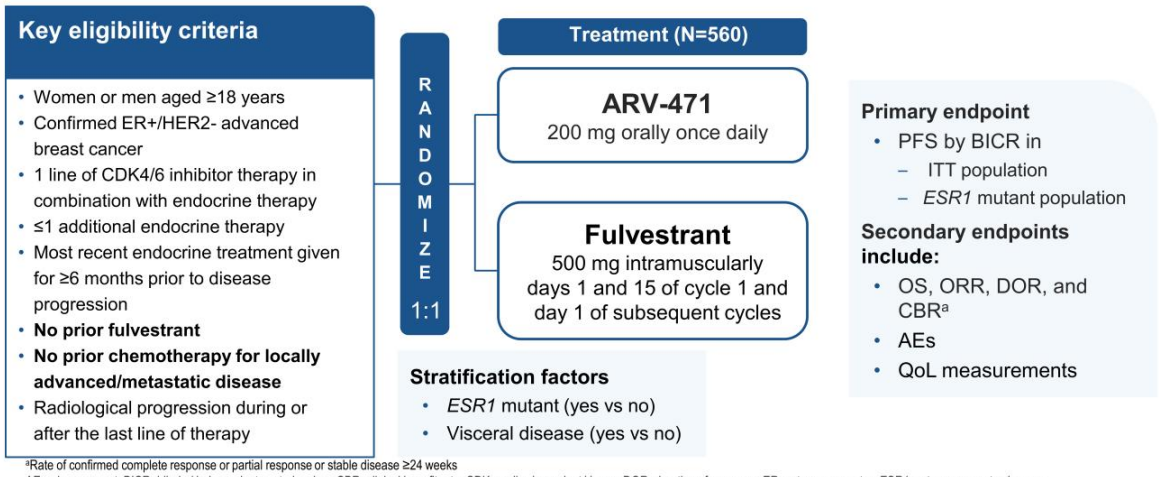
Phase 3 VERITAC-2 Trial



[a]Rate of confirmed complete response or partial response or stable disease ≥24 weeks

AE=adverse event; BICR=blinded independent central review; CBR=clinical benefit rate; CDK=cyclin-dependent kinase; DOR=duration of response; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; HER2=human epidermal growth factor receptor 2; ITT=intention to treat; ORR=overall response rate; OS=overall survival; QoL=quality of life; PFS=progression-free survival

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Conclusions

John G. Houston, Ph.D.

President and Chief Executive Officer, Arvinas

Continued efficacy and favorable tolerability put ARV-471 on a path to two pivotal studies beginning soon

Efficacy

- ARV-471 demonstrates strong CBR and mPFS in heavily treatment-resistant patients
- Activity in this difficult to treat population illustrates the potential of PROTAC technology

Tolerability

- Favorable tolerability profile at 200 and 500 mg qd
- At 200 mg phase 3 dose, no dose reductions and one discontinuation
- ARV-471's tolerability is well suited for development across the disease continuum

Initiating Ph 3 trials

- Monotherapy 2L Ph 3 in less treatment-experienced patients (Q4 2022)
  - Trial designed to address role in both *ESR1*mut and all-comers
- Palbo combo 1L Ph 3 in patients with ER dependent tumors (Q1 2023)
- Broader development initiated with other combos and in early breast cancer

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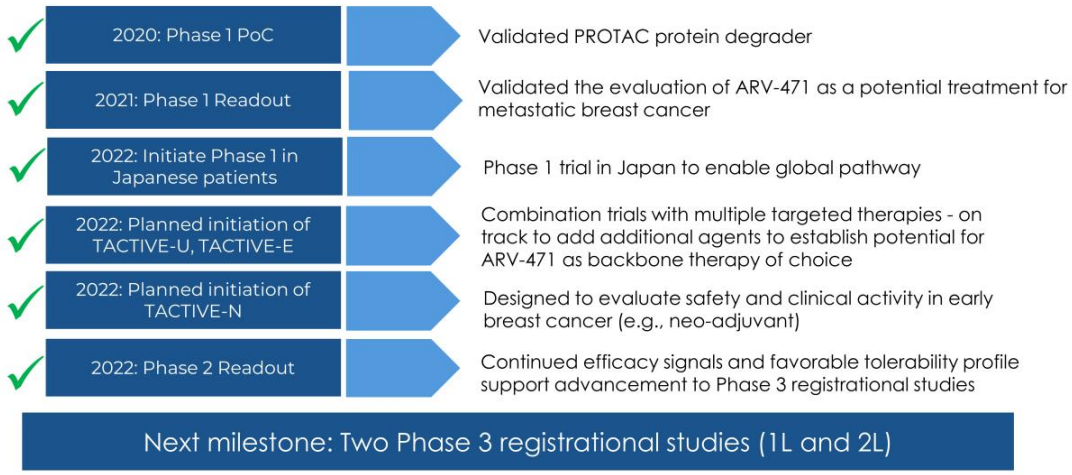
ARV-471 is an investigational compound. Its safety and efficacy has not been established
[a]Rate of confirmed complete response or partial response or stable disease ≥24 weeks
CBR=clinical benefit rate; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; PFS=progression-free survival

VERITAC data confirm ARV-471 has the potential to be a best-in-class ER-targeting therapy



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Q&A