

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 21, 2022

**Arvinas, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-38672  
(Commission  
File Number)

47-2566120  
(IRS Employer  
Identification No.)

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

06511  
(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.**

Arvinas, Inc. (the "Company") today disclosed top-line results from the Phase 2 cohort expansion portion (VERITAC) of a Phase 1/2 clinical trial with ARV-471, a novel investigational PROTAC® estrogen receptor (ER) protein degrader. ARV-471 is being co-developed with Pfizer, Inc. for the treatment of patients with locally advanced or metastatic ER positive / human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer.

This disclosure was originally planned for December 8, 2022. However, on November 21, 2022, the 2022 San Antonio Breast Cancer Symposium ("SABCS") incorrectly published for conference participants Arvinas' and Pfizer's joint abstract, omitting a key safety data table, and inadvertently released the corresponding full data presentation on the SABCS website. These full data were originally scheduled to be presented in an oral presentation titled "ARV-471, a PROTAC® estrogen receptor (ER) degrader in advanced ER-positive/human epidermal growth factor receptor 2 (HER2)-negative breast cancer: phase 2 expansion (VERITAC) of a phase 1/2 study."

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.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Company Presentation, dated November 21, 2022</a>
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 21, 2022

By: /s/ Sean Cassidy  
Sean Cassidy  
Chief Financial Officer

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## **ARV-471, a PROTAC® estrogen receptor (ER) degrader in advanced ER-positive/human epidermal growth factor receptor 2 (HER2)-negative breast cancer: phase 2 expansion (VERITAC) of a phase 1/2 study**

Sara A Hurvitz,<sup>1</sup> **Anne F Schott**,<sup>2</sup> Cynthia Ma,<sup>3</sup> Erika P Hamilton,<sup>4</sup> Rita Nanda,<sup>5</sup> George Zahrah,<sup>6</sup> Natasha Hunter,<sup>7</sup> Antoinette R Tan,<sup>8</sup> Melinda L Telli,<sup>9</sup> Jesus Anampa Mesias,<sup>10</sup> Rinath Jeselsohn,<sup>11</sup> Pamela Munster,<sup>12</sup> Haolan Lu,<sup>13</sup> Richard Gedrich,<sup>13</sup> Cecile Mather,<sup>13</sup> Janaki Parameswaran,<sup>13</sup> Hyo S Han<sup>14</sup>

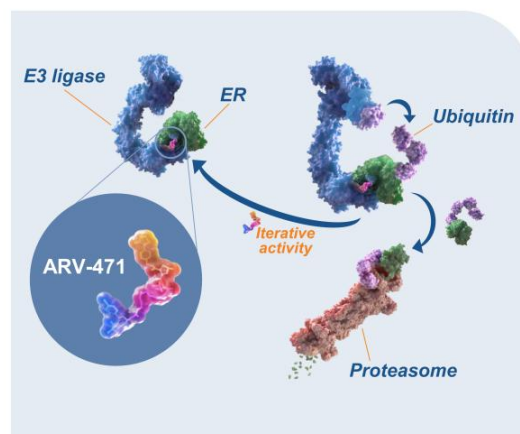
<sup>1</sup>UCLA Jonsson Comprehensive Cancer Center, Los Angeles, CA; <sup>2</sup>Rogel Cancer Center, University of Michigan Health, Ann Arbor, MI; <sup>3</sup>Washington University, St Louis, MO; <sup>4</sup>Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN; <sup>5</sup>University of Chicago Medicine, Chicago, IL; <sup>6</sup>Norwalk Hospital, Norwalk, CT; <sup>7</sup>Seattle Cancer Care Alliance, Seattle, WA; <sup>8</sup>Levine Cancer Institute, Atrium Health, Charlotte, NC; <sup>9</sup>Stanford University School of Medicine, Stanford, CA; <sup>10</sup>Albert Einstein College of Medicine, Bronx, NY; <sup>11</sup>Dana-Farber Cancer Institute, Boston, MA; <sup>12</sup>University of California San Francisco, San Francisco, CA; <sup>13</sup>Arvinas Operations, Inc, New Haven, CT; <sup>14</sup>Moffitt Cancer Center, Tampa, FL

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## Background

- ARV-471 is a selective, orally administered PROTAC® protein degrader that targets wild-type and mutant ER<sup>1</sup>
- ARV-471 directly binds an E3 ubiquitin ligase and ER to trigger ubiquitination of ER and its subsequent proteasomal degradation
  - In contrast, SERDs indirectly recruit the ubiquitin-proteasome system, secondary to conformational changes and/or immobilization of ER<sup>2</sup>
- Limitations of the SERD fulvestrant include its intramuscular route of administration<sup>3</sup> and only 40%–50% ER protein degradation at its optimal dose<sup>4,5</sup>
- ARV-471 treatment yielded substantially greater ER degradation and tumor growth inhibition than fulvestrant in breast cancer xenograft models<sup>1</sup>



ER=estrogen receptor; PROTAC=PROteolysis TArgeting Chimera; SERD=selective estrogen receptor degrader

1. Flanagan, JJ, et al. *Cancer Research*. 2019;79(4 Suppl):P5-04.

3. Nathan MR and Schmid P. *Oncol Ther*. 2017;5:17-29.

5. Robertson JFR, et al. *Breast Cancer Res*. 2013;15(2):R18.

2. Harker AB, et al. *Cancer Cell*. 2020;37(4):496-513.

4. Kuter I, et al. *Breast Cancer Res Treat*. 2012;133(1):237-246.

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## Phase 1/2 Study Design<sup>a</sup>

First-in-human, open-label, 3-part study of ARV-471 alone or in combination with palbociclib in patients with ER+/HER2- locally advanced/metastatic breast cancer

Phase 1 dose escalation (Part A)	Phase 2 cohort expansion (Part B; VERITAC)	Phase 1b combination (Part C)
<b>Treatment</b> <ul style="list-style-type: none"> <li>• ARV-471 orally</li> </ul>	<b>Treatment</b> <ul style="list-style-type: none"> <li>• ARV-471 orally</li> </ul>	<b>Treatment</b> <ul style="list-style-type: none"> <li>• ARV-471 plus palbociclib orally</li> </ul>
<b>Primary objective</b> <ul style="list-style-type: none"> <li>• Evaluate the safety and tolerability of ARV-471 in order to estimate the MTD and select the RP2Ds</li> </ul>	<b>Primary objective</b> <ul style="list-style-type: none"> <li>• Assess the antitumor activity of ARV-471</li> </ul>	<b>Primary objective</b> <ul style="list-style-type: none"> <li>• Evaluate the safety and tolerability of ARV-471 plus palbociclib and select the RP2D of the combination</li> </ul>

<sup>a</sup>ClinicalTrials.gov: NCT04072952

ER=estrogen receptor; HER2=human epidermal growth factor receptor 2; MTD=maximum tolerated dose; RP2D=recommended phase 2 dose

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## Phase 1 ARV-471 Dose Escalation Results<sup>1</sup>

<b>Phase 1 dose escalation (Part A)</b>
<b>Treatment</b> <ul style="list-style-type: none"> <li>• ARV-471 orally</li> </ul>
<b>Primary objective</b> <ul style="list-style-type: none"> <li>• Evaluate the safety and tolerability of ARV-471 in order to estimate the MTD and select the RP2Ds</li> </ul>

- As of September 30, 2021, 60 patients received ARV-471
  - Total daily doses ranged from 30–700 mg
- ARV-471 was well tolerated at all doses, with no DLTs or grade ≥4 TRAEs; most TRAEs were grade 1/2
- The CBR<sup>a</sup> was 40% (95% CI: 26–56) in 47 evaluable patients
- 3 patients had confirmed PRs
- Preliminary PK data showed dose-related increases for AUC<sub>24</sub> and C<sub>max</sub> from 30–500 mg daily doses
- At the 200-mg and 500-mg doses, mean exposure on day 15 exceeded the nonclinical efficacious range by >2-fold and >5-fold, respectively<sup>2</sup>
- ER degradation up to 89% was observed; median and mean ER degradation across dose levels was 67% and 64%, respectively

<sup>a</sup>Rate of confirmed complete response or partial response or stable disease ≥24 weeks; evaluable patients were enrolled ≥24 weeks prior to the data cutoff

AUC<sub>24</sub>=area under the curve from 0 to 24 hours; CBR=clinical benefit rate; C<sub>max</sub>=maximum plasma concentration; DLT=dose-limiting toxicity; ER=estrogen receptor; MTD=maximum tolerated dose; PK=pharmacokinetic; PR=partial response; RP2D=recommended phase 2 dose; TRAE=treatment-related adverse event

1. Hamilton E, et al. Presented at SABCS; Dec 7-10, 2021; Poster PD13-08. 2. Snyder LB, et al. Presented at AACR; April 10-15, 2021; Oral Presentation 44.

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## 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 nonmeasurable 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<sup>a</sup>**  
**(n=35)**

**ARV-471**  
**500 mg orally QD<sup>a</sup>**  
**(n=36)**

#### Primary endpoint

- CBR (rate of confirmed CR or PR or SD ≥24 weeks)<sup>b</sup>

#### 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

<sup>a</sup>Enrollment in the 200-mg QD cohort began before enrollment in the 500-mg QD cohort

<sup>b</sup>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 (%) <sup>a</sup>	
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 <i>ESR1</i> status, n (%) <sup>b</sup>	
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)

<sup>a</sup>Baseline ECOG PS status was unknown in 1 patient. <sup>b</sup>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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## 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 <sup>a</sup>	1 (3)	0	1 (1)
Leading to discontinuation	1 (3)	2 (6)	3 (4)
Leading to dose reduction	0	3 (8)	3 (4)

- 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)<sup>b</sup>
  - 500-mg QD cohort
    - ECG T-wave abnormality (n=1)<sup>c</sup>
    - Back pain/spinal cord compression (n=1)

<sup>a</sup>Acute respiratory failure in the setting of disease progression and unrelated to ARV-471 treatment

<sup>b</sup>Patient had QT prolongation at baseline, received a concomitant QT-prolonging drug during ARV-471 treatment, and had hypokalemia

<sup>c</sup>Patient had ECG T-wave abnormality at baseline

ALT=alanine aminotransferase; ECG=electrocardiogram; QD=once daily; TEAE=treatment-emergent adverse event

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

n (%)	200 mg QD (n=35)			500 mg QD (n=36)			Total (N=71)		
	Grade 1	Grade 2	Grade 3/4 <sup>a</sup>	Grade 1	Grade 2	Grade 3/4 <sup>b</sup>	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

<sup>a</sup>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)

<sup>b</sup>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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## Primary Endpoint: Clinical Benefit Rate<sup>a</sup> (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)

<sup>a</sup>Rate of confirmed complete response or partial response or stable disease ≥24 weeks  
CBR=clinical benefit rate; QD=once daily

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## Primary Endpoint: Clinical Benefit Rate<sup>a</sup> (VERITAC)

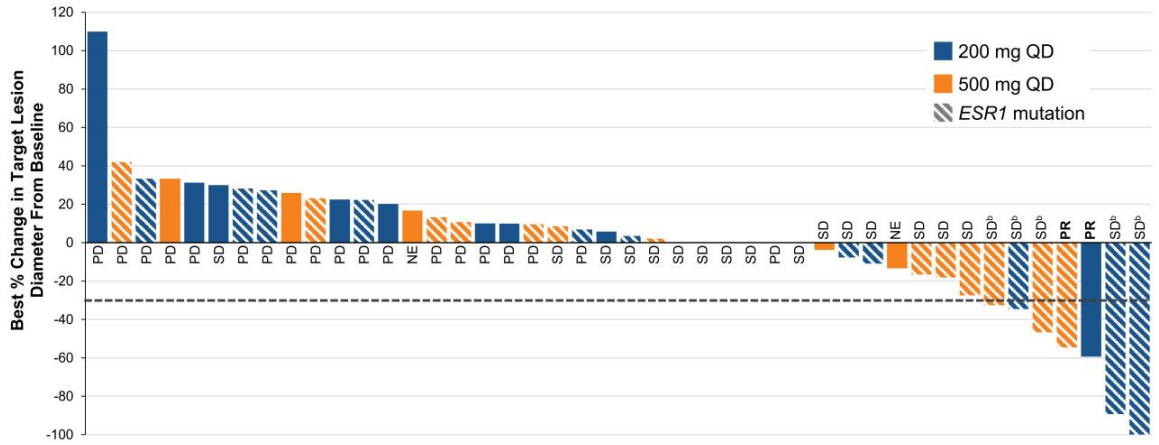
	200 mg QD (n=35)	500 mg QD (n=36)	Total (N=71)
CBR, % (95% CI)	37.1 (21.5–55.1)	38.9 (23.1–56.5)	38.0 (26.8–50.3)
Patients with mutant <i>ESR1</i>	(n=19)	(n=22)	(n=41)
CBR, % (95% CI)	47.4 (24.4–71.1)	54.5 (32.2–75.6)	51.2 (35.1–67.1)

<sup>a</sup>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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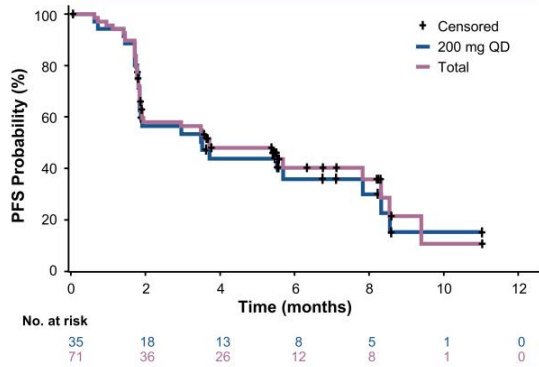
# Tumor Response<sup>a</sup> (VERITAC)



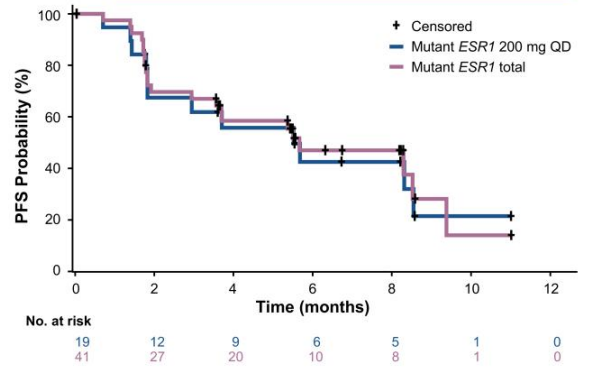
<sup>a</sup>Includes patients with measurable disease (n=44); 1 patient with measurable disease at baseline and PD as best overall response was excluded due to lack of complete set of target lesion measurements on-study  
<sup>b</sup>Patient had an unconfirmed partial response  
 ESR1=estrogen receptor 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<sup>a</sup> (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 <i>ESR1</i>	
	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)

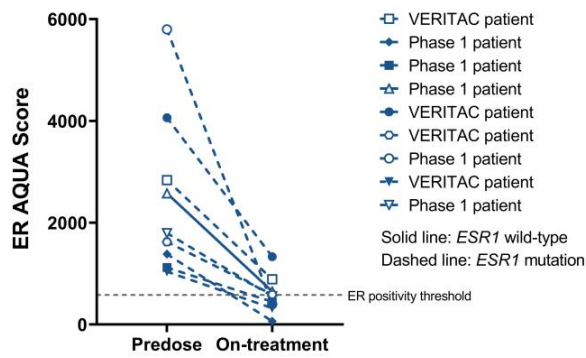


<sup>a</sup>Limited follow-up in 500-mg QD cohort led to ≥50% of patients censored for PFS (curve not shown)

*ESR1*=estrogen receptor 1 gene; mPFS=median progression-free survival; PFS=progression-free survival; QD=once daily

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## ER Degradation<sup>a</sup> With 200 mg QD ARV-471 (Phase 1/VERITAC)



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

<sup>a</sup>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



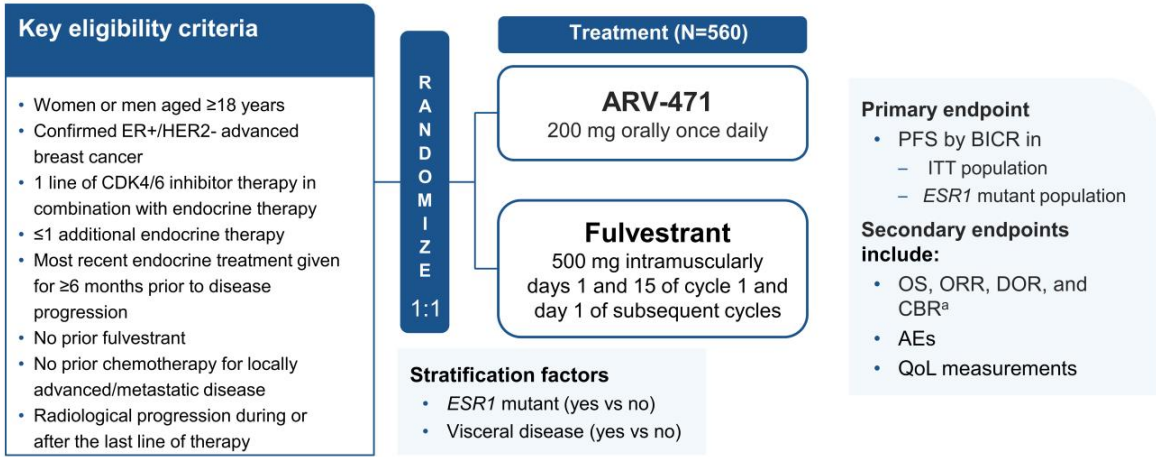
## Conclusions

- ARV-471 showed clinical activity in the VERITAC expansion cohorts of heavily pretreated patients (4 median prior regimens, 100% with prior CDK4/6 inhibitors, and 79% with prior fulvestrant) with ER+/HER2- advanced breast cancer
  - CBR was 37.1% and 38.9% in the 200- and 500-mg QD cohorts, respectively
  - Clinical benefit was also observed in the *ESR1* mutation subgroup (CBR of 47.4% and 54.5% in the 200- and 500-mg QD cohorts, respectively)
- ARV-471 had a manageable AE profile; most AEs were grade 1/2
- ARV-471 200 mg QD was selected as the phase 3 monotherapy dose based on comparable efficacy, favorable tolerability, and robust ER degradation

AE=adverse event; CBR=clinical benefit rate; CDK=cyclin-dependent kinase; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; HER2=human epidermal growth factor receptor 2; QD=once daily

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## Phase 3 VERITAC-2 Trial



<sup>a</sup>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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## Acknowledgments

- We thank the patients who participated in this study and their caregivers, as well as the investigators, researchers, and coordinators who contributed to this study
- This study is sponsored by Arvinas Estrogen Receptor, Inc
- Presentation development support was provided by Apollo Medical Communications and funded by Arvinas Operations, Inc

### Plain Language Summary

Please scan this Quick Response (QR) code with your smartphone app to view a plain language summary.



