



Veru Inc.
Nasdaq:VERU

Oncology Biopharmaceutical Company Focused on Breast Cancer and Prostate Cancer

Veru Corporate Presentation

Jefferies London Healthcare Conference
November 16 – November 19, 2021

Forward looking statements



This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "project," "potential," "estimate," "should," "will," "would" or the negative of these terms or other words of similar meaning. These statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to: risks related to the development of Veru Inc.'s (the "Company") product portfolio, including risks regarding the regulatory pathway to secure FDA or other regulatory approval of the Company's drug candidates, the anticipated timeframe for FDA submissions and approvals, costs for clinical studies and regulatory submissions, clinical study results, including potential benefits and absence of adverse events, and the depth of the Company's drug pipeline, the market potential for the Company's drug candidates; potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID 19, and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified drug candidate or at all; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk in obtaining any regulatory approval and the products being commercially successful; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and Company operations; product demand and market acceptance; competition in the Company's markets and therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product introductions; the risk in sales being affected by regulatory developments, including a reclassification of the products or repeal of the Patient Protection and Affordable Care Act; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters including costs and delays resulting from the extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments; the risk that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; risks related to the costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including Company's Annual Report on Form 10-K for the year ended September 30, 2020 and subsequent quarterly reports on Form 10-Q. This documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. All forward-looking statements are based on information available to us as of the date hereof, and Company does not assume any obligation and does not intend to update any forward-looking statements, except as required by law.

Veru Drug Pipeline

Breast Cancer

Enobosarm

Sabizabulin 32mg

Prostate Cancer

Sabizabulin 32mg

VERU-100

COVID-19

Sabizabulin 9mg

BPH

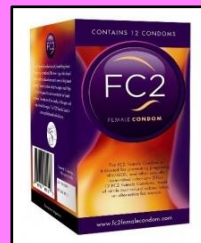
ENTADFI™ PDUFA – December 2021

- Late-stage clinical pipeline focused on breast cancer & prostate cancer
- 6 pivotal and pivotal-enabling clinical studies planned to commence in calendar year 2021

UREV

Women's Health Division

FC2 Female Condom (internal condom)



FC2 FY 2020 Net Revenues: \$ 40.6 mm

FC2 FYTD 2021 Net Revenues: \$ 44.8 mm

Sexual Health Business FYTD 2021 Operating Income: \$ 32.8 mm

FC2 Q3 FY 2021 Net Revenues: \$ 17.7 mm



Veru Financials

Cash: \$123.2 mm
Receivables: \$8.3 mm

(as of June 30, 2021)

Veru FY 2020 Net Revenues: \$ 42.6 mm

Veru FYTD 2021 Net Revenues: \$ 45.6 mm

Veru FYTD 2021 Gross Profit: \$ 35.6 mm

Veru Q3 FY 2021 Net Revenues: \$ 17.7 mm

Veru Q3 FY 2021 Gross Profit: \$ 13.9 mm

Drug candidate pipeline

Oncology biopharmaceutical company focused on breast cancer and prostate cancer



Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Breast Cancer						
Enobosarm	Selective androgen receptor targeted agonist	AR+ER+HER2- metastatic breast cancer (3 rd line metastatic)				Phase 3 ARTEST: 210 Patients - Enrolling
Sabizabulin	Oral cytoskeleton disruptor	ER+HER2- metastatic breast cancer (3 rd line metastatic)			Phase 2b: Planned Q4 2021 - 200 Patients	
Enobosarm + abemaciclib combination	Selective androgen receptor targeted agonist + CDK4/6 inhibitor	AR+ER+HER2- metastatic breast cancer (2 nd line metastatic)				Phase 3 ENABLAR-2: Planned Q4 2021 - 180 Patients
Sabizabulin + enobosarm	Oral cytoskeleton disruptor + Selective androgen receptor targeted agonist	Metastatic triple negative breast cancer				Phase 2b: Planned Q1 2022 - 111 Patients
Prostate Cancer						
Sabizabulin	Oral cytoskeleton disruptor and androgen receptor transport disruptor	Metastatic castration and AR targeting agent resistant prostate cancer				Phase 3 VERACITY: 245 Patients - Enrolling
VERU-100	GnRH antagonist 3-month subcutaneous depot injection	Hormone sensitive advanced prostate cancer			Phase 2: 35 Patients - Enrolling	
Virology						
Sabizabulin	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS				Phase 3: 300 Patients - Enrolling

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Breast Cancer						
Enobosarm	Selective androgen receptor targeted agonist	AR+ER+HER2- metastatic breast cancer (3 rd line metastatic)	Phase 3 ARTEST: 210 Patients - Enrolling			
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Enobosarm + abemaciclib combination	Selective androgen receptor targeted agonist + CDK4/6 inhibitor	AR+ER+HER2- metastatic breast cancer (2 nd line metastatic)	Phase 3 ENABLAR-2: Planned Q4 2021 - 180 Patients			
Sabizabulin + enobosarm	Oral cytoskeleton disruptor + Selective androgen receptor targeted agonist	Metastatic triple negative breast cancer	Phase 2b: Planned Q1 2022 - 111 Patients			

Current Endocrine Therapies

Selective estrogen receptor modulators (tamoxifen and toremifene)

ER antagonists and degraders (fulvestrant)

Aromatase inhibitors (AI)

- AROMASIN® (exemestane) - steroidal AI

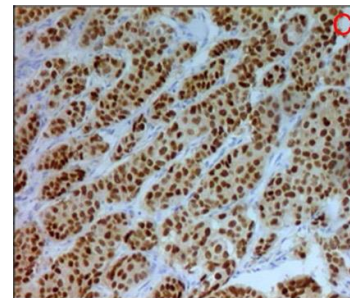
- ARIMIDEX® (anastrozole) and FEMARA® (letrozole) - nonsteroidal AI

CDK 4/6 inhibitors in combination with nonsteroidal AI or fulvestrant

Resistance to endocrine and CDK4/6 inhibitor therapies eventually occurs which requires alternative treatment approaches including chemotherapy^{1, 2}

Androgen receptor is the most abundantly expressed sex hormone receptor in breast cancers with up to 95% of breast cancers²⁻⁶

- What is the androgen receptor's function in breast tissue?
- Does activation of the androgen receptor stimulate or suppress breast cancer growth?
 - In normal and cancerous breast tissue, androgens inhibit cellular proliferation¹⁻³
 - AR positivity is an independent predictor of beneficial breast cancer outcome^{2,3,5,6}
- Historically, androgens have been used in breast cancer treatment with good efficacy, but their masculinizing effects, increase in hematocrit, and liver toxicity have prohibited their use as a viable treatment
- The development of novel strategies to target and to activate AR, tumor suppressor, as a treatment for AR+ER+ breast cancer that have become resistant to drugs that target the ER is warranted³



Ductal infiltrating breast carcinoma 3+ AR nuclear positivity⁷



The androgen receptor is a tumor suppressor in estrogen receptor-positive breast cancer

Theresa E. Hickey¹, Luke A. Selth^{1,2,3}, Kee Ming Chia⁴, Geraldine Laven-Law⁵, Heloisa H. Milioli⁶, Daniel Roden⁶, Shalini Jindal⁷, Mun Hui⁸, Jessica Finlay-Schultz⁹, Esmaeil Ebrahimie¹⁰, Stephen N. Birrell¹¹, Suzan Stelloo^{6,12}, Richard Iggo¹³, Sarah Alexandrou¹⁴, C. Elizabeth Caldon¹⁵, Tarek M. Abdel-Fatah¹⁶, Ian O. Ellis¹⁷, Wilbert Zwart¹⁸, Carlo Palmieri¹⁹, Carol A. Sartorius⁵, Alex Swarbrick²⁰, Elgene Lim²¹, Jason S. Carroll¹⁰ and Wayne D. Tilley^{1,3,22}

The role of the androgen receptor (AR) in estrogen receptor (ER)-positive breast cancer is controversial, constraining implementation of AR-directed therapies. Using a diverse, clinically relevant panel of cell-line and patient-derived models, we demonstrate that AR activation, not suppression, exerts potent antitumor activity in multiple disease contexts, including resistance to standard-of-care ER and CDK4/6 inhibitors. Notably, AR agonists combined with standard-of-care agents enhanced therapeutic responses. Mechanistically, agonist activation of AR altered the genomic distribution of ER and essential co-activators (p300, SRC-3), resulting in repression of ER-regulated cell cycle genes and upregulation of AR target genes, including known tumor suppressors. A gene signature of AR activity positively predicted disease survival in multiple clinical ER-positive breast cancer cohorts. These findings provide unambiguous evidence that AR has a tumor suppressor role in ER-positive breast cancer and support AR agonism as the optimal AR-directed treatment strategy, revealing a rational therapeutic opportunity.

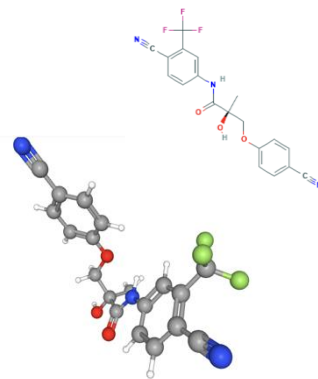
¹Birrell et al, J Steroid Biochem Mol Biol 52:459-67, 1995 | ²Peters et al, Cancer Res 69: 6131-40, 2009 | ³Hickey et al, Nature Medicine 2021 | ⁴Moinfar et al, Cancer 98:703-11, 2003 | ⁵Hu et al, Clin Cancer Res 17:1867-74, 2011 | ⁶Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | ⁷Bronte et al, Trans Oncol 11: 950-956, 2018

Enobosarm, first-in-class, novel oral selective AR targeting agonist for the treatment for AR+ER+ metastatic breast cancer

- **Enobosarm is a non-steroidal, selective androgen receptor agonist^{1, 2}**
 - Once-a-day oral daily dosing
 - Selectivity to activate the androgen receptor with no cross-reactivity to other steroidal hormone receptors
 - Selective tissue activities translate to a favorable side-effect profile
 - Non-masculinizing (no unwanted hair growth or acne)
 - No liver toxicity
 - No changes in hematocrit
 - Not a substrate for aromatase, thus cannot be aromatized to estrogen
 - Builds and heals bone- potential to treat antiestrogen-induced osteoporosis and prevent skeletal related events^{3,4,5}
 - Anabolic on muscle to improve muscle mass and physical function^{2,6}
- **Enobosarm suppresses AR+ER+ breast cancer in cell and patient-derived xenograft models of endocrine sensitive and resistant disease⁷**

Enobosarm has been evaluated in 25 clinical trials comprising 2,091 subjects (348 subjects dosed at > 9mg) which includes:

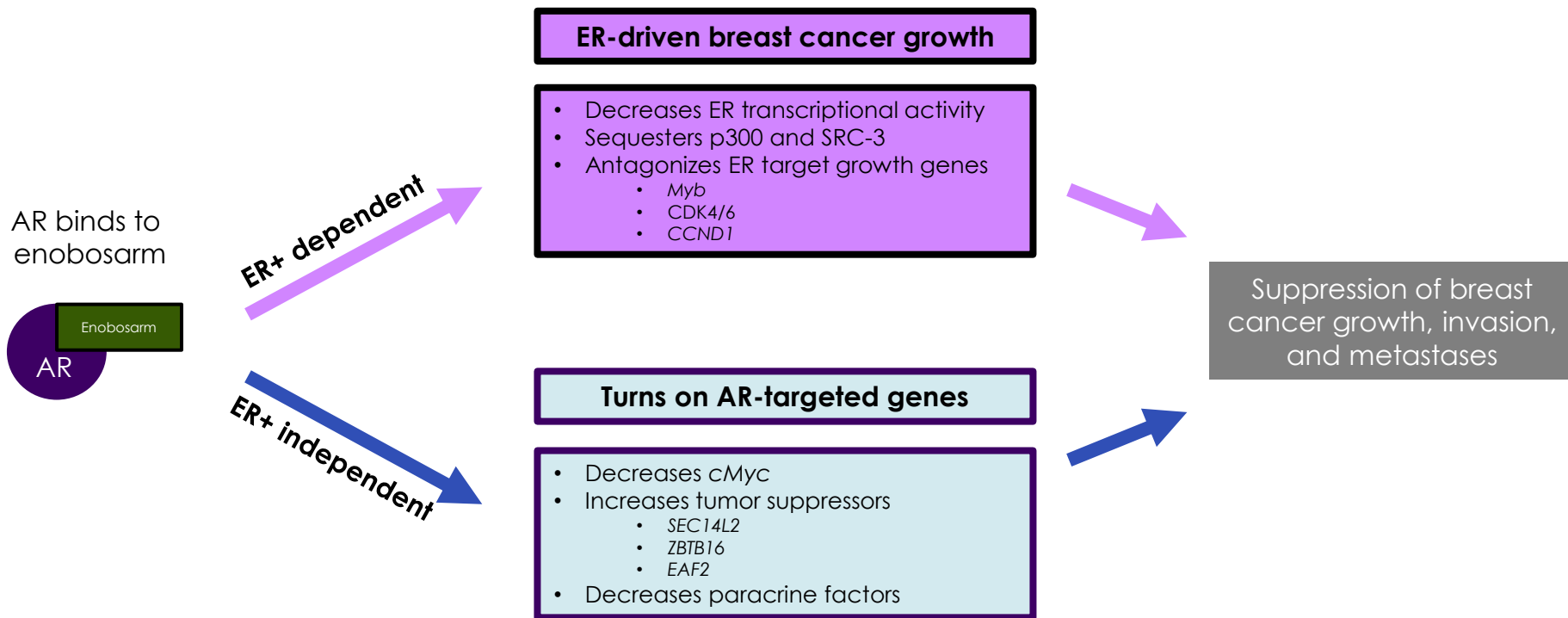
- 6 Phase 2 studies in breast cancer (5) or breast disease (1)
- 12 Phase 1 studies for NDA label completed



Chemical structure of Enobosarm

Mechanism of action of enobosarm in breast cancer^{1,2}

Androgen receptor activation by enobosarm leads to breast cancer tumor suppression



¹Adapted from Hickey et al, Nature Medicine February 2021 | ² Narayanan R et al. PLOS one 9:e103202, 2014

Phase 2 clinical trial (G200802) design

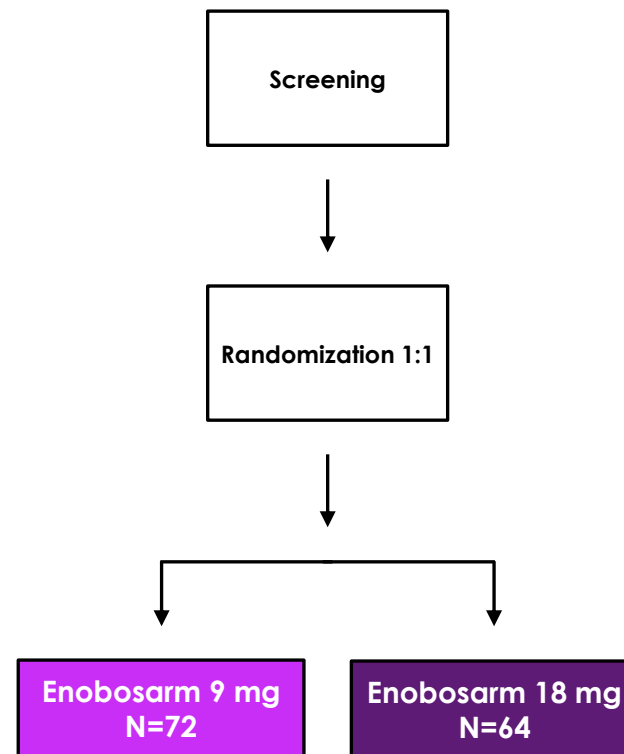
Targeting AR+ ER+ HER2- metastatic breast cancer in a heavily pretreated population¹

Trial design

- Open label, multicenter, multinational, randomized parallel design Phase 2 study to assess the efficacy and safety of enobosarm 9 mg or 18 mg oral daily dose in postmenopausal subjects with AR+ER+ metastatic breast cancer
- Efficacy primary endpoint- To assess the clinical benefit rate (CBR) (CR + PR + SD) in subjects with AR+ breast cancer treated at 6 months (by RECIST 1.1)

Patient population - 136 women enrolled

- ER+ metastatic or locally recurrent breast cancer not amenable to surgery
 - AR status was assessed centrally (>10%) and AR+ patients were included in the evaluable patients
 - Patients that were AR negative, not determined or uninformative were not in the evaluable population
- Previously responded to adjuvant endocrine Tx for ≥ 3 years, or most recent endocrine Tx for metastatic disease ≥ 6 months



¹Palmieri C et al. Phase 2 Clinical Trial results. San Antonio Breast Cancer Symposium Satellite Spotlight, December 2020.

Demographics	9 mg cohort	18 mg cohort
Age (median), years (range)	60.5 (35-83)	62.5 (42-81)
Caucasian (%)	98.0	94.2
Initial presentation of Stage IV metastatic breast cancer	12%	26.9%
Median months since initial diagnosis (range)	110.0 (19-435)	86.0(15-323)
Median months since metastatic diagnosis (range)	34.3 (1-167)	27.4 (1-225)
Source of tissue AR primary/metastatic (%)	52/44	57.7/40.4
Median % of cells staining AR+ (range)	53.4 (11-96)	51.4 (14-98)
AR status confirmed centrally (%)	94.0	86.5
Bone only non-measurable (%)	38.0	32.7
Prior chemotherapy (%)	90.0	92.3
Median prior lines of endocrine therapy (range)	3.2 (1-7)	3.2 (1-7)

Phase 2 clinical trial (G200802)

Overall safety and efficacy summary



Safety

- Enobosarm was well tolerated
- Majority of events were Grade 1 and 2

	9 mg N=75	18 mg N=61
Patients with any SAEs	8 (10.7%)	10 (16.4%)
Grade 3 Drug Related Adverse Events	5	9
Grade 4 Drug Related Adverse Events	1	1
Patients with Treatment-Emergent Adverse Events Leading to Death	0	0

Grade 3 and 4 Drug Related Adverse Events	9 mg N=75	18 mg N=61
Increased alanine aminotransferase	1 (1.3%)	2 (3.3%)
Increased aspartate aminotransferase	2 (2.7 %)	
Hypercalcemia	2 (2.6%)	2 (3.3%)
Headache	1 (1.3%)	1 (1.6%)
Anemia	1 (1.3%)	
Dry mouth		1 (1.6%)
Decreased white blood cell count		1 (1.6%)
Decreased appetite		1 (1.6%)
Fatigue	1 (1.3%)	2 (3.3%)
Tumor flare		2 (3.3%)
Agitation		1 (1.6%)
Lymphadenopathy		1 (1.6%)
Acute kidney injury		1 (1.6%)

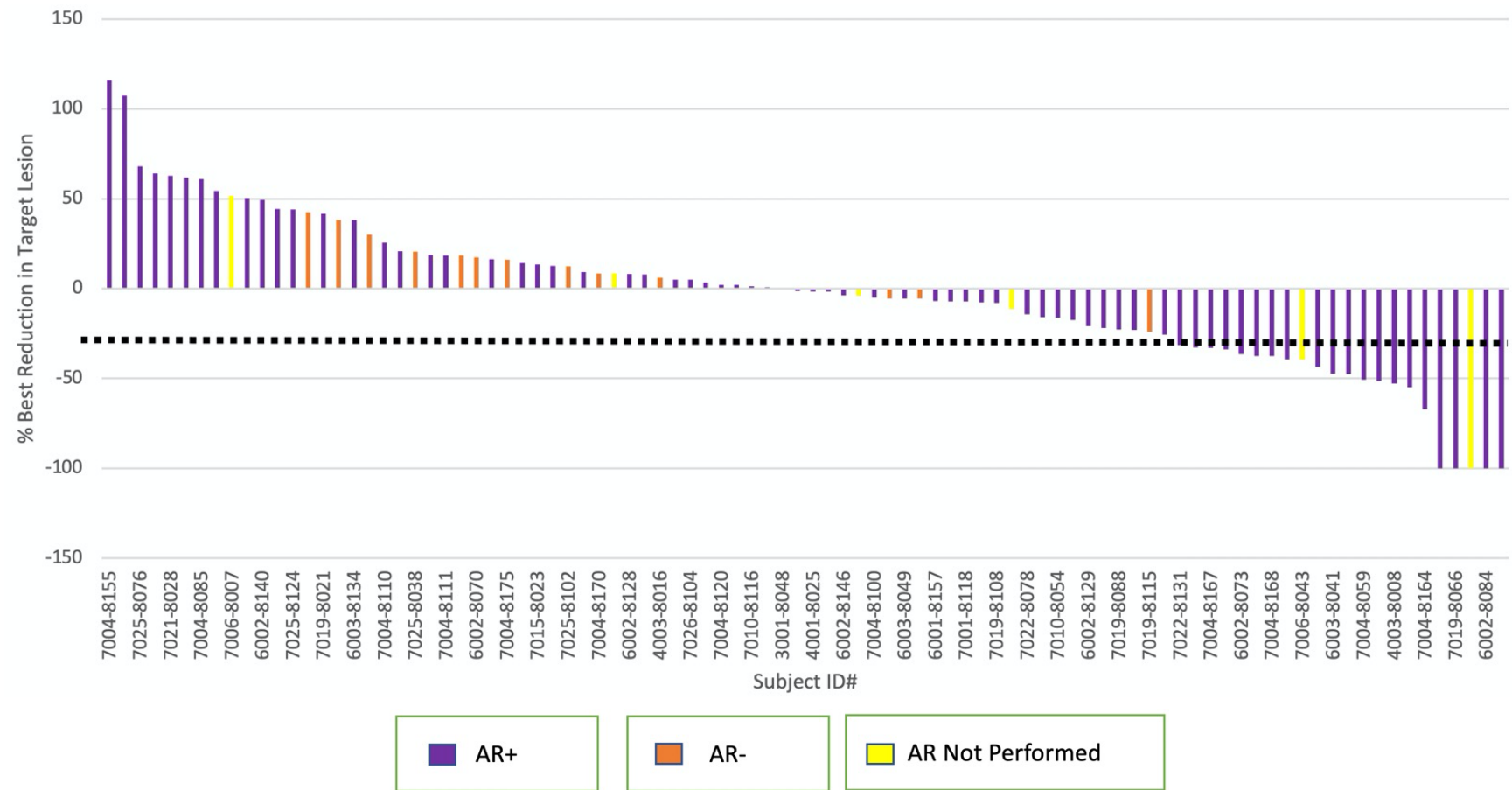
Efficacy

Evaluable population (AR+)

	9mg cohort	18mg cohort
Number of evaluable patients	50	52
Primary endpoint: CBR at 24 weeks	32% (95% CI: 19.5%;46.7%)	29% (95% CI: 17.1%;43.1%)

Phase 2 clinical trial (G200802)- AR is required for an objective tumor response

Best overall % target lesion reduction – Enobosarm 9 and 18 mg cohorts combined



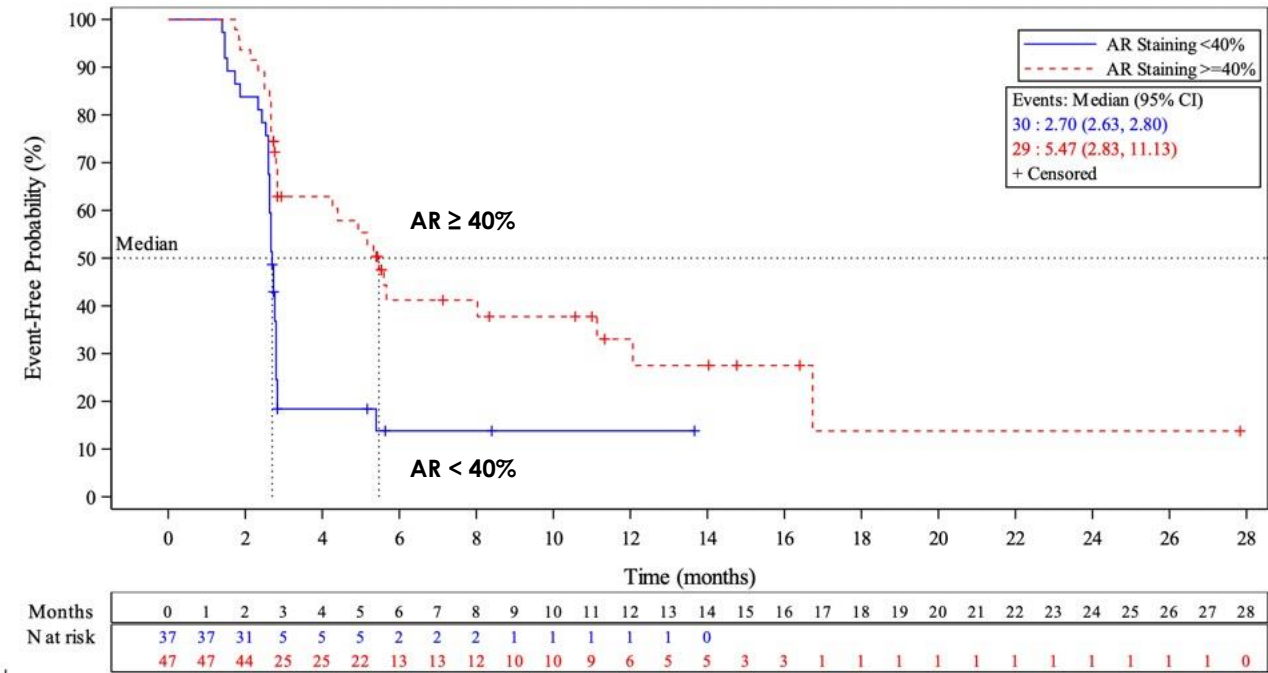
Post-hoc AR expression subset analysis:

- Subset of ITT with known AR status and have measurable disease (n=84)
- Combined both the 9mg and 18 mg cohorts to increase power of analysis

% AR staining	% of patients (n)	CBR at 24 wks*	Best ORR**	Median rPFS***
≥ 40%	56% (47)	52%	34%	5.47 months
< 40%	44% (37)	14%	2.7%	2.70 months

*p<0.0004; **p<0.0003; ***p<0.001

Phase 2 clinical trial (G200802)
Radiographic progression free survival– Enobosarm 9 and 18 mg combined cohorts



p<0.001

Phase 2 clinical trial (G200802)- Post-hoc AR expression subset analysis

Duration of previous estrogen blocking agent response was similar regardless of AR status



- Analysis of ITT (FAS) group with known AR status and have measurable disease (n=84)
- Had received at least 2 prior therapies in a metastatic setting prior to randomization to Phase 2 study and duration of response information was available
- In estrogen blocking agent resistant breast cancer, the presence of AR was not sufficient to influence median duration of therapy with another estrogen blocking agent

	< 40% AR nuclei staining	≥ 40% AR nuclei staining
n=	15	22
Mean # of prior therapies	2.87 ± 1.06	2.72 ± 0.83
Median duration of therapy	13 months	14 months

- **Enobosarm AR targeted treatment demonstrated clinical benefit with objective tumor responses in women with heavily pretreated estrogen blocking agent resistant AR+ ER+ HER2- metastatic breast cancer**
- **The presence of AR and expression of AR \geq 40% enriched for subjects most likely to respond to enobosarm treatment**
- **Quality of life measurements demonstrated overall improvement including mobility, anxiety/depression and pain**
- **Enobosarm appears safe and well tolerated without masculinizing effects, increase in hematocrit, or liver toxicity**
- **The 9 mg dose selected for Phase 3 clinical study**
 - 9 mg cohort had similar tumor responses with a slightly better toxicity profile than the 18 mg dose cohort
- **Enobosarm represents a new class of endocrine therapy that targets and activates the AR, tumor suppressor, in AR+ ER+ HER2- metastatic breast cancer**

Enobosarm and CDK4/6 inhibitors in estrogen blocking agent resistant AR+ER+HER2- metastatic breast cancer

Preclinical models (Patient derived xenografts)^{1,2}

• Estrogen blocking agent resistant breast cancer

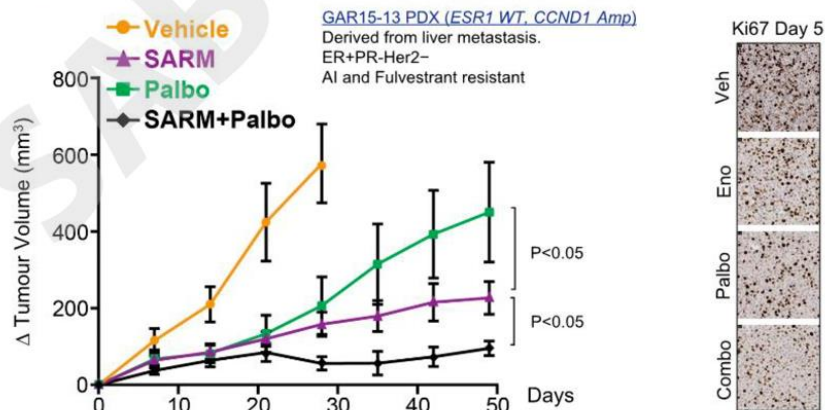
- CDK4/6 inhibitor inhibits growth of estrogen blocking agent resistant breast cancer^{1,2}
- Enobosarm monotherapy has greater inhibition of estrogen blocking agent resistant breast cancer than a CDK4/6 inhibitor^{1,2}
- Enobosarm + CDK4/6 inhibitor had greater inhibition of estrogen blocking agent resistant breast cancer than either alone^{1,2}

• Estrogen blocking agent and CDK4/6 inhibitor resistant breast cancer

- Enobosarm suppressed breast cancer cells that are resistant to both CDK 4/6 inhibitor and estrogen blocking agent²
- Enobosarm and CDK4/6 inhibitor further suppressed breast cancer cells that are resistant to both CDK4/6 inhibitor and estrogen blocking agent – enobosarm restores CDK 4/6 inhibitor sensitivity²

San Antonio Breast Cancer Symposium®, December 10-14, 2019.

AR agonism in combination with a CDK4/6 inhibitor *in vivo*



SARM= enobosarm and Palbo=Palbociclib, CDK4/6 inhibitor

- **Objective tumor responses**
 - 30% overall
- **CBR at 24 weeks**
 - 50% overall
- **Mean duration on study (either PFS or censored)**
 - 7.3 months (9 mg and 18 mg groups)
 - 10.0 months (9 mg dose group)

Palbociclib resistant subjects with measurable disease

9 mg patient ID	Outcome
7004-8120	
7019-8066	Complete Response
7026-8083	
7019-8087	Complete Response
7019-8106	Stable Disease

18 mg patient ID	Outcome
6003-8133	
7001-8001	Partial Response
7001-8118	Stable Disease
7004-8100	
7022-8078	

AR% Staining	ORR	rPFS (mean) months
<40	0/3 (0%)	3.13
≥ 40	3/7 (43%)	9.04

NCCN 2020 guidelines: CDK 4/6 inhibitors are standard of care for treatment of ER+HER2- metastatic breast cancer

If disease progression on CDK4/6 inhibitor treatment, there are limited data to support additional line of treatment with another CDK 4/6 inhibitor containing regimen

First-Line Metastatic

Nonsteroidal aromatase
inhibitor
+
CDK4/6 inhibitor

Fulvestrant
+
CDK 4/6 inhibitor

Second-Line Metastatic

Fulvestrant
+
CDK 4/6; if CDK4/6 inhibitor
was not previously used

ENABLAR-2 AR+ (≥40%)
Enobosarm
+
Abemaciclib, CDK4/6
inhibitor

Third-Line Metastatic

ARTEST AR+ (≥40%)
Enobosarm monotherapy

AR+ (<40%)
Sabizabulin monotherapy

Phase 3 registration, open label, randomized ARTEST clinical trial (V3002401)(NCT#04869943)

3rd line metastatic setting – AR staining $\geq 40\%$ - enrolling



ARTEST Clinical Trial Design

Phase 3 open label, multicenter, multinational, randomized, active control pivotal study evaluating the efficacy and safety of enobosarm 9mg oral daily dose versus active control (exemestane \pm everolimus or a SERM) in metastatic AR+ ER+ HER2- breast cancer in subjects who have failed a nonsteroidal aromatase inhibitor, fulvestrant, and CDK4/6 inhibitor therapy (3rd line metastatic setting)

ARTEST Patient Population

- AR+ ER+ HER2-metastatic or recurrent locally advanced breast cancer, not amenable to curative treatment by surgery or radiotherapy, with objective evidence of disease progression
- Must have had received a nonsteroidal AI inhibitor, fulvestrant, and CDK 4/6 inhibitor for metastatic disease
 - Previously responded to hormone Tx for metastatic disease ≥ 6 months
 - No prior chemotherapy for the treatment of metastatic breast cancer
 - Centrally confirmed $\geq 40\%$ AR nuclei staining from breast cancer sample

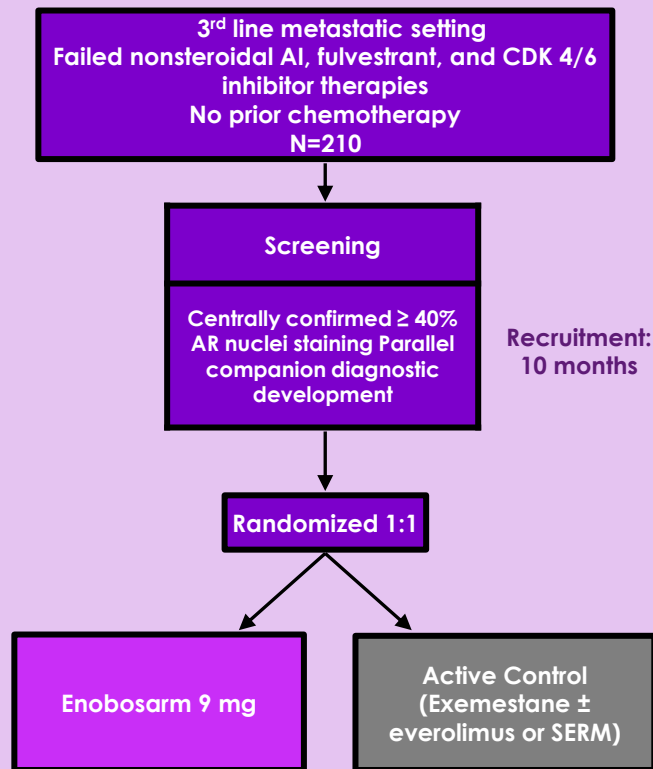
ARTEST Efficacy Endpoints

- **Primary endpoint:**
 - Median radiographic progression free survival (rPFS)
- **Secondary endpoints:**
 - Overall response rate (CR+PR)
 - Duration of response
 - Overall survival
 - Change in Short Physical Performance Battery (SPPB)
 - Change in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ)

ARTEST Sample Size Assumptions

- Total sample size: 210
- $\alpha = 0.05$
- 99% power
- 20% drop out rate
- 123 events
- Active control group (exemestane \pm everolimus or a SERM): estimated median rPFS = 3 months¹⁻³
- Enobosarm arm: estimated median rPFS=6 months

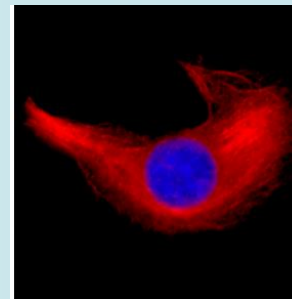
Phase 3 Pivotal AR+ER+HER2- Metastatic Breast Cancer



¹Yeruva, S et al. *npj Breast Cancer* 4: 1, 2018 | ²Cook, M et al. *The Oncologist* 26:101, 2021 | ³Rozenblit M et al. *Breast Cancer Research* 23:14, 2021

Sabizabulin is an oral targeted cytotoxic and cytostatic anticancer agent that disrupts the cytoskeleton

- **Microtubules are critical components of the cytoskeleton and a validated target for anticancer drugs**
- **Sabizabulin targets microtubules at both the “colchicine binding site” on β -tubulin and an unique site on α -tubulin to crosslink α and β subunits to disrupt cytoskeleton**
 - Effects microtubule dynamics at low nM concentrations:
 - Inhibits microtubule polymerization
 - Causes microtubule depolymerization
- **Favorable toxicity profile no neurotoxicity and no neutropenia or myelosuppression**
- **Not a substrate for multidrug resistance proteins (P-gp, MRPs, and BCRP)**
- **Demonstrated anticancer activity against taxane, vinca alkaloid, doxorubicin, enzalutamide, and abiraterone resistant prostate cancer models, and clinically, in Phase 1b/2 clinical trial in metastatic castration resistant prostate cancer**
- **Has broad activity against other tumor types as well: Triple negative breast cancer (taxane resistant)⁷, Cervical cancer (taxane resistant)⁸, Lung cancer (taxane resistant)⁹, Ovarian cancer (taxane resistant)¹⁰, Uterine cancer¹¹, Pancreatic cancer¹², Melanoma¹³, Human promyelocytic leukemia (vincristine resistant)¹⁴**



¹ Chen J et al. J Med Chem 55:7285-7289 2012 | ² Li CM et al. Pharm Res 29:3053-3063 2012 | ³ Lu Y et al. J Med Chem 57:7355-7366 2014 | ⁴ 28 day rat and dog toxicity studies on file at Veru, Inc. | ⁵ Dumontet C et al. Nature Reviews Drug Discovery 9:790, 2010 | ⁶ Markowski M et al J Clin Onc 37:167, 2019 | ⁷ Deng S et al Mol Cancer Ther 19:348-63, 2020 | ⁸ Kashyap VK et al Cancer Lett 470:64-74, 2020 | ⁹ Foyez M et al Cancer Letters 495:76, 2020 | ^{10,11} Data on file Veru, Inc. 2020 | ¹² Kashyap V et al J Experimental and Clinical Can Res 38:29, 2019 | ¹³ Chen J et al J Med Chem 55:7285-7289, 2012; Hwang DJ et al ACS Med Chem Lett 6:993-997, 2015 | ¹⁴ Data on file Veru, Inc. 2014

Phase 2b open label, randomized sabizabulin clinical trial (V2011201)

3rd line metastatic setting – AR staining < 40%- anticipated start Q4 2021

Clinical Trial Design

Phase 2b open label, multicenter, multinational, randomized, active control study evaluating the efficacy and safety of sabizabulin oral daily dose versus active control (exemestane ± everolimus or a SERM) in metastatic ER+ HER2- breast cancer in subjects who have failed a nonsteroidal aromatase inhibitor, fulvestrant, and CDK4/6 inhibitor therapy (3rd line metastatic setting)

ARTEST Patient Population

- ER+ HER2-metastatic or recurrent locally advanced breast cancer, not amenable to curative treatment by surgery or radiotherapy, with objective evidence of disease progression
- Must have had received a nonsteroidal AI inhibitor, fulvestrant, and CDK 4/6 inhibitor for metastatic disease
 - Previously responded to hormone Tx for metastatic disease ≥ 6 months
 - No prior chemotherapy for the treatment of metastatic breast cancer
 - Centrally confirmed ≥ 40% AR nuclei staining from breast cancer sample

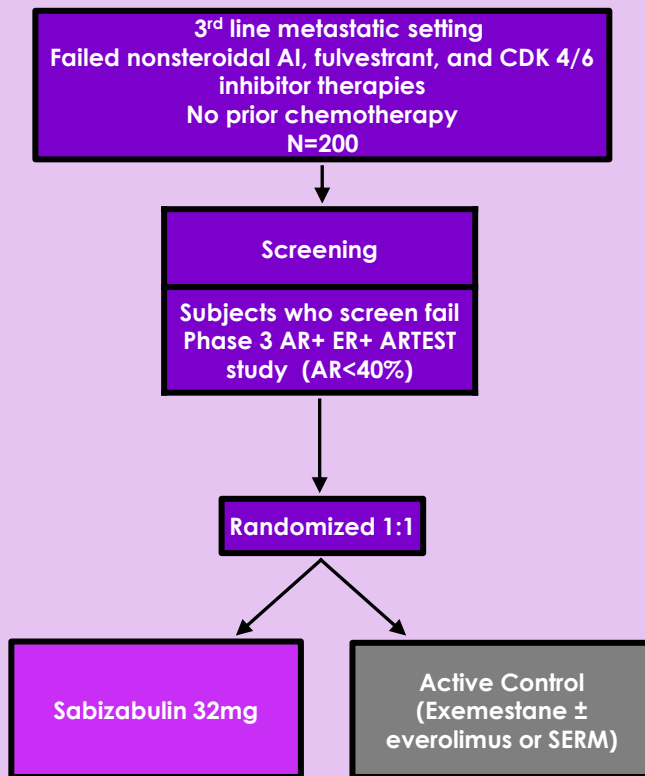
Efficacy Endpoints

- **Primary endpoint:**
 - Median radiographic progression free survival (rPFS)
- **Secondary endpoints:**
 - Overall response rate (CR+PR)
 - Duration of response
 - Overall survival
 - Change in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ)
 - CBR

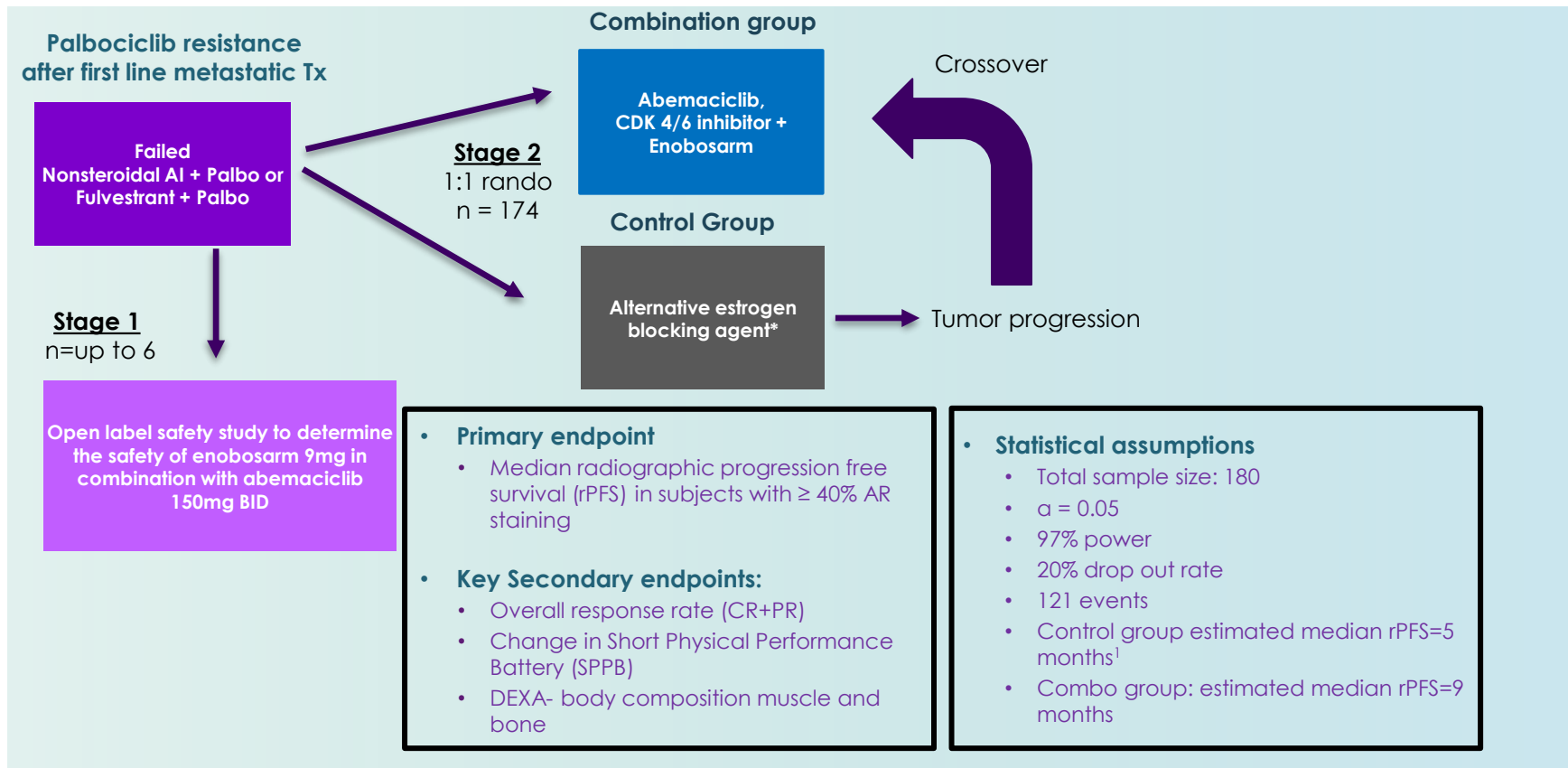
Assumptions

- **Active control group (exemestane± everolimus or a SERM):** estimated median rPFS = 3 months¹⁻³
- **Sabizabulin arm:** estimated median rPFS=6 months

Phase 2b ER+HER2- (AR<40%) Metastatic Breast Cancer



Anticipated start date is calendar Q4 2021



¹ Ibrance FDA Package Insert (2019)



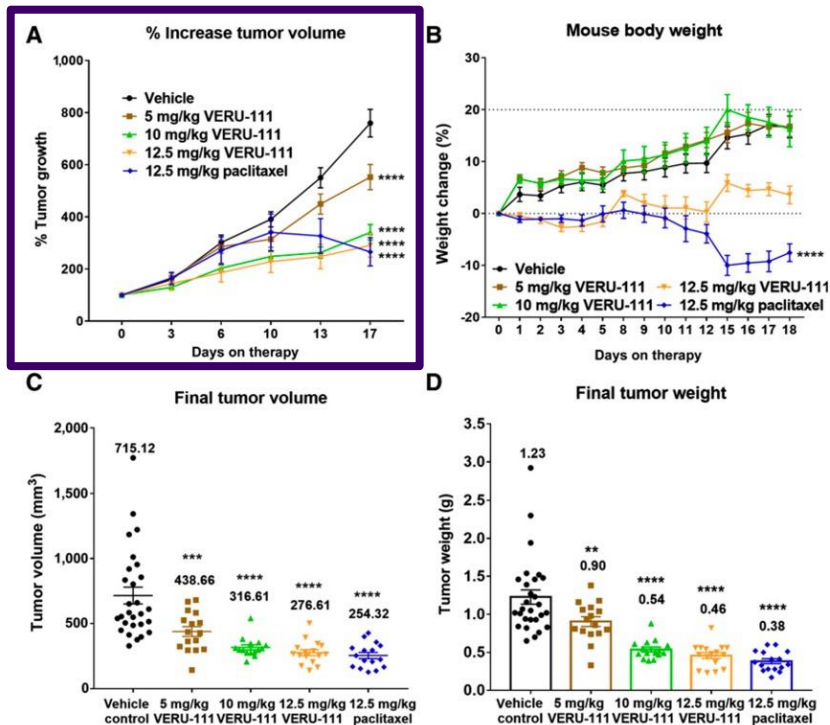
Sabizabulin 32mg

for the treatment of chemotherapy resistant
metastatic triple negative breast cancer

Preclinical studies in taxane resistant triple negative breast cancer¹

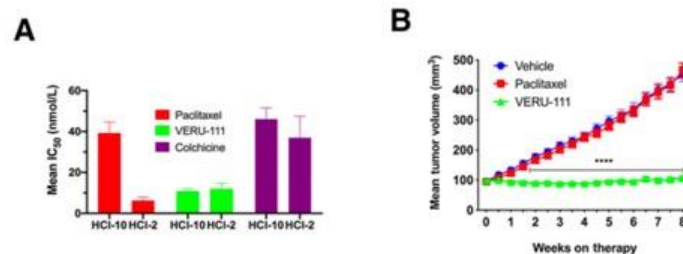
Taxane sensitive

Sabizabulin (VERU-111) has antitumor activity in MDA-MB-231 TNBC Model¹

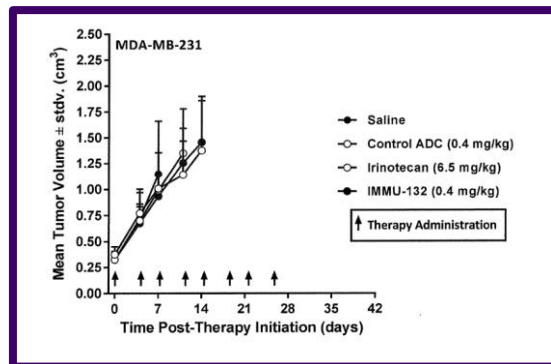


Taxane resistant

- HCI-10-Luc2 TNBC - taxane resistant
- HCI-2-Luc2 TNBC – taxane sensitive



TRODELVY (IMMU-132) has no activity in MDA-MB-231 TNBC Animal Model²



- Preclinical models of AR+ TNBC show enobosarm has antitumor activity in animal models¹
- Phase 2 clinical trial²
 - Open label, single arm
 - Enobosarm 18 mg oral daily dosing
 - Pembrolizumab 200mg IV every 3 weeks
 - 18 women were enrolled and 16 were evaluable with AR+ metastatic triple negative breast cancer
 - Efficacy endpoints
 - 25% clinical benefit rate at 16 weeks
 - 1 CR and 1 PR
 - Safety
 - Combination was well tolerated

The Oncologist®

Clinical Trial Results

A Phase II Clinical Trial of Pembrolizumab and Enobosarm in Patients with Androgen Receptor-Positive Metastatic Triple-Negative Breast Cancer

YUAN YUAN^a, JIN SUN LEE,^a SUSAN E. YOST,^a PAUL H. FRANKEL,^b CHRISTOPHER RUEL,^b COLT A. EGELSTON,^c WEIHUA GUO,^c JOHN D. GILLECE,^e MEGAN FOLKERTS,^e LAUREN REINING,^e SARAH K. HIGHLANDER,^e KIM ROBINSON,^a SIMRAN PADAM,^a NORMA MARTINEZ,^a AILEEN TANG,^a DANIEL SCHMOLZE,^d JAMES WAISMAN,^a MINA SEDRAK,^a PETER P. LEE,^c JOANNE MORTIMER^a
Departments of ^aMedical Oncology and Therapeutics Research, ^bBiostatistics, ^cImmune-Oncology, and ^dPathology, City of Hope Comprehensive Cancer Center and Beckman Research Institute, Duarte, California, USA; ^ePathogen and Microbiome Division, Translational Genomics Research Institute North, Flagstaff, Arizona, USA

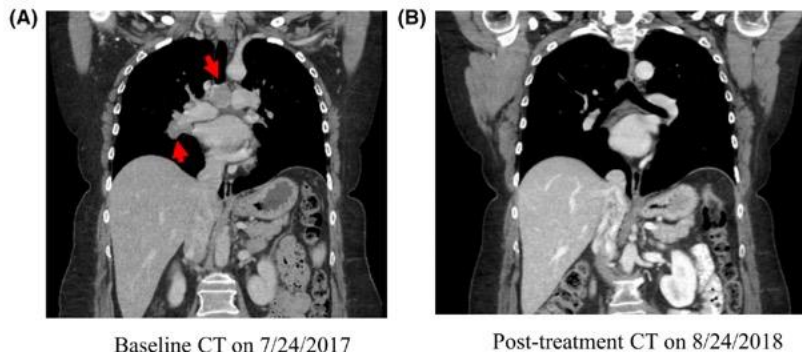


Figure 2. CT imaging of exceptional response. (A): Baseline CT on July 24, 2017, showed subcarinal and right hilar conglomerate lymph adenopathy (the red arrows pointing the target lesions). (B): The bulky subcarinal adenopathy and right hilar is no longer seen on August 24, 2018. Patient continues to have no evidence of disease as of July 2020. Abbreviation: CT, computed tomography.

¹ Narayanan R et al. PLOS ONE 9:e103202, 2014 | ² Yuan Y et al. The Oncologist 25:1-18, 2020

Trial study design

- Patients previously treated with a least 2 systemic chemotherapies for metastatic triple negative breast cancer
- Safety run-in of sabizabulin 32mg + enobosarm 9mg
- Single arm, open label study
 - Oral Sabizabulin 32 mg
- Expected to initiate Q1 2022 - 111 subjects
- Primary endpoint
 - ORR
 - Duration of response
- Other key endpoints
 - Median rPFS
 - Safety

Metastatic
Triple negative
breast cancer
failed 2 previous
chemotherapies

N=111

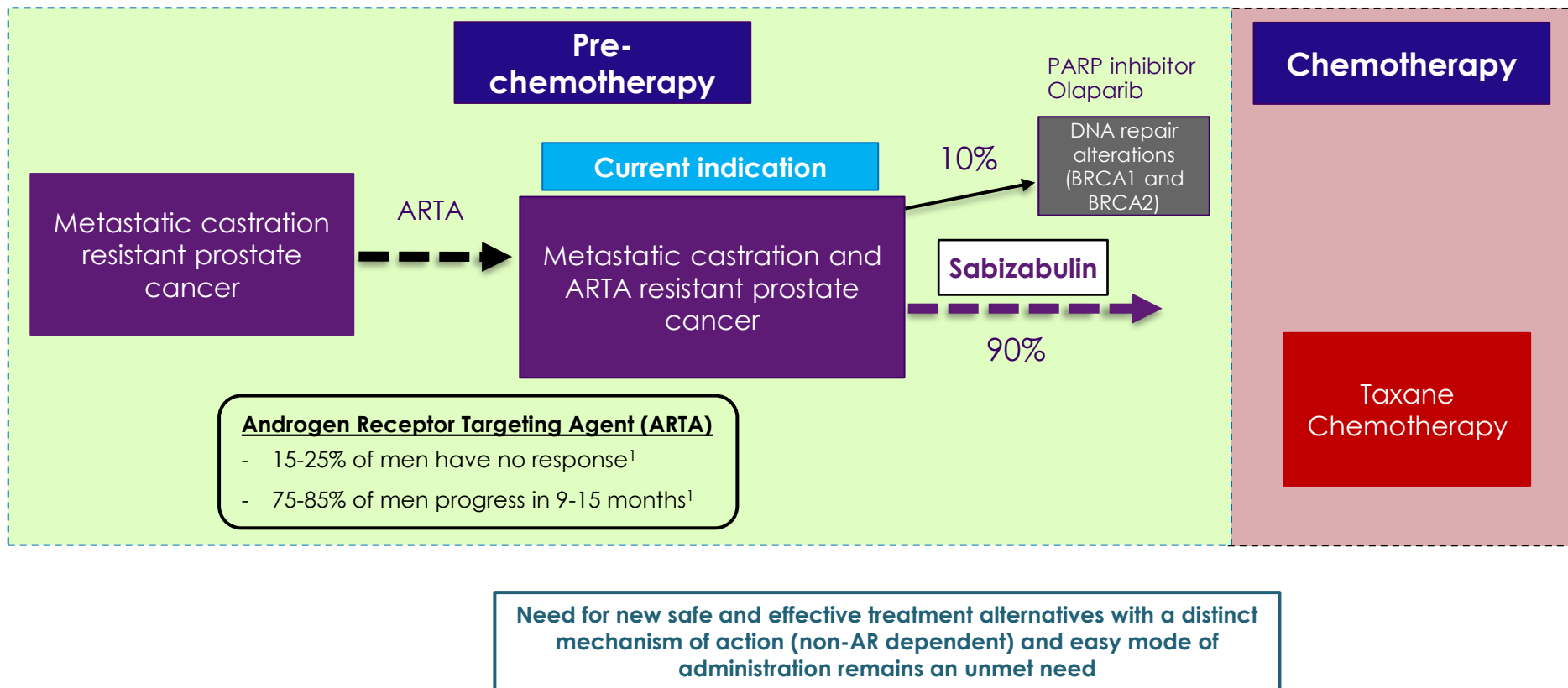
sabizabulin

Primary
endpoints

ORR and duration
of response

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prostate Cancer						
Sabizabulin	Oral cytoskeleton disruptor and androgen receptor transport disruptor	Metastatic castration and AR targeting agent resistant prostate cancer	Phase 3 VERACITY: 245 Patients - Enrolling			
VERU-100	GnRH antagonist 3-month subcutaneous depot injection	Hormone sensitive advanced prostate cancer	Phase 2: 35 Patients - Enrolling			

Sabizabulin prostate cancer treatment paradigm: Focus is on the prechemotherapy space which is a growing unmet need



Phase 1b- Dose escalation to evaluate safety of sabizabulin in men with metastatic castration resistant prostate cancer who progressed on AR targeting agent therapy and up to one taxane

- 7 US sites – Johns Hopkins Kimmel Comprehensive Cancer Center (lead center)
- 39 patients enrolled
- Trial design -2 part dosing schedule using standard 3+3 dose escalation strategy
 - Part 1- 7-day dose schedule to determine MTD – At each dose level, orally administered daily on Day 1-7 every 21 days (i.e. 7 days on, 14 days off)
 - Part 2- Expanded dose schedule – If 7-day dosing tolerated/safe, patients were eventually dosed daily until disease progression/toxicity

Phase 2- Evaluate safety and efficacy of sabizabulin RP2D 63mg daily in metastatic castration resistant prostate cancer who progressed on AR targeting agent therapy, but prior to IV chemotherapy

- 13 U.S. clinical centers
- 41 men enrolled
- Completed enrollment in September 2020
- Trial design
 - Open label
 - Recommended Phase 2 dose is 63mg/day
 - PK study to evaluate Phase 2 dosage versus Phase 3 dosage formulations

Phase 1b and 2 clinical studies

Baseline demographics

Characteristic	Phase 1b N=39	Phase 2 N=41
Age, years		
Median (range)	74 (61-92)	73 (57-86)
Race/Ethnicity, n (%)		
Caucasian	28 (72%)	31 (76%)
African American	8 (21%)	4 (10%)
Hispanic	3 (8%)	5 (12%)
Other	0	1 (2%)
ECOG performance status, n (%)		
0	21 (54%)	30 (73%)
1	16 (41%)	10 (24%)
2	2 (5%)	1 (2%)
Metastatic disease location		
Bone only	21 (55%)	24 (59%)
Lymph node only	6 (16%)	8 (20%)
Bone and lymph node	8 (21%)	7 (17%)
Visceral only	1 (3%)	0
Bone and visceral	1 (3%)	1 (2%)
Lymph node and visceral	0	1 (2%)
Prior therapies		
Abiraterone	14 (36%)	7 (17%)
Enzalutamide	8 (20%)	13 (32%)
Abiraterone and enzalutamide or apalutamide or proxalutamide	17 (44%)	14 (34%)
Apalutamide or proxalutamide	0	5 (12%)
Abiraterone and enzalutamide and apalutamide or proxalutamide	0	2 (5%)
Taxane	9 (23%)	3 (7%)

Sabizabulin clinical development

Safety- Phase 1b (expansion cohort) and Phase 2 clinical study

**Most prevalent adverse events regardless of grade (>10% frequency) in patients that received 63 mg dose
N=54**

Adverse Event	All Grades regardless of relationship to study drug	Grade ≥ 3 regardless of relationship to study drug
Diarrhea	32 (59.3%)	4 (7.4%)
Fatigue	18 (33.3%)	3 (5.6%)
Nausea	17 (31.5%)	1 (1.9%)
Decreased appetite	17 (31.5%)	0
Constipation	9 (16.7%)	0
ALT increased	10 (18.5%)	3 (5.6%)
AST increased	9 (16.7%)	2 (3.7%)
Back pain	8 (14.8%)	1 (1.9%)
Vomiting	7 (13.0%)	1 (1.9%)
Abdominal pain	6 (11.1%)	0
Dysgeusia	6 (11.1%)	0

Diarrhea was mostly (88%) grade 1 and 2 and medically manageable as only 1 patient discontinued clinical study because of this adverse event; expect this adverse event to be less in Phase 3 because of better oral bioavailability of Phase 3 dosage form and reduced exposure of GI tract to non-absorbed sabizabulin

At the recommended Phase 2 dose (RP2D) of 63 mg oral daily dose of sabizabulin

- Sabizabulin was well tolerated with no reports of clinically relevant neutropenia or neurotoxicity
- Adverse events were mostly grade 1 and 2¹
- Safety profile appears similar as what is reported for an androgen receptor targeting agent
- Daily chronic drug administration is feasible and safe

¹ Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose

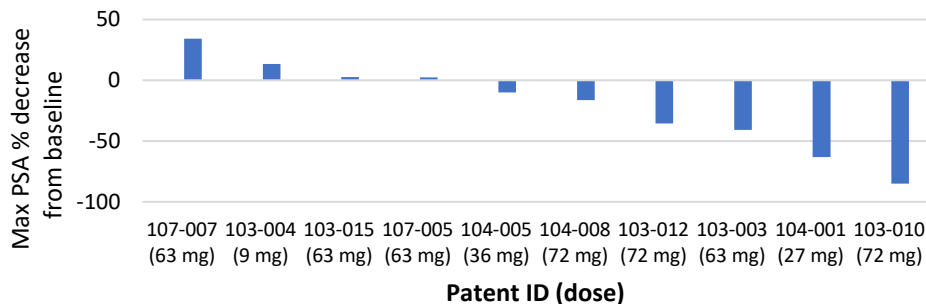
Sabizabulin Phase 1b efficacy

PCWG3 criteria to evaluate efficacy after 12 weeks of treatment (4 cycles)

- **10 men reached at least four cycles of continuous dosing**
 - Disease (4 Bone; 3 LN; and 3 LN+Bone)
 - Previous treatment- (5 Abi; 2 Enz; and 3 Abi+Enz)
- **PSA responses**
 - 6/10 had decrease in PSA
 - 4/10 had $\geq 30\%$ decline in PSA
 - 2/10 had $\geq 50\%$ decline in PSA
- **Best objective tumor responses**
 - 2 men had partial response (PR) (two additional objective responses occurred in subjects who did not reach 4 cycles)
 - 8 men had stable disease (SD)
- **Median radiographic progression free survival**
 - >12 months (range 6.0-30+ months)
- **2/10 men still on study as of October 2021**

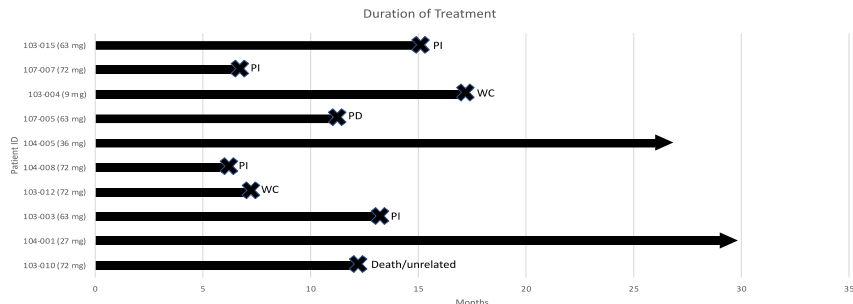
PSA waterfall plot

Ten men have reached ≥ 4 cycles of continuous dosing



Swimmers' plot

Ten men have reached ≥ 4 cycles of continuous dosing



Sabizabulin clinical development

Efficacy- Phase 1b (expansion cohort) and Phase 2 study

Sabizabulin had evidence of significant and durable objective tumor responses	
In ITT population, all patients with measurable disease at baseline (n=29)	ORR (5PR +1CR observed): 20.7% ¹
All evaluable patients that would qualify for Phase 3 (n=26)	ORR: 23.1% ¹
In all patients ¹ that received ≥ 63 mg (n=55)	Median rPFS is estimated to be at least: 7.4 months (Actual median rPFS has not been reached in the Phase 2 as there are still 10 men on study ¹)

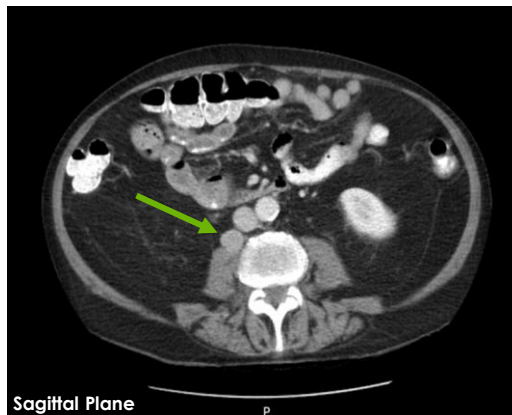
¹Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose as of February 2021 and excluded superscan disease where follow up of lesions is not possible

Patient: 104-001

- mCRPC with lymph node only disease
- Prior treatment included:
 - Sipuleucel-T
 - Enzalutamide
 - Abiraterone
- Efficacy
 - Still on study 31 months
 - -63% PSA from 21 day cycle initiation baseline
 - ORR= PR

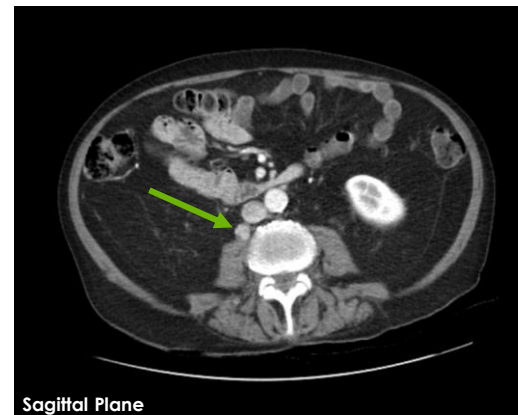
March 08, 2019: Screening CT scan

RP LN 1.7cm X 1.5cm
(measurable target lesion)



June 10, 2020: 15 months follow-up

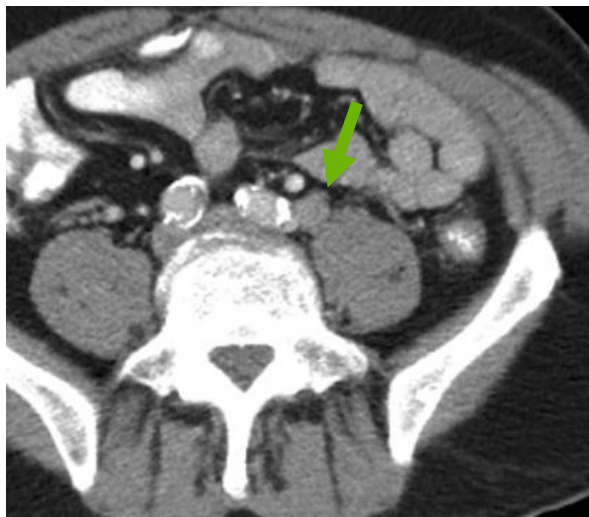
RP LN 1.1cm X 1.0cm
(-33% decrease to nonpathologic node)



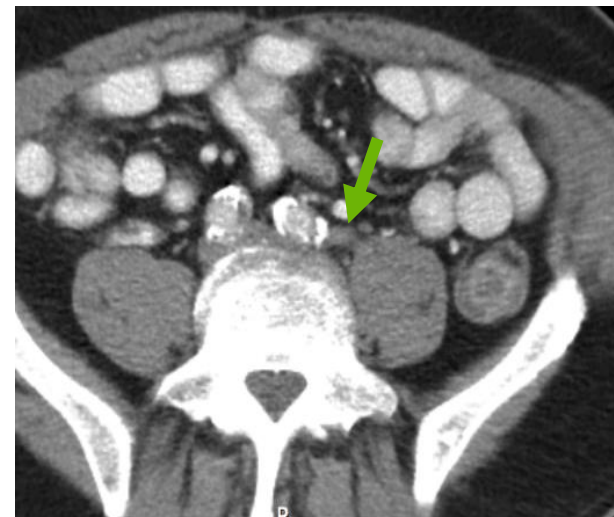
Patient: 104-017

- mCRPC with lymph node only disease
- Prior treatment included:
 - Apalutamide
- Efficacy
 - Still on study 15 months
 - -69% PSA from 21-day cycle initiation baseline
 - ORR= CR

July 8, 2020: Screening CT scan
Left common femoral node 1.4 cm
(target lesion)



September 29, 2020: 3 months follow-up
Left common femoral node 0.7 cm
(-50% decrease to nonpathologic node)



Sabizabulin was well tolerated with evidence of significant and durable objective tumor responses

- At the recommended Phase 2 dose (RP2D) of 63mg oral daily dose of sabizabulin
 - Well tolerated with no reports of significant neutropenia or neurotoxicity
 - Daily chronic drug administration is feasible and safe
 - Safety profile appears similar to that reported in package inserts for an androgen receptor targeting agent
- Evidence of cytotoxic and cytostatic antitumor activity was observed including PSA reductions and objective and durable tumor responses (CR+PR)
- Based on this target product profile: may be potentially prescribed by both Urologists and Medical Oncologists

VERACITY - Randomized, Active-Controlled, Open label Phase 3 Study of Sabizabulin 32mg for the Treatment of Metastatic Castration-Resistant Prostate Cancer in Patients Whose Prior Treatment Failed with at Least One Androgen Receptor Targeting Agent – Lead PI – Robert Dreicer, MD, University of Virginia

• Efficacy endpoints

• Primary endpoints

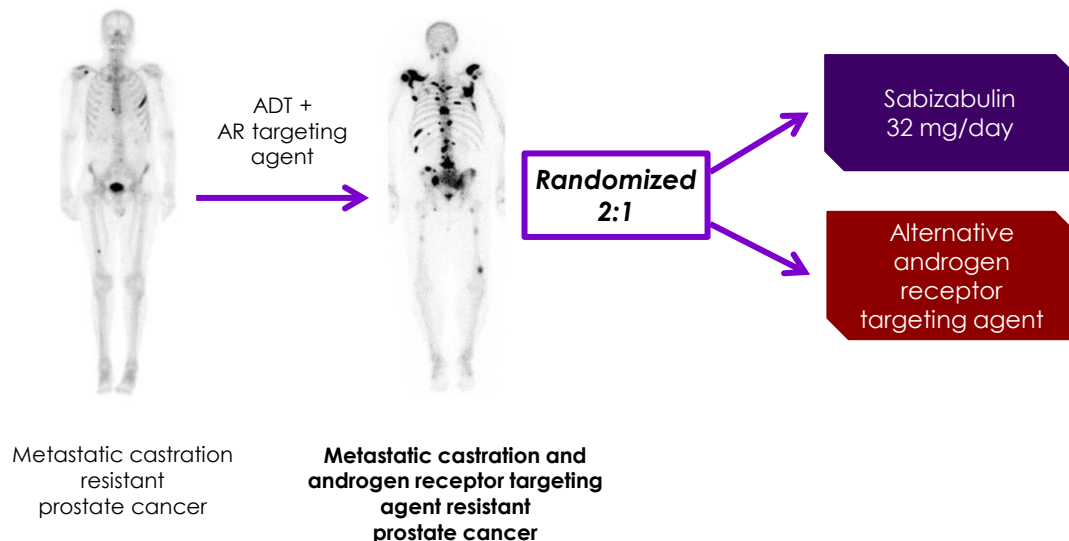
- Radiographic progression free survival (rPFS)

• Secondary endpoints

- Objective response rate
- Duration of objective response
- OS (interim analysis)
- Time to IV chemo
- Pain progression

• Assumptions

- Median rPFS- 7.4 months for sabizabulin vs 3.7 months for alternative AR targeting agent*
- Sample size - 245 men
 - 2:1 randomization
 - 155 events expected
 - $\alpha = 0.05$
 - 98% power
 - Drop out= 30%
 - 10 months recruitment time, 12 month follow up after last patient first dose

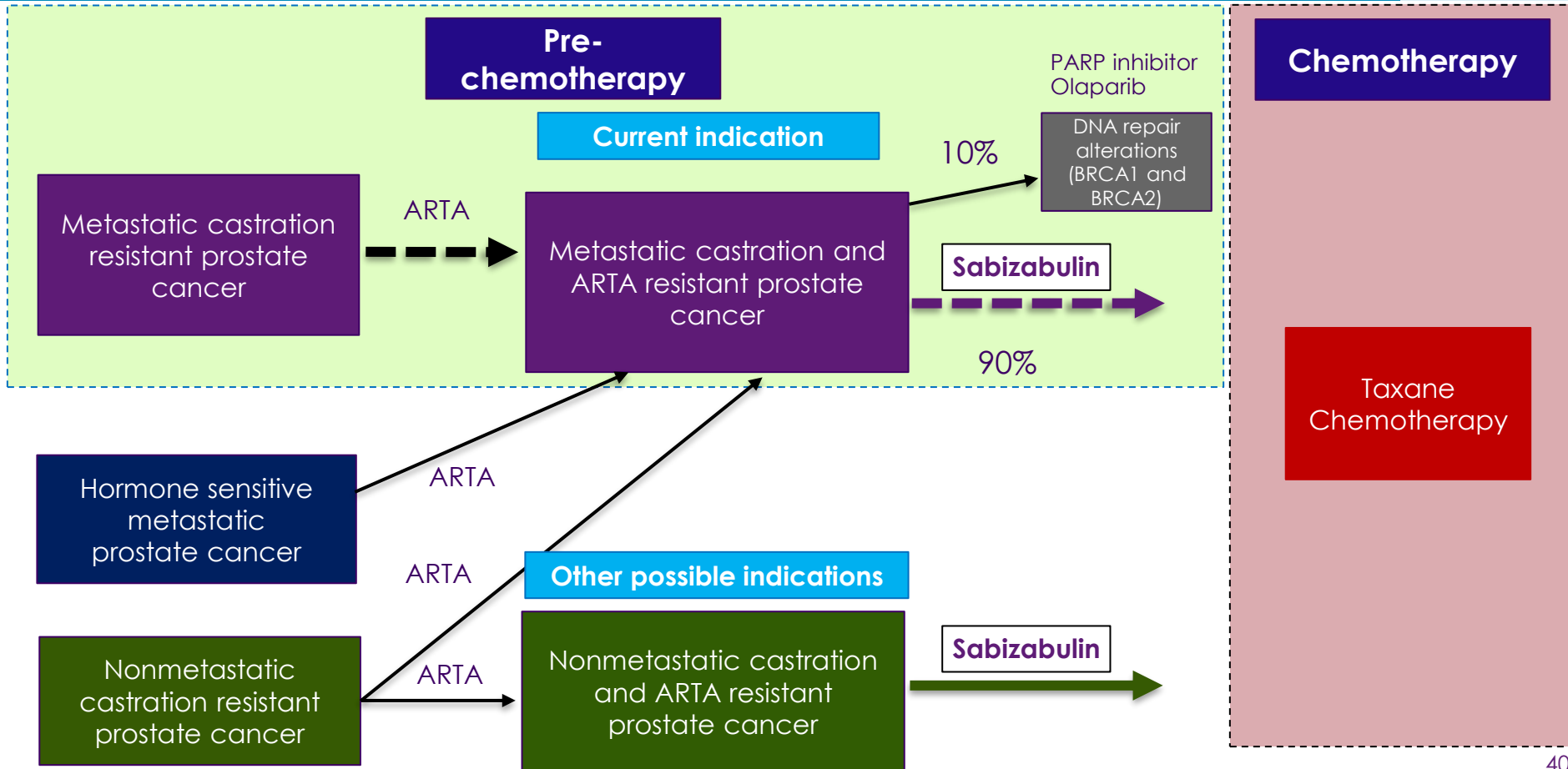


*Based on Olaparib study¹ and CARD study² an alternative androgen receptor targeting agent is expected to have a median rPFS of 3.6-3.7 months in this similar population

¹ de Bono J et al. NEJM April 28,2020 | ² de Wit R et al. NEJM 381:2506-18 2019

Sabizabulin prostate cancer treatment paradigm:

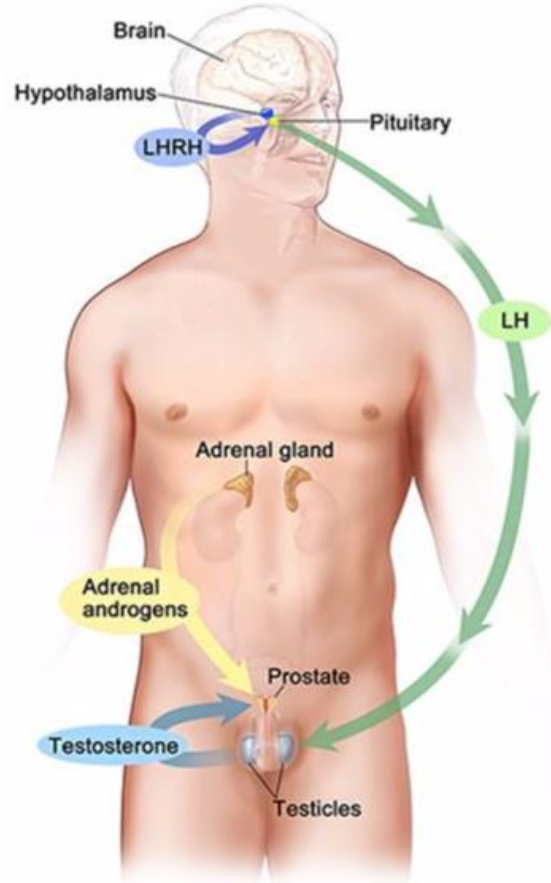
Focus is on the prechemotherapy space- largest segment of advanced prostate cancer



LHRH agonist

Long-acting products:
LUPRON® Depot (IM) and
ELIGARD® (SC) are leuprolide
products

- Concerns over initial surge in T levels- "T surge"
- Escapes from castration T levels – periodic increases in T levels¹
- Up to 17% of men do not achieve castration¹
- Does not suppress FSH
- Black box warning for cardiovascular safety concerns



GnRH antagonist

FIRMAGON® (degarelix) (SC)

- Painful subcutaneous injections: large loading and maintenance doses
 - Loading 6mL (2 X 3 mL)
 - Maintenance 4 mL
- No long acting depot available
- Must be given every month

¹ Gomella LG et Rev Urol 2009 11:52-60.

New potential product to addresses limitations of current ADT

Long-acting 3 month depot GnRH antagonist may provide better alternative



VERU-100 target product profile¹

- Novel proprietary GnRH antagonist decapeptide delivery formulation
- 3-month slow release subQ depot with no loading dose
 - Better compliance
 - Injectable delivery formulation is consistent with current medical practice patient visit schedule and billing/reimbursement procedures (Medicare Part B)
- Better castration
 - Immediate testosterone suppression no initial testosterone surge
 - Suppression of testosterone to less than 20ng/dL
 - Fewer testosterone escapes (micro-increases in testosterone)
- No black box warning for cardiovascular adverse effects for this class of drugs

Phase 2

Open label, dose finding VERU-100 GnRH antagonist long acting 3-month depot clinical trial

Actively enrolling approx. 35 men

Planned Phase 3 (1H 2022)

Open label, VERU-100 GnRH antagonist long acting 3-month depot clinical trial

N=100 subjects for 1 year

¹Developed in collaboration with Drug Delivery Experts, LLC (San Diego, California)



Sabazibulin 9 mg

for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome

Situation by WHO Region



Daily


Weekly

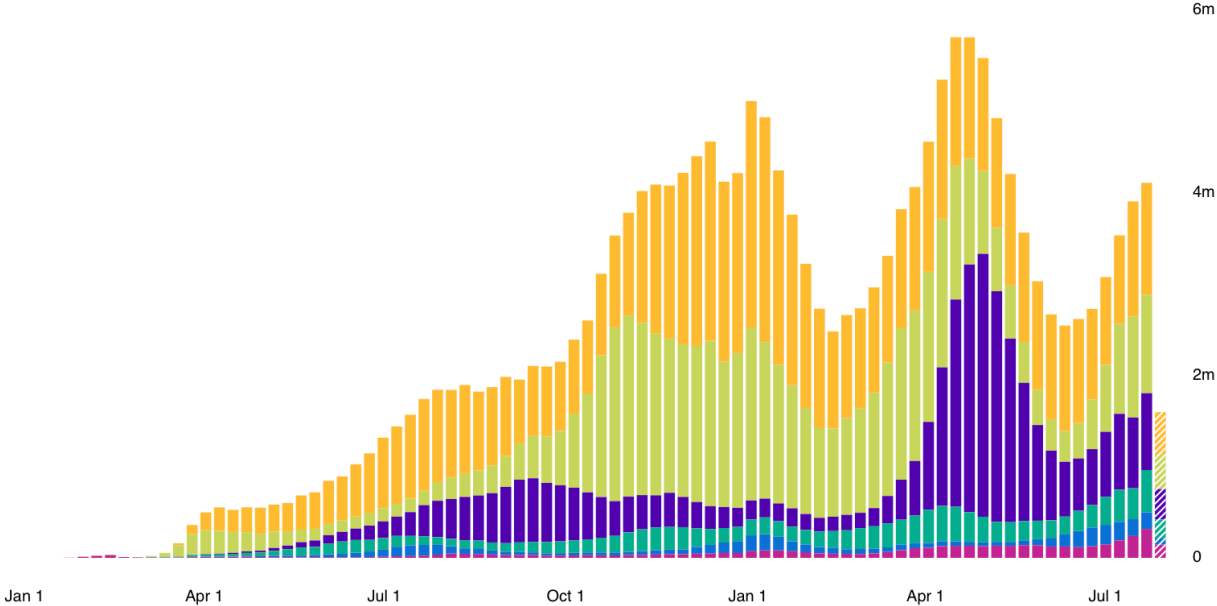
Cases

Deaths

Count 

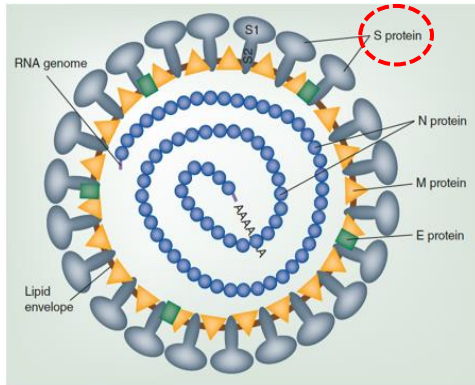
Americas	77,688,636 confirmed
Europe	60,566,865 confirmed
South-East Asia	38,711,821 confirmed
Eastern Mediterranean	12,804,451 confirmed
Africa	5,023,726 confirmed
Western Pacific	4,669,948 confirmed

Source: World Health Organization
 Data may be incomplete for the current day or week.



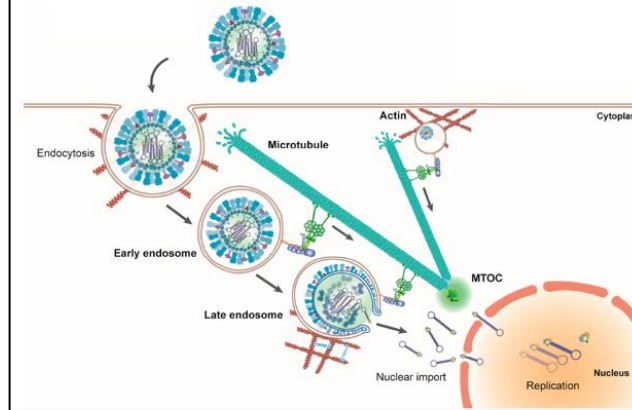
Coronavirus's spike(S) protein is the key structure that interacts with microtubules in the cytoskeleton during intracellular trafficking⁴

SARS-CoV-2 structure⁴

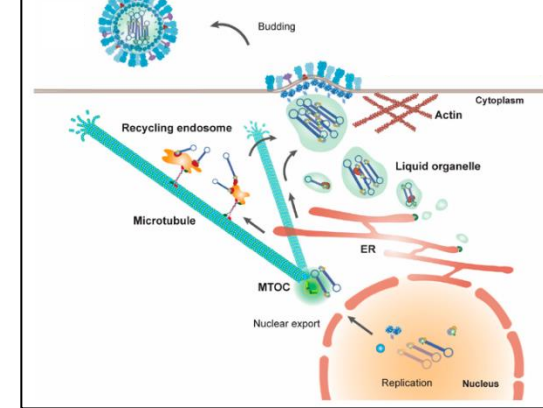


- Virus's most critical task is to hijack the host's internal transportation system, the microtubules in the cytoskeleton¹⁻³
- Sabizabulin disrupts the microtubule trafficking system
 - Antiviral
 - Anti-inflammatory

Coronavirus entry³



Coronavirus egress³



¹ Ren et al Scientific Reports 5:11451,2015; ² Rudiger et al Virology 497:185-197, 2016 | ³Taken and adapted from Simpson et al. Viruses 12:117, 2020 | ⁴Taken from Alsaadi et al Future Virology 14:275, 2019

Double-Blind, Placebo-Controlled, Phase 2 Study of Sabizabulin for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)¹

Trial design

- Approximately 40 subjects were randomized 1:1 (20 18mg sabazibulin and 20 Placebo groups)
- Hospitalized subjects with COVID-19 infection symptoms for less than 8 days and who are at high risk for ARDS were enrolled
- Subjects received study drug for up to 21 days
- The primary efficacy endpoint of the study was the proportion of patients that are alive and without respiratory failure at Day 29
- Most important secondary endpoints were all-cause mortality (death), days in ICU, and days on mechanical ventilation
- Enrollment completed December 2020

Patient demographics

		Sabizabulin	Placebo
Number of patients		19	20
Mean age (±SD)		59.3 (11.4)	57.8 (13.3)
Gender	Males (%)	10 (53%)	17 (85%)
	Females (%)	9 (47%)	3 (15%)
Mean WHO Score at baseline (±SD)		4.47 (0.61)	4.7 (0.57)
Standard of care treatment use on study	Remdesivir (%)	9 (47%)	15 (75%)
	Dexamethasone (%)	13 (68%)	15 (75%)
	No dexamethasone or remdesivir (%)	4 (21%)	2 (10%)

¹ Veru Inc, Clinical Trial Protocol, VERU-111 SARS-CoV-2 (May 2020)

Endpoints

Primary Endpoint	Placebo	Sabizabulin	Relative Reduction	p-value
Treatment failures, i.e. death or respiratory failure at Day 29 (MITT)	6/20 (30%)	1/18 (5.6%)	81%	p=0.05
Secondary Endpoints	Placebo	Sabizabulin	Relative Reduction	p-value
Deaths (ITT)	6/20 (30%)	1/19 (5.3%)	82%	p=0.04
Treatment failures, i.e. death or respiratory failure at Day 29 in >60 years of age	4/8 (50%)	1/11 (9%)	82%	p=0.05
Treatment failures, i.e. death or respiratory failure at Day 15 in patients with a WHO Score of Disease Severity ≥ 5 at baseline	7/13 (54%)	1/9 (11%)	80%	p=0.04
Mean days in ICU +/- SE	9.55 \pm 11.54 (n=20)	3.00 \pm 7.16 (n=18)	69%	p=0.04
Endpoints – patients that received standard of care (remdesivir and/or dexamethasone)	Placebo	Sabizabulin	Relative Reduction	p-value
Days in ICU	8.83 \pm 13.07 (n=18)	1.43 \pm 3.96 (n=14)	84%	p=0.02
Days on mechanical ventilation	6.00 \pm 10.57 (n=18)	0 (n=14)	100%	p=0.04

Safety

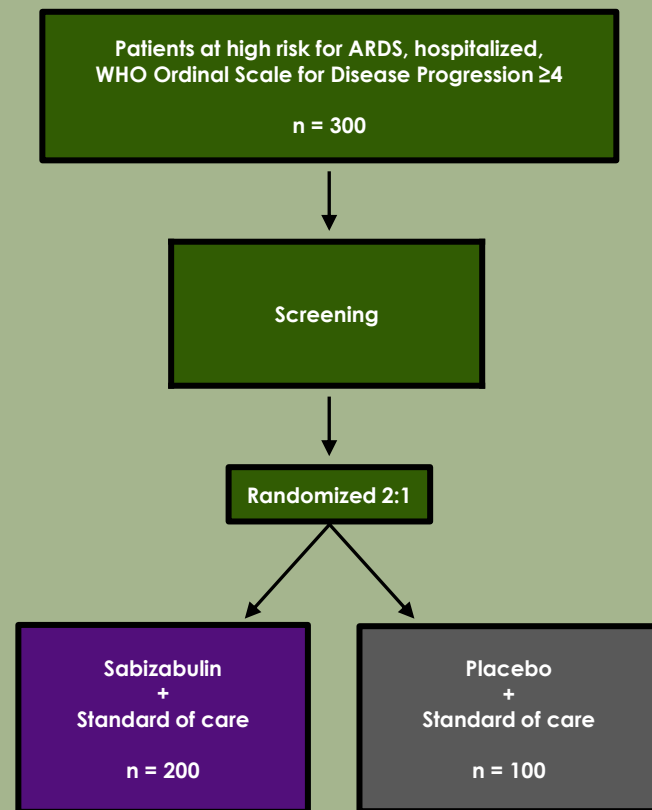
- There were no treatment related adverse events observed on the study
- There were no treatment related serious adverse events observed on the study
- There is no imbalance against sabizabulin in adverse events observed in the study

Any adverse event that occurred in ≥ 2 patients on study

Preferred Term	Sabizabulin 18 mg (n=19) N (%) / events	Placebo (n=20) N (%) / events
Any	10 (52.6)/27	11 (55.0)/41
Constipation	2 (10.5)/2	2 (10.0)/2
Septic shock	1 (5.3)/1	2 (10.0)/2
Alanine aminotransferase increased	1 (5.3)/1	2 (10.0)/2
Aspartate aminotransferase increased	2 (10.5)/2	1 (5.0)/1
Acute kidney injury	0	2 (10.0)/2
Pneumomediastinum	0	2 (10.0)/2
Pneumothorax	1 (5.3)/1	3 (15.0)/3
Respiratory failure	0	4 (20.0)/4

Double-Blind, Placebo-Controlled, Phase 3 Study of Sabizabulin for the Treatment of in Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (V3011902)(NCT#04842747) – enrolling

- Trial size is N=300 with a 2:1 randomization
- Dosing: daily dosing up to 21-days or until discharge from hospital
- Treatment arms: Sabizabulin 9 mg Formulated Capsule vs. Placebo
- All patients will be allowed standard of care on the study (Remdesivir/dexamethasone/convalescent plasma)
- Key inclusion criteria: high risk for ARDS, hospitalized, WHO Ordinal Scale for Disease Progression ≥ 4
- Primary endpoint: proportion of patients who die prior to Day 60 (mortality)
- Key secondary endpoints: Respiratory failure, days in ICU, days on mechanical ventilation, days in the hospital, and viral load
- Multinational clinical sites in United States, Brazil, Mexico, Argentina, and Colombia with aim to complete recruitment by year end





ENTADFI™ for BPH

ENTADFI™ capsule (tadalafil 5mg + finasteride 5mg combo) for treatment of BPH with improvement of erectile dysfunction³



ENTADFI™

Co-administration of CIALIS (tadalafil 5 mg) and PROSCAR (finasteride 5 mg) is currently approved for the initial treatment of symptoms of BPH for up to 26 weeks¹

- Drug-drug interaction and co-administration studies are completed for combination indication²

Each component is approved for:

- CIALIS (tadalafil 5 mg) daily- symptoms of **BPH and erectile dysfunction**
- PROSCAR (finasteride 5 mg)- symptoms and signs of prostate enlargement to decrease prostate size, reduces risk of acute urinary retention and need for surgery and prevents growth
- PROPECIA (finasteride 1mg) daily- symptoms of **male pattern hair loss**

The solution: proprietary ENTADFI™ tablet formulation:
Increases convenience and compliance

ONLY TREATMENT THAT PREVENTS BPH PROGRESSION & ALSO IMPROVES ERECTILE DYSFUNCTION
PDUFA date 12/2021

ED symptom score²
Men with baseline ED

ED symptom score²
Men without baseline ED

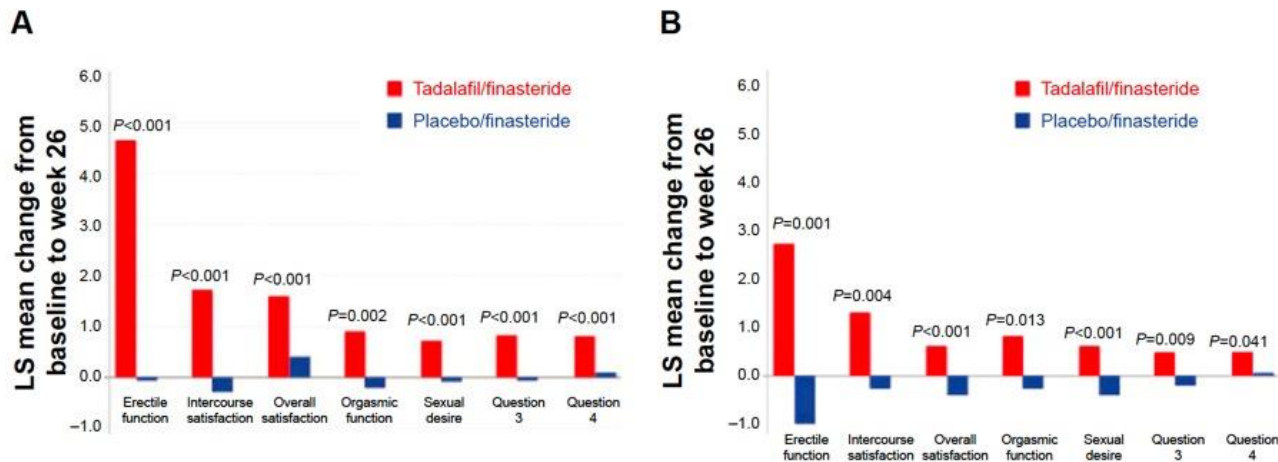


Figure 2 Comparison of treatment results with regard to IIEF scores reported by Glina et al.²⁷

Notes: (A) IIEF domains in men with baseline erectile dysfunction. (B) IIEF domains in men without baseline erectile dysfunction. (A and B) Question 3 related to vaginal penetrative ability. Question 4 related to erection maintenance. Figure reproduced with permission from John Wiley and Sons, from Glina S, Roehrborn CG, Esen A, et al. Sexual function in men with lower urinary tract symptoms and prostatic enlargement secondary to benign prostatic hyperplasia: results of a 6-month, randomized, double-blind, placebo-controlled study of tadalafil coadministered with finasteride. *Journal of Sexual Medicine*. 2015;12(1):129–138. Copyright © 2014 International Society for Sexual Medicine.

Abbreviations: IIEF, International Index of Erectile Function; LS, least squares.

- International, randomized, double-blind study in approximately 700 men
- 350 men treated with placebo + 5mg finasteride each day
- 345 men treated with 5mg tadalafil + 5mg finasteride each day

Market Potential

US and global markets expected to be >\$200 million³ through telemedicine channels



UREV Women's Health Division



FC2® Female Condom (internal condom) business revenues are growing

FC2 Female Condom (internal condom) is the only FDA approved female use product to prevent pregnancy and transmission of sexually transmitted infections

Rapidly growing US prescription business for high margin revenues

Prescription business is growing:

- Existing and anticipated new contracts with additional telemedicine and internet pharmacy partners
- Establishing a direct to patient telemedicine and pharmacy services Veru portal

Sold in U.S. and 149 other countries

Manufacturing plant with annual capacity of 100 million units

Public sector customers include UNFPA, USAID, Brazil, and South Africa

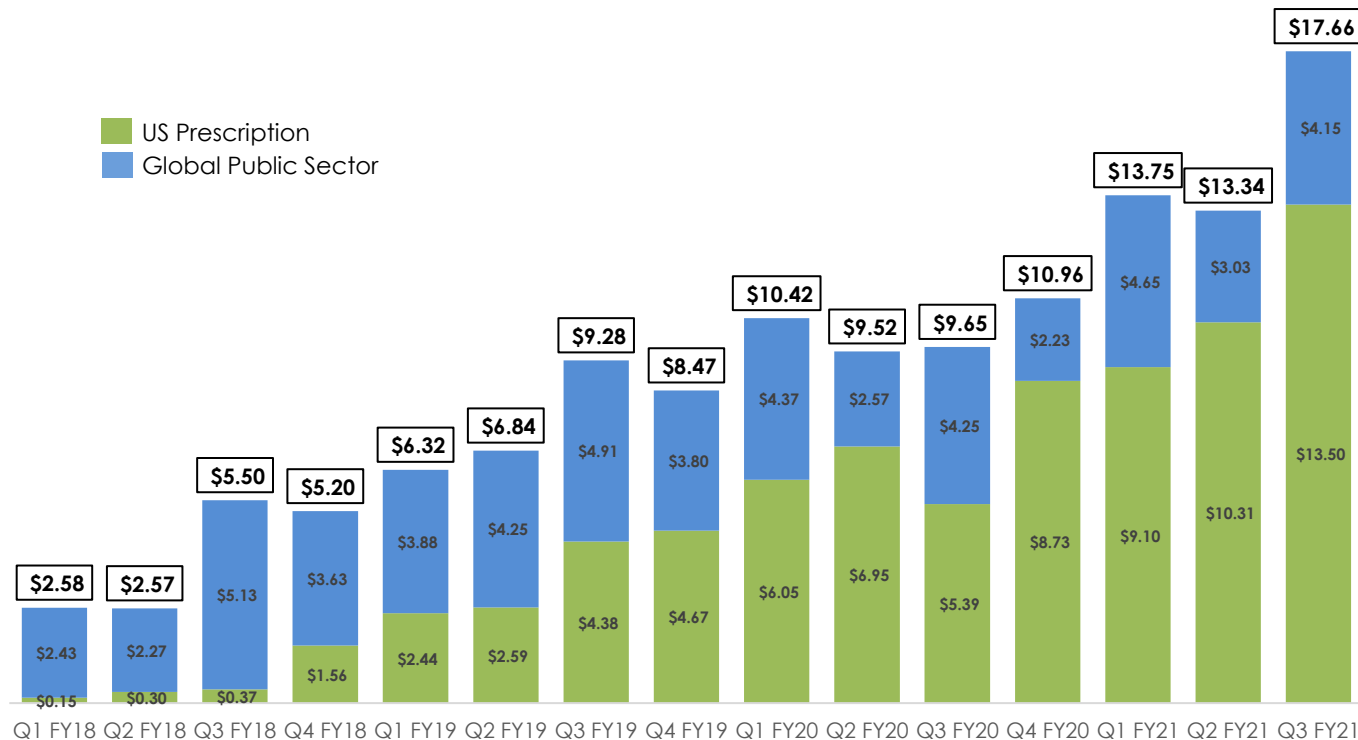
FC2 business profitable from FY 2006-present¹



Medical Device

¹For fiscal year 2006 through fiscal year 2016, profitability is based on Veru's net income attributable to common stockholders. Beginning fiscal year 2017, the first fiscal year which includes the financial results of Aspen Park Pharmaceuticals, Inc., profitability is based on operating income from our commercial segment.

FC2 global public sector & FC2 US prescription revenues (\$ mm)



FC2 Revenues

FY 2018: \$ 15.9 mm
FY 2019: \$ 30.9 mm
FY 2020: \$ 40.6 mm
FYTD 2021: \$ 44.8 mm

FC2 US Prescription 12-Pack Units Sold

FY 2018: 24,000
FY 2019: 159,000
FY 2020: 342,000
FYTD 2021: 413,000

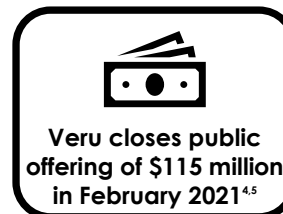
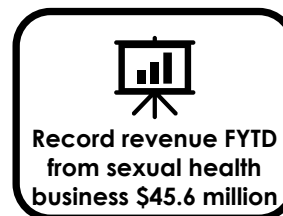
Veru – Fiscal year Results of operations	
FYTD 2021 Net Revenues (3 quarters)	\$ 45.6 mm
FY 2020 Net Revenues	\$ 42.6 mm
FY 2019 Net Revenues	\$ 31.8 mm
FY 2018 Net Revenues	\$ 15.9 mm
FY 2017 Net Revenues	\$ 13.7 mm

Veru – Fiscal Year To Date Results of operations (3 quarters)	
FYTD 2021 Net Revenues	\$ 45.6 mm
FYTD 2021 Gross Profit	\$ 35.6 mm
FYTD 2021 Operating Income	\$ 14.8 mm
FYTD 2021 Adjusted Operating Loss ¹	\$ 3.6 mm

Veru – Quarter 3 Results of operations	
Q3 FY 2021 Net Revenues	\$ 17.7 mm
Q3 FY 2021 Gross Profit	\$ 13.9 mm
Q3 FY 2021 Operating Loss	\$ 2.9 mm

UREV – Women's Health Results of operations	
FC2 FY 2020 Net Revenues	\$ 40.6 mm
Q3 FY 2021 Net Revenues	\$ 17.7 mm

Veru – Balance Sheet as of June 30, 2021	
Cash	\$ 123.2 mm
Receivables	\$ 8.3 mm
PREBOOST Payment Due	\$ 5.0 mm ³
US/UK NOL carryforward	\$ 42.0/\$61.3 mm
Common Shares Outstanding ²	~ 79.9 mm



¹ Represents a non-GAAP financial measure calculated by subtracting \$18.4 mm gain on PREBOOST sale from Operating Income, a GAAP measure

² An aggregate of 10.8 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 79.9 million common shares above

³ PREBOOST sale was \$15 million in cash and \$2.5 million in receivables at 12 months and \$2.5 million in receivables at 18 months

⁴ Cash received from the public offering, net of underwriting discounts and commissions, was \$108.1 million

⁵ Veru issued 7,419,354 shares of common stock in the public offering

Milestones

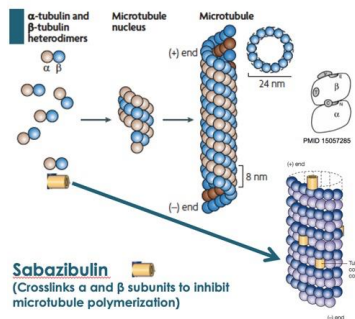
Program	Mechanism	Indication	2021	2022	2023	2024
Breast Cancer						
Enobosarm	Selective androgen receptor targeted agonist	AR+ER+HER2- metastatic breast cancer (3 rd line metastatic)	<div><div>Phase 3 Initiation</div><div>Phase 3 data</div><div>NDA</div></div> <div>Phase 3 ARTEST study</div>			
Sabizabulin	Oral cytoskeleton disruptor	ER+HER2- metastatic breast cancer (3 rd line metastatic)	<div><div>Phase 2b Initiation</div><div>Phase 2b data</div></div>			
Enobosarm + abemaciclib combination	Selective androgen receptor targeted agonist + CDK4/6 inhibitor	AR+ER+HER2- metastatic breast cancer (2 nd line metastatic)	<div><div>Phase 3 Initiation</div><div>Phase 3 data</div></div> <div>Phase 3 ENABLAR-2 study</div>			
Sabizabulin + enobosarm	Oral cytoskeleton disruptor+Selective androgen receptor targeted agonist	Metastatic triple negative breast cancer	<div><div>Phase 2 Initiation</div><div>Phase 2 data</div></div>			
Prostate Cancer						
Sabizabulin	Oral cytoskeleton disruptor and androgen receptor transport disruptor	Metastatic castration and AR targeting agent resistant prostate cancer	<div><div>Phase 3 Initiation</div><div>Phase 3 data</div><div>NDA</div></div> <div>Phase 3 VERACITY study</div>			
VERU-100	GnRH antagonist 3-month subcutaneous depot injection	Hormone sensitive advanced prostate cancer	<div><div>Phase 2 Initiation</div><div>Phase 2 data</div><div>Phase 3 Initiation</div><div>Phase 3 data</div><div>NDA</div></div>			
Virology						
Sabizabulin	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS	<div><div>Phase 3 Initiation</div><div>Phase 3 data</div><div>EUA/NDA</div></div> <div>Phase 3 COVID study</div>			



Appendix

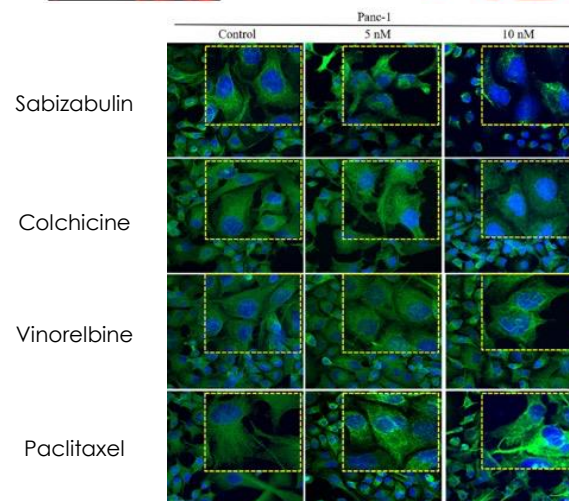
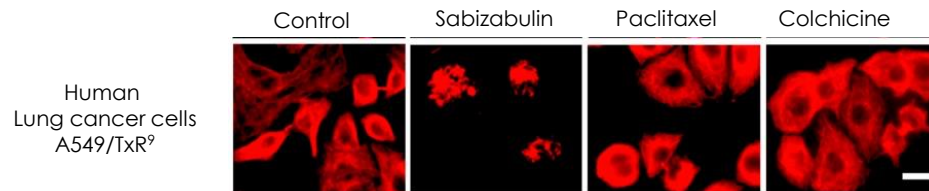
Sabizabulin is an oral agent that targets and disrupts the cytoskeleton

AR independent Targets cytoskeleton to crosslink and inhibit microtubule assembly¹



- Targets the “colchicine binding site” on β -tubulin and unique site on α -tubulin to crosslink α and β subunits to inhibit microtubule polymerization (low nM concentration)
- Not a substrate for multidrug resistance proteins (P-gp, MRPs, and BCRP)
- Favorable toxicity profile no neurotoxicity and no neutropenia or myelosuppression
- Demonstrated activity against taxane, vinca alkaloid, doxorubicin, enzalutamide, and abiraterone resistant prostate cancers
- Has broad activity against other tumor types as well: Triple negative breast cancer (taxane resistant)⁷, Cervical cancer (taxane resistant)⁸, Lung cancer (taxane resistant)⁹, Ovarian cancer (taxane resistant)¹⁰, Uterine cancer¹¹, Pancreatic cancer¹², Melanoma¹³, Human promyelocytic leukemia (vincristine resistant)¹⁴

Only sabizabulin, not the other classes of microtubule targeting agents, disrupts and fragments microtubules



¹ Chen J et al. J Med Chem 55:7285-7289 2012 | ² Li CM et al. Pharm Res 29:3053-3063 2012 | ³ Lu Y et al. J Med Chem 57:7355-7366 2014 | ⁴ 28 day rat and dog toxicity studies on file at Veru, Inc. | ⁵ Dumontet C et al. Nature Reviews Drug Discovery 9:790, 2010 | ⁶ Markowski M et al J Clin Onc 37:167, 2019 | ⁷ Deng S et al Mol Cancer Ther 19:348-63, 2020 | ⁸ Kashyap VK et al Cancer Lett 470:64-74, 2020 | ⁹ Foyez M et al. Cancer Letters 495:76, 2020 | ^{10,11} Data on file Veru, Inc. 2020 | ¹² Kashyap V et al J Experimental and Clinical Can Res 38:29, 2019 | ¹³ Chen J et al J Med Chem 55:7285-7289, 2012; Hwang DJ et al ACS Med Chem Lett 6:993-997, 2015 | ¹⁴ Data on file Veru, Inc. 2014