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): June 8, 2023

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):

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

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. o

Item 7.01 Regulation FD Disclosure.

On June 8, 2023, Arvinas, Inc. (the "Company") issued a press release announcing interim data from the Company's Phase 1/2 dose escalation and expansion trial of ARV-766 in men with metastatic castration-resistant prostate cancer ("mCRPC"). The Company will provide an overview of these data during a fireside chat at the Jefferies Healthcare Conference on June 8, 2023. Copies of the press release and presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated into this Item 7.01 by reference.

The information in this Item 7.01, including Exhibits 99.1 and 99.2, 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.
A copy of the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this "Current Report") and is incorporated herein by reference.

Item 8.01 Other Events

On June 8, 2023, the Company announced interim data from the Company's Phase 1/2 dose escalation and expansion trial of ARV-766 in men with mCRPC. ARV-766 is an investigational orally bioavailable PROTAC® protein degrader designed to degrade all clinically relevant resistance-driving point mutations of the androgen receptor ("AR"), including L702H, a mutation associated with resistance to abiraterone and other AR-pathway novel hormonal agents ("NHA").

The Phase 1 dose escalation portion of the ARV-766 trial was designed to assess its safety, tolerability, and pharmacokinetics in men with mCRPC who have progressed on standard of care therapies, as well as to identify recommended Phase 2 doses for further dose optimization. The Phase 2 expansion cohort is designed to evaluate the antitumor activity of ARV-766 at the two recommended doses (100 mg and 300 mg) and determine the appropriate dose for future development.

Data from the Phase 1/2 dose escalation and expansion trial (data cut off April 2023) show that ARV-766 was well-tolerated and demonstrated promising activity in a heavily pre-treated, post-NHA, all-comers patient population. In both the Phase 1 dose escalation and Phase 2 dose expansion, 100% of patients were previously treated with at least one or more NHAs. Patients had a median of 4 prior lines of therapy in the Phase 1 trial and 5 prior lines of therapy in the Phase 2 trial. Multiple prior therapies have been associated with a decreased responsiveness to AR-directed therapies and an increase in tumor heterogeneity. AR ligand binding domain ("LBD") mutations were present in 28% (13 of 47) of patients' tumors in the Phase 1/2 trial as determined by plasma DNA analysis.

Overall, 42% of patients with AR LBD mutations achieved reductions in prostate specific antigen ("PSA") levels of greater than or equal to than 50% or ("PSA50"). Three of five patients with L702H mutations achieved PSA50, and three of three patients with co-occurring T878/H875/L702 mutations achieved PSA50. Of four patients with AR LBD mutations where Response Evaluation Criteria in Solid Tumors was evaluable, one achieved a confirmed partial response, and one achieved an unconfirmed partial response.

ARV-766 has been well tolerated and the majority of treatment related adverse events ("TRAEs") have been Grade 1 or 2, with no Grade ≥4 TRAEs. None of the 34 patients treated in the Phase 1 dose escalation portion experienced a dose limiting toxicity. The most frequent TRAEs (>10%) in Phase 1 have been fatigue, nausea, and diarrhea. At the time of data cutoff, no TRAE of >10% frequency was observed Phase 2.

47 patients across the Phase 1 and 2 trials were evaluable for safety. No patients discontinued treatment of ARV-766 due to TRAE in Phase 1, and one patient discontinued treatment due to a TRAE in Phase 2. Two of 47 patients (both in Phase 1) were dose reduced due to TRAE.

Based on pharmacokinetics, tolerability, and signals of activity in the Phase 1 dose escalation trial, 100 mg and 300 mg, once daily, were selected as the recommended Phase 2 expansion doses. The Phase 2 expansion (N = ~80) began enrolling in October 2022.

As previously reported, with respect to its AR franchise, including bavdegalutamide and ARV-766, each an investigational orally bioavailable PROTAC® protein degrader designed to selectively target and degrade the AR being developed as a potential treatment for men with prostate cancer, the Company anticipates achievement of the following milestones in the second half of 2023:

- Submission and presentation of updated data, including radiographic progression free survival, from the ongoing Phase 1/2 trial with bavdegalutamide at a medical congress;
- Initiation of a global Phase 3 trial with bavdegalutamide in mCRPC;
- Completion of enrollment in the Phase 1b combination study with bavdegalutamide plus abiraterone; and
- Initiation of a Phase 1b/2 trial with ARV-766 in combination with abiraterone in patients who have not previously received NHAs.

Forward-Looking Statements

This Current Report on Form 8-K, including the documents furnished as Exhibit 99.1 and 99.2 hereto, contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential advantages and therapeutic benefits of ARV-766 and any anticipated milestones with respect to bavdegalutamide and ARV-766 in 2023. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company's strategy, future operations, 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.

The Company may not actually achieve the plans, intentions or expectations disclosed in its 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 the Company makes as a result of various risks and uncertainties, including but not limited to: whether the Company will be able to successfully conduct and complete clinical development for bavdegalutamide and ARV-766, including whether the Company initiates and completes clinical trials for the Company's product candidates, and receives results from the Company's clinical trials on the Company's expected timelines, or at all, and other important factors discussed in the "Risk Factors" sections contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. The forward-looking statements contained in this Current Report on Form 8-K reflect the Company's current views with respect to future events, and the Company 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 the Company's views as of any date subsequent to the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 8, 2023.
99.2	Company Presentation, dated June 8, 2023.
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: June 8, 2023

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

Arvinas Announces Interim Data from the ARV-766 Phase 1/2 Dose Escalation and Expansion Trial Showing Promising Signals of Efficacy in Late-line mCRPC, Including in Patients with AR L702H Mutations

– 42% of patients with AR ligand binding domain (LBD) mutations achieved PSA_{50}; in patients with AR L702H mutations, 3 of 5 achieved PSA_{50} –

– ARV-766 was well-tolerated, and activity in a heavily pre-treated patient population supports its potential as a treatment in earlier line settings such as castration-sensitive prostate cancer (CSPC), with planned initiation of a pre-NHA trial in 2H 2023 –

NEW HAVEN, Conn., June 8 -- Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today announced promising interim data from the Company's Phase 1/2 dose escalation and expansion trial of ARV-766 in men with metastatic castration-resistant prostate cancer (mCRPC). ARV-766 is an investigational orally bioavailable PROTAC® protein degrader designed to degrade all clinically relevant resistance-driving point mutations of the androgen receptor (AR), including L702H, a mutation associated with resistance to abiraterone and other AR-pathway novel hormonal agents (NHA). The company will provide an overview of these data during a fireside chat at the Jefferies Healthcare Conference today, June 8, 2023, at 11 a.m. ET, which will be available to view in the Investors and Media section of the Arvinas website.

Data from the Phase 1/2 dose escalation and expansion trial show that ARV-766 was well-tolerated and demonstrated promising activity in a heavily pre-treated, post-NHA, all-comers patient population:

- 42% of patients with AR ligand binding domain (LBD) mutations achieved PSA_{50}
  - In all patients with L702H mutations, 3 of 5 achieved PSA_{50}
    - In patients with co-occurring T878/H875/L702 mutations, 3 of 3 achieved PSA_{50}
- RECIST (Response Evaluation Criteria in Solid Tumors) partial responses were observed:
  - Of four RECIST-evaluable patients with AR LBD mutations, one achieved a confirmed partial response, and one achieved an unconfirmed partial response
- ARV-766 has been well tolerated and the majority of treatment-related adverse events (TRAEs) have been Grade 1 or 2, with no Grade ≥4 TRAEs and no dose limiting toxicities
- Low rates of discontinuation (1 of 47) and dose reductions (2 of 47)

"Tumor resistance mechanisms such as AR LBD mutations are increasing with earlier use of NHAs, leaving limited treatment options for men with prostate cancer in the post-NHA setting," said John Houston, Ph.D., president and chief executive officer at Arvinas. "It's very exciting to see ARV-766 show signs of efficacy in these late-line patients, including in patients with L702H mutations. Our AR franchise now includes data showing two active clinical compounds with good tolerability profiles and the potential to address high unmet need in castrate-resistant and castrate-sensitive prostate cancer."

"The patients in this trial received extensive prior therapy for mCRPC and had limited alternative treatment options," said Ron Peck, M.D., chief medical officer at Arvinas. "These data increase our confidence in our ability to bring innovative treatment options to a patient population with significant unmet need. We are excited by the progress in our AR franchise and the potential for bavdegalutamide

and ARV-766 to address settings across the continuum of prostate cancer and potentially other AR-driven cancers."

About the Phase 1/2 dose escalation and expansion trial of ARV-766

The Phase 1/2 dose escalation and expansion trial of ARV-766 is a seamless trial that includes a Phase 1 dose escalation portion and a Phase 2 dose expansion portion (data cutoff: April 2023). The Phase 1 dose escalation of ARV-766 was designed to assess its safety, tolerability, and pharmacokinetics (PK) in men with mCRPC who have progressed on standard of care therapies, as well as to identify recommended Phase 2 doses for further dose optimization. The Phase 2 expansion cohort is designed to evaluate the antitumor activity of ARV-766 at the two recommended doses (100 mg and 300 mg) and determine the appropriate dose for future development.

In both the Phase 1 dose escalation and Phase 2 dose expansion, 100% of patients were previously treated with at least one or more novel hormonal agents. Patients had a median of 4 prior lines of therapy in the Phase 1 trial and 5 prior lines of therapy in the Phase 2 trial. Multiple prior therapies have been associated with a decreased responsiveness to AR-directed therapies and an increase in tumor heterogeneity.

AR LBD mutations were present in 28% (13 of 47) of patients' tumors in the Phase 1/2 trial as determined by plasma DNA analysis.

Efficacy

Across the Phase 1 and interim Phase 2 data, ARV-766 achieved a 42% PSA_{50} in patients with AR LBD mutations. Three of 5 patients with AR L702H mutations achieved PSA_{50}; the three responding AR L702H patients had co-occurring T878/H875 mutations.

Two of 4 RECIST-evaluable patients with tumors harboring AR LBD mutations had a best observed response of partial response (1 confirmed partial response, 1 unconfirmed partial response).

Safety

ARV-766 has been well tolerated to date and the majority of TRAEs in the Phase 1 dose escalation data and the Phase 2 interim dose expansion data were Grade 1/2. There have been no Grade ≥4 TRAEs. None of the 34 patients treated in the Phase 1 dose escalation portion experienced a dose limiting toxicity. The most frequent TRAEs (>10%) in Phase 1 have been fatigue, nausea, and diarrhea. At the time of data cutoff, no TRAE of >10% frequency was observed in Phase 2.

Forty-seven (47) patients across the Phase 1 and 2 trials were evaluable for safety. No patients discontinued treatment of ARV-766 due to TRAEs in Phase 1, and one patient discontinued treatment due to a TRAE in Phase 2. Two of 47 patients (both in Phase 1) were dose reduced due to TRAEs.

Based on pharmacokinetics, tolerability, and signals of activity in the Phase 1 dose escalation trial, 100 mg and 300 mg, once daily, were selected as the recommended Phase 2 expansion doses. The Phase 2 expansion (N = ~80) began enrolling in October 2022.

Anticipated 2023AR Franchise (bavdegalutamide/ARV-766) Milestones

- Submit and present updated data, including radiographic progression free survival, from the ongoing Phase 1/2 trial with bavdegalutamide at a medical congress (2H 2023).
- Initiate a global Phase 3 trial with bavdegalutamide in mCRPC (2H 2023).
- Complete enrollment in the Phase 1b combination study with bavdegalutamide plus abiraterone (2H 2023).
- Initiate a Phase 1b/2 trial with ARV-766 in combination with abiraterone in patients who have not previously received novel hormonal agents (2H 2023).

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 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 three investigational clinical-stage programs in development: bavdegalutamide and ARV-766 for the treatment of men with metastatic castration-resistant prostate cancer; and vepdegestrant (ARV-471) 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. 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 the potential advantages and therapeutic benefits of bavdegalutamide (ARV-110) and ARV-766, the development and regulatory status of our product candidates, such as statements with respect to the potential of our lead product candidates bavdegalutamide and ARV-766, the initiation of and timing of the timing of clinical trials, including the timing to complete enrollment, as well as the presentation and/or publication of data from those trials and plans for registration for our product candidates, the potential utility of our technology, the potential commercialization of any of our product candidates, and the sufficiency of our cash resources. All statements, other than statements of historical facts, contained in this press release, including statements regarding our 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.

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 will be able to successfully conduct and complete development for bavdegalutamide and ARV-766, whether we initiate and complete clinical trials for our product candidates and receive results from our clinical trials on our expected timelines or at all; obtain marketing approval for and commercialize bavdegalutamide and ARV-766 and our other product candidates on our current timelines or at all; whether our cash and cash equivalent resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent other reports on file with the Securities and Exchange Commission. The forward-looking statements contained in this press release reflect our current views 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 release.

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ARV-766: Phase 1 and interim Phase 2 data

June 8, 2023

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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 potential advantages and therapeutic benefits of bavdegalutamide (ARV-110) and ARV-766, the development and regulatory status of our product candidates, such as statements with respect to the potential of our lead product candidates bavdegalutamide and ARV-766, the initiation of and timing of the timing of clinical trials, including the timing to complete enrollment, as well as the presentation and/or publication of data from those trials and plans for registration for our product candidates, the potential utility of our technology, the potential commercialization of any of our product candidates, and the sufficiency of our cash resources s. 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: including but not limited to: whether we will be able to successfully conduct and complete development for bavdegalutamide and ARV-766, whether we initiate and complete clinical trials for our product candidates and receive results from our clinical trials on our expected timelines or at all; obtain marketing approval for and commercialize bavdegalutamide and ARV-766 and our other product candidates on our current timelines or at all; whether our cash and cash equivalent resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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 U.S. 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.

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.

ARV-766 is showing promising efficacy signals in late-line mCRPC and is well-tolerated, supporting its potential as an earlier-line treatment

ARV-766 is showing promising efficacy signals in a heavily pretreated patients, including in patients with androgen receptor (AR) L702H mutations

- 42% of patients with AR ligand binding domain (LBD) mutations achieved PSA_{50}
  - 3 of 3 patients with co-occurring AR T878/H875/L702H mutations achieved PSA_{50}
- RECIST partial responses were observed:
  - Two of four RECIST-evaluable patients with AR LBD mutations achieved partial responses (1 confirmed, 1 unconfirmed)

ARV-766 has been well tolerated to date

- Majority of treatment related adverse events (TRAEs) are Grade 1 or 2, with no Grade ≥4 TRAEs
- Low rates of discontinuation or dose reduction

The emerging efficacy signals and tolerability profile of ARV-766 support continued development in mCRPC and CSPC, and Arvinas will initiate a trial in pre-NHA patients in 2H 2023

mCRPC, metastatic castrate-resistant prostate cancer; CSPC, castrate-sensitive prostate cancer; LBD, ligand binding domain; RECIST, Response Evaluation Criteria in Solid Tumors

ARV-766: A novel AR degrader designed to address multiple resistance mechanisms, including AR L702H point mutations

- Tumor resistance mechanisms are increasing with earlier use of novel hormonal agents (abiraterone/enzalutamide), leaving limited treatment options in the post-NHA space
- The prevalence of AR LBD mutations is increasing, especially L702H

The prevalence of AR LBD mutations, especially L702H, has increased over time

AR LBD mutation	2016[1]	2020[2]	2023[3]
L702H	**~2%**	**~9%**	**~11%**
T878X*	~6%	~6%	~8%
H875Y	~4%	~4%	~5%

- In total, the prevalence of AR LBD mutations in mCRPC is 20-25%[4,5,6]
- **ARV-766 was designed to target L702H and all other clinically relevant AR mutations**, including T878X*, H875Y, and less frequent mutations

*878X = T878A or T878S; mCRPC, metastatic castrate-resistant prostate cancer; LBD, ligand binding domain

1 Coutinho et al 2016 DOI: 10.1530/ERC-16-0422. 2 Ledet et al 2020 DOI: 10.1634/theoncologist.2019-0115. 3 Antonarakis et al, Abstract 395182, ASCO/GU 2023. 4 Beltran H. Eur Urol. 2013;63(5):920-926. 5 Wyatt AW. JAMA Oncol.2016;2(12):1598-1606. 6 Bernard-Tessier et al, Abstract 39698, ASCO/GU 2023

The Phase 1/2 trial of ARV-766 is enrolling a post-NHA, all-comers, heavily pretreated patient population

Parameters	Phase 1 (n=34)	Phase 2 (interim data)* (n=13)
Median age (range), years	70 (59–86)	67 (60–76)
ECOG performance status, n (%)		
0	20 (59)	9 (69)
1	14 (41)	4 (31)
Visceral disease†, n (%)	23 (68)	7 (54)
Measurable disease at baseline, n (%)	15 (44)	3 (23)
Median duration of treatment (weeks)	10.8 (3.9 – 38.1)	8.0 (2.3 – 15.9)
Median no. of prior systemic anti-cancer regimens (all setting)	4	5
Prior radiotherapy, n (%)	19 (61)	12 (92)
Type of prior therapy, n (%)		
Novel hormonal agent	34 (100)	13 (100)**
Abi alone	8 (24)	4 (31)
Enza/Daro/Apa alone	8 (23)	6 (46)
Combination NHA	18 (53)	2 (15)
Chemotherapy	24 (71)	4 (31)

ECOG, Eastern Cooperative Oncology Group; NHA, novel hormonal agent
*Phase 2 enrollment ongoing (April 2023 data cutoff date); **Prior NHA data on one subject was entered into the database after the data cutoff
†Soft tissue disease other than lymph node, including liver or lung

AR LBD Mutations Were Present in 28% (13 of 47) of Patients' Tumors in the Phase 1/2 Trial

Parameters	Phase 1 (n=34)	Phase 2 (interim data)† (n=13)
AR LBD Mutation Status, n (%)		
LBD Mutant	10 (29)	3 (23)
H875Y/T878X†† without L702H	4 (12)	3 (23)
H875Y/T878X†† with L702H	3 (9)	0 (0)
L702H alone	2 (6)	0 (0)
Other LBD missense mutations	1 (3)	0 (0)
Non-LBD Mutant†††	23 (68)	9 (69)
Unknown/Missing	1 (3)	1 (8)

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† Enrollment ongoing (April 2023 data cutoff date). ††T878X = T878A or T878S. †††Includes wild type, amplified, and other non-LBD mutations

ARV-766 has been well tolerated, with no grade ≥4 TRAEs and low rates of dose reduction and discontinuation

Phase 1

TRAE >5%, n (%)	Total (n=34)			
	Gr 1	Gr 2	Gr 3	Total
Any TRAE	9 (27)	7 (21)	2 (6)	18 (53)
Fatigue	3 (9)	3 (9)	1 (3)	7 (21)
Nausea	2 (6)	2 (6)	0 (0)	4 (12)
Diarrhea	3 (9)	1 (3)	0 (0)	4 (12)
Vomiting	2 (6)	0 (0)	0 (0)	2 (6)
Dry Mouth	2 (6)	0 (0)	0 (0)	2 (6)
AST increased	2 (6)	0 (0)	1 (3)	3 (9)
Cr increased	2 (6)	1 (3)	0 (0)	3 (9)
Hypophosphataemia	3 (9)	0 (0)	0 (0)	3 (9)
Subjects with any TRAE leading to tx discontinuation				0 (0)
Subjects with any TRAE leading to dose interruption				1 (3)
Subjects with any TRAE leading to dose reduction				2 (6)

TRAE, treatment related adverse event; AST, aspartate aminotransferase; Cr, creatinine; tx, treatment
Gr 1 decreased appetite (2), Gr 2 alopecia (2), Gr 1 dry skin (2), Gr 1 & 2 rash maculopapular (2), Gr 1 headache (2) not included in the Table

Phase 2 (ongoing)

TRAE >5%, n (%)	100 mg (n = 6)			300 mg (n = 7)		
	Gr 1	Gr 2	Gr 3	Gr 1	Gr 2	Gr 3
Any TRAE	2 (33)	0 (0)	0 (0)	1 (14)	3 (43)	1 (14)
Abdominal pain	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	1 (14)
Nausea	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)
Diarrhea	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)
Dyspepsia	1 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry Mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)
Dysgeusia	1 (17)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)
Fatigue	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)
Anemia	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)
Subjects with any TRAE leading to tx discontinuation						1 (14)
Subjects with any TRAE leading to dose interruption				1 (14)	1 (14)	1 (14)
No dose reductions						

100 mg: Gr 1 Alk Phos increased (1) not included in the Table
300 mg: Gr 1 neutrophil decreased (1), Gr 1 WBC decreased (1), Gr 1 alopecia (2), Gr 1 dry skin (1), Gr 1 onychoclasis (1), Gr 1 pruritus (1), Gr 2 dehydration (1), Gr 2 hypertension (1) not included in the Table

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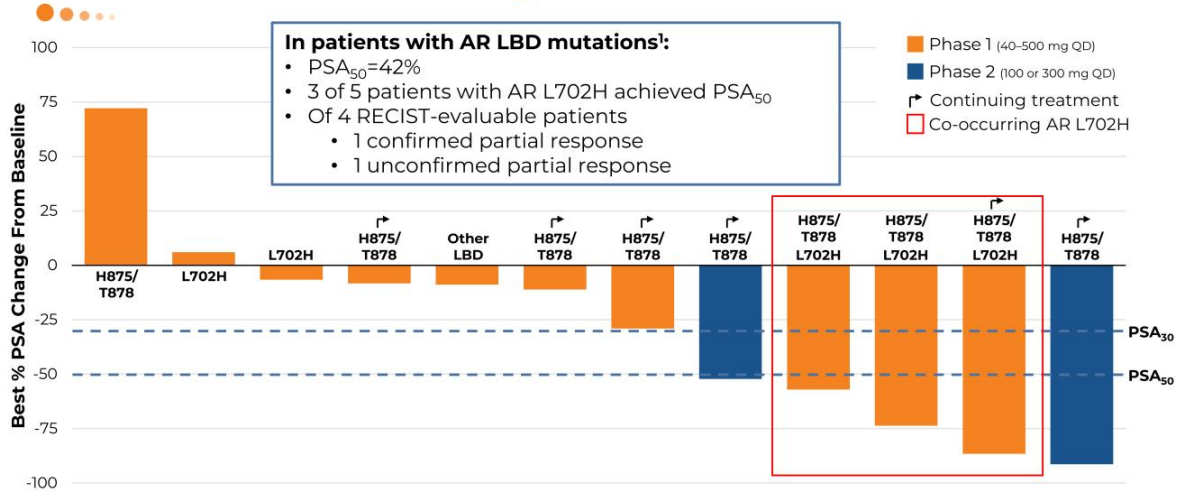
3 of 3 patients with co-occurring AR H875/T878/L702H mutations achieved best PSA reductions ≥50%[1]



1 Analysis includes biomarker-evaluable, AR LBD-positive patients with ≥4 weeks of PSA follow-up.

LBD, ligand-binding domain; PSA, prostate-specific antigen; PSA_{30}, best PSA declines ≥30%; PSA_{50}, best PSA declines ≥50%; H875, H875Y; T878, T878A or T878S; RECIST, Response Evaluation Criteria in Solid Tumors

Arvinas' AR franchise is on track for development across the treatment landscape in mCRPC and CSPC

ARV-766: Promising data in mCRPC, and moving into pre-NHA patients in 2H23

- Phase 1/2 data showing promising efficacy signals and a good tolerability profile, including in patients with AR L702H mutations, supporting further development in mCRPC
- Profile also supports an additional, broader opportunity to advance ARV-766 in earlier treatment settings

Next milestone: Pre-NHA combo of ARV-766 + abiraterone to initiate in 2H23

Bavdegalutamide: Phase 3 trial in mCRPC to initiate in 2H23

- Precision medicine opportunity in a growing population with few treatment options
  - In the U.S. alone: Addressable population of 8,000-11,000 patients with AR LBD+ mutations[1]
  - Addresses an unmet need for durable and tolerable treatments in late-line settings

Next milestone: Updated data from the Phase 1/2 trial, including radiographic progression-free survival (rPFS), at a medical congress in 2H23

mCRPC, metastatic castrate resistant prostate cancer; CSPC, castrate sensitive prostate cancer; LBD, ligand-binding domain; NHA, novel hormonal agent
1 Excludes patients with AR L702H alone