



Veru Inc.
Nasdaq:VERU

Oncology Biopharmaceutical Company Focused on Breast Cancer and Prostate Cancer

Veru Corporate Presentation
Oppenheimer 32nd Annual Healthcare Conference
March 15-17, 2022

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, in its breast cancer and prostate cancer programs, its COVID-19 program or any future clinical development, 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 or other COVID-19 treatments come into use the need for a new COVID-19 treatment candidate may be reduced or eliminated; government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; the risk in obtaining any regulatory approval and the products being commercially successful; our ability to successfully launch and commercialize ENTADFI on our own or in collaboration with any potential partners; our ability to successfully market ENTADFI and FC2 Female Condom (internal condom) on our own telehealth platforms; 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, 2021 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

Zuclomiphene

COVID-19

Sabizabulin 9mg

Late-stage clinical pipeline focused on breast cancer & prostate cancer

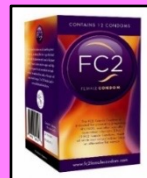
Phase 3 COVID-19 clinical study in hospitalized patients with COVID-19 at high risk for ARDS

UREV Sexual Health Division

ENTADFI[®]
(tadalafil and finasteride)
capsules

FDA APPROVED for BPH December 2021

FC2 Female Condom (internal condom)



FC2 FY 2021 Net Revenues:	\$ 60.4 mm
FC2 FY 2021 Operating Income:	\$ 44.0 mm
FC2 Q1 FY 2022 Net Revenues:	\$ 14.1 mm



Veru Financials

Cash: \$116.1 mm
Receivables: \$8.1 mm

(as of December 31, 2021)

Veru FY 2020 Net Revenues:	\$ 42.6 mm
Veru FY 2021 Net Revenues:	\$ 61.3 mm
Veru FY 2021 Gross Profit:	\$ 47.9 mm
Veru Q1 FY 2022 Net Revenues:	\$ 14.1 mm
Veru Q1 FY 2022 Gross Profit:	\$ 11.8 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 targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	<div>Phase 3 ARTEST: 210 Patients</div> <div>Ongoing</div>			
Sabizabulin	Oral cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)	<div>Phase 2b: 200 Patients</div> <div>Planned Q1 2022</div>			
Enobosarm + abemaciclib combination <i>Lilly</i>	Selective androgen receptor targeting agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	<div>Phase 3 ENABLAR-2: 186 Patients</div> <div>Lilly clinical collaboration and supply agreement</div> <div>Planned Q1 2022</div>			
Sabizabulin + enobosarm	Oral cytoskeleton disruptor + Selective androgen receptor targeting agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	<div>Phase 2b: 111 Patients</div> <div>Planned</div>			
Prostate Cancer						
Sabizabulin	Oral cytoskeleton disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV-chemo	<div>Phase 3 VERACITY: 245 Patients</div> <div>Ongoing</div>			
VERU-100	Long-acting GnRH antagonist peptide subcutaneous 3-month depot injection	Advanced hormone sensitive prostate cancer	<div>Phase 2: ~35 Patients</div> <div>Ongoing</div>			
Zuclomiphene citrate	Oral nonsteroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	<div>Phase 2b</div> <div>Planned</div>			
COVID-19 infection						
Sabizabulin	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS	<div>Phase 3: 300 Patients</div> <div>Ongoing</div>			

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Breast Cancer						
Enobosarm	Selective androgen receptor targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR \geq 40% (3rd line metastatic setting)		Phase 3 ARTEST: 210 Patients		
						Ongoing
Sabizabulin	Oral targeted cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)		Phase 2b: up to 200 Patients		
						Planned Q1 2022
Enobosarm + abemaciclib combination <i>Lilly</i>	Selective androgen receptor agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR \geq 40% (2nd line metastatic setting)		Phase 3 ENABLAR-2: 186 Patients		
				Lilly clinical collaboration and supply agreement		Planned Q1 2022
Sabizabulin + enobosarm	Oral targeted cytoskeleton disruptor + Selective androgen receptor targeting agonist	Metastatic triple negative breast cancer after two systemic chemotherapies		Phase 2b: 111 Patients		
						Planned Q1 2022

Current Endocrine Therapies

Selective estrogen receptor modulators (tamoxifen and toremifene)

ER antagonists and degraders (fulvestrant)

Aromatase inhibitors (AI)

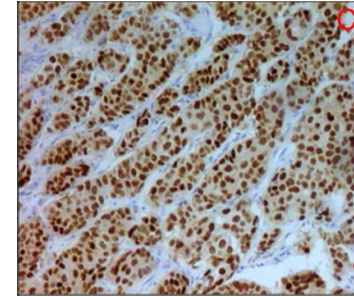
- AROMASIN[®] (exemestane) - steroidal AI

- 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}

- 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 proliferation ¹⁻³
 - 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
- Novel strategies are warranted *to target and to activate AR, tumor suppressor, as a treatment for AR+ER+ breast cancer* ³



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-Law¹, Heloise H. Milioli^{1,4}, Daniel Roden¹, Shalini Jindal¹, Mun Hui⁴, Jessica Finlay-Schultz¹, Esmaeil Ebrahimie¹, Stephen N. Birrell¹, Suzan Stelloo^{5,6}, Richard Iggo^{1,7}, Sarah Alexandrou¹, C. Elizabeth Caldon¹, Tarek M. Abdel-Fatah¹, Ian O. Ellis⁸, Wilbert Zwart¹, Carlo Palmieri⁹, Carol A. Sartorius⁵, Alex Swarbrick¹, Elgene Lim¹, Jason S. Carroll¹⁰ and Wayne D. Tilley^{1,3,11}

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.

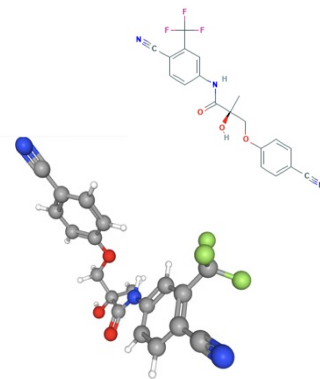
¹Birrell et al, J Steroid Biochem Mol Biol 52:459-67, 1995 | ²Peters et al, Cancer Res 69: 6131-40, 2009 | ³Hickey et al, Nature Medicine 2021 | ⁴Moinfar et al, Cancer 98:703-11, 2003 | ⁵Hu et al, Clin Cancer Res 17:1867-74, 2011 | ⁶Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | ⁷Bronte et al, 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 nonsteroidal, 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 estrogen sensitive and resistant disease⁷**

Enobosarm has been evaluated in 25 clinical trials of 1450 subjects which includes:

- 3 Phase 2 studies in breast cancer (250 subjects)
- 12 Phase 1 studies for NDA label completed



Chemical structure of Enobosarm

Phase 2 clinical trial (G200802) design

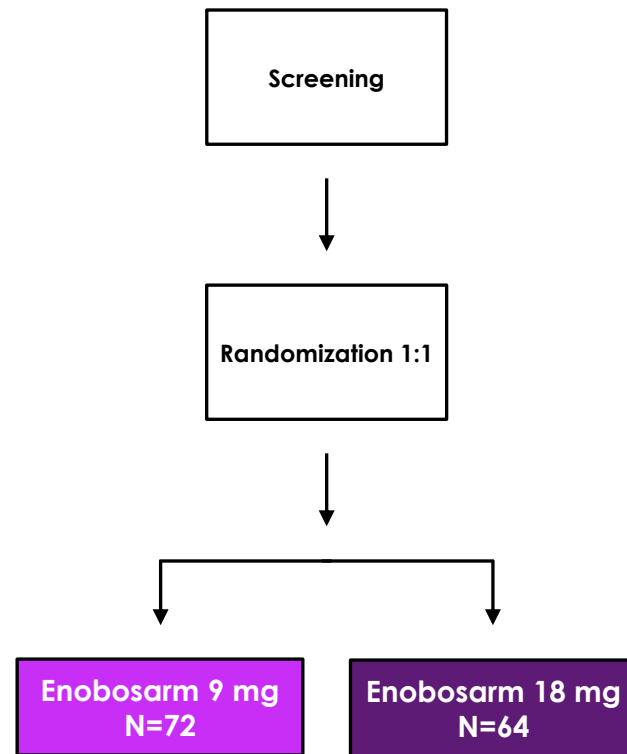
Targeting AR+ ER+ HER2- metastatic breast cancer in a heavily pretreated population¹

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%)

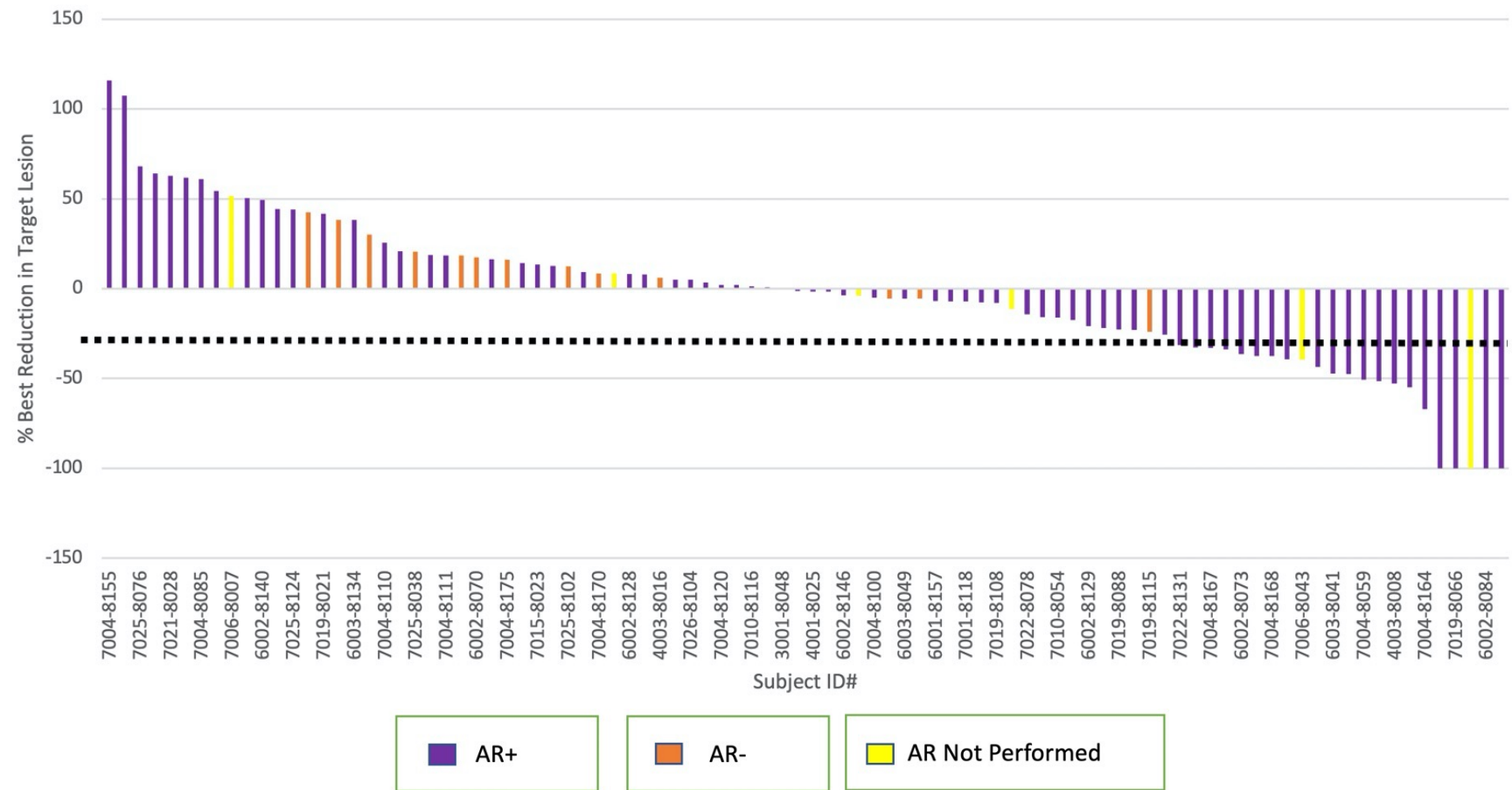
Efficacy

Evaluable population (AR+)

	9 mg cohort	18 mg 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:

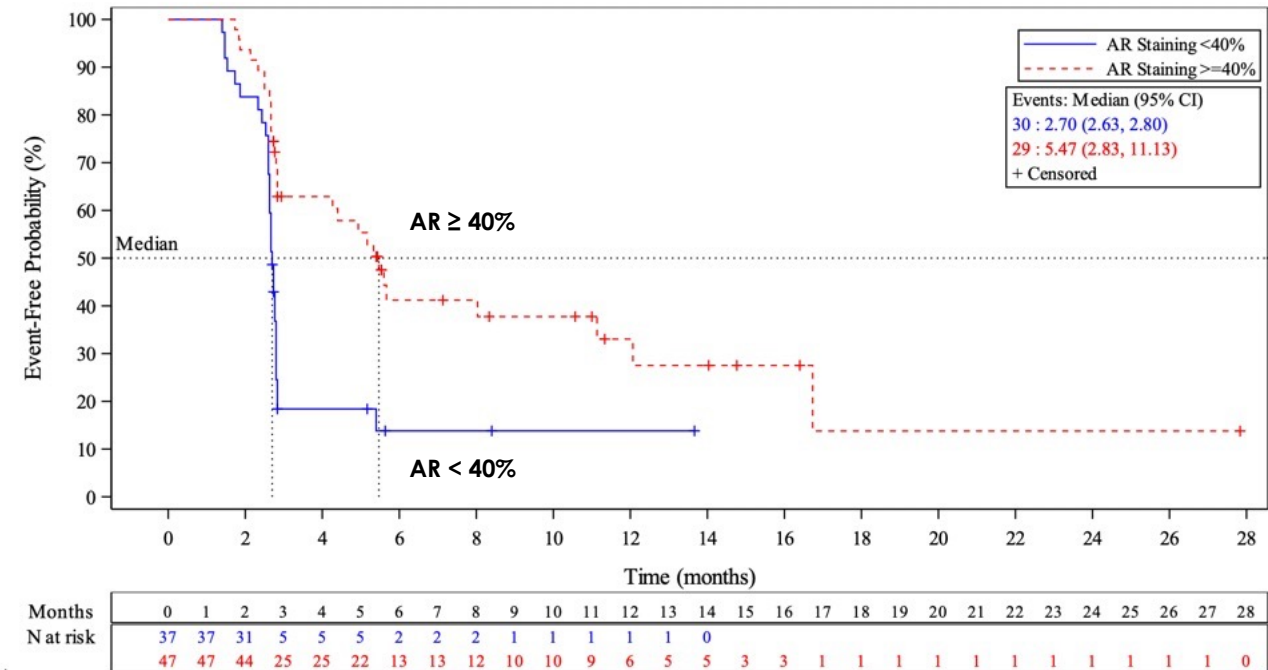
- Subset of ITT with known AR status and have measurable disease (n=84)
- Combined both the 9 mg and 18 mg cohorts to increase power of analysis

% 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

- Enobosarm selective AR targeting 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 to treat CDK4/6 inhibitor and estrogen blocking agent resistant AR+ER+HER2- metastatic breast cancer

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

• Estrogen blocking agent resistant breast cancer

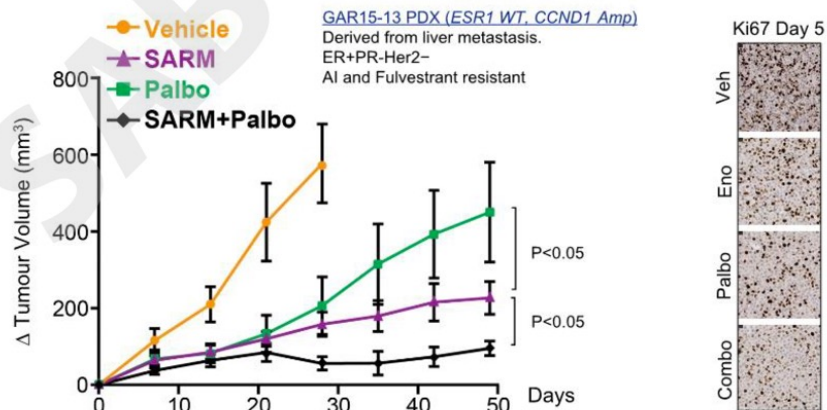
- CDK4/6 inhibitor inhibits growth of estrogen blocking agent resistant breast cancer^{1,2}
- Enobosarm monotherapy has greater inhibition of estrogen blocking agent resistant breast cancer than a CDK4/6 inhibitor^{1,2}
- Enobosarm + CDK4/6 inhibitor had greater inhibition of estrogen blocking agent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

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

Palbociclib resistant subjects with measurable disease

- **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)

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

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

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

Third-Line Metastatic

ARTEST AR+ ($\geq 40\%$)
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

Designated Fast Track program by FDA

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 progressed on nonsteroidal aromatase inhibitor, fulvestrant, and CDK4/6 inhibitor therapy (3rd line metastatic setting)

ARTEST Patient Population

- AR+ ER+ HER2-metastatic 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

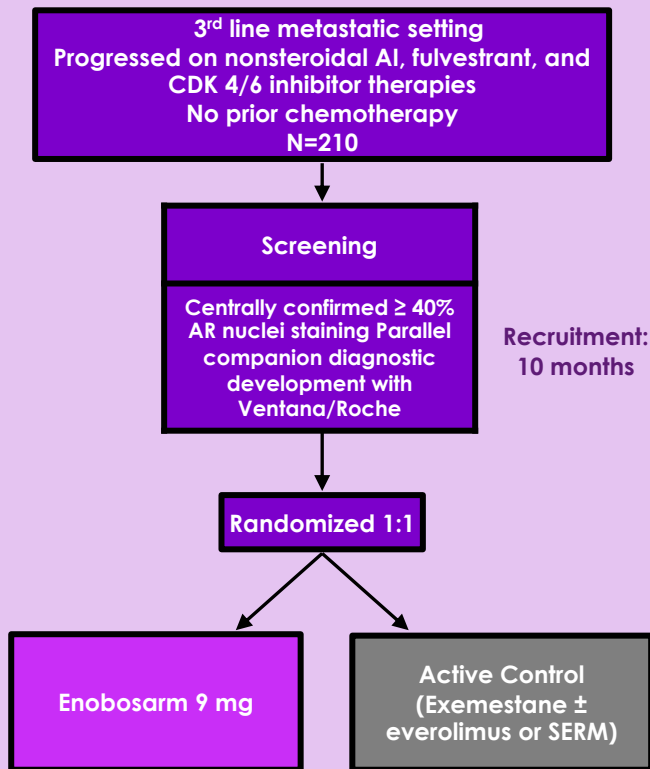
ARTEST Efficacy Endpoints

- **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

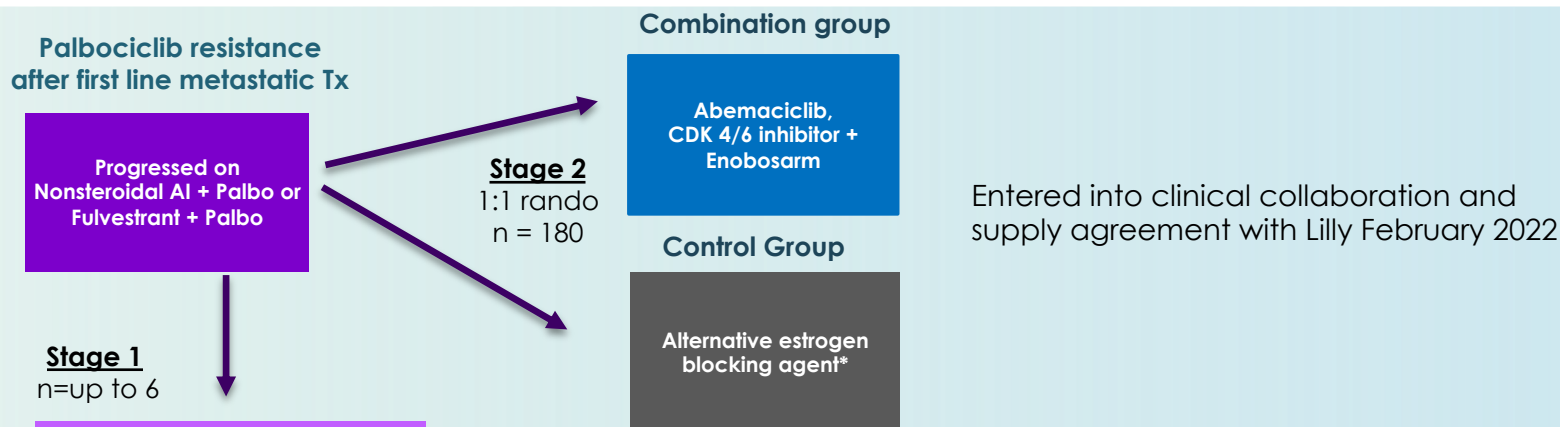
Phase 3 Pivotal AR+ER+HER2-Metastatic Breast Cancer



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

Phase 3 (V2000701) ENABLAR-2 study- 2nd line metastatic setting- AR staining $\geq 40\%$ Open label, dose finding, efficacy and safety of CDK4/6 inhibitor (abemaciclib) + enobosarm combination versus active control estrogen blocking agent in AR+ER+HER2- metastatic breast cancer

Anticipated start date is calendar Q1 2022



Open label safety study to determine
the safety of enobosarm 9mg in
combination with abemaciclib
150mg BID

• Primary endpoint

- Median radiographic progression free survival (rPFS) in subjects with $\geq 40\%$ AR staining

• Key Secondary endpoints:

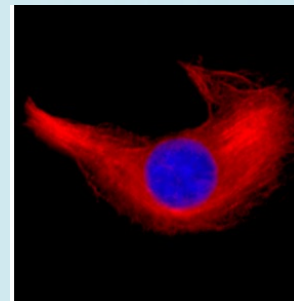
- Overall response rate (CR+PR)
- Change in Short Physical Performance Battery (SPPB)
- DEXA- body composition muscle and bone

• Statistical assumptions

- Total sample size: 180
- $\alpha = 0.05$
- 97% power
- 20% drop out rate
- 121 events
- Control group estimated median rPFS=5 months¹
- Combo group: estimated median rPFS=9 months

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 Q1 2022

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 progressed on nonsteroidal aromatase inhibitor, fulvestrant, and CDK4/6 inhibitor therapy (3rd line metastatic setting)

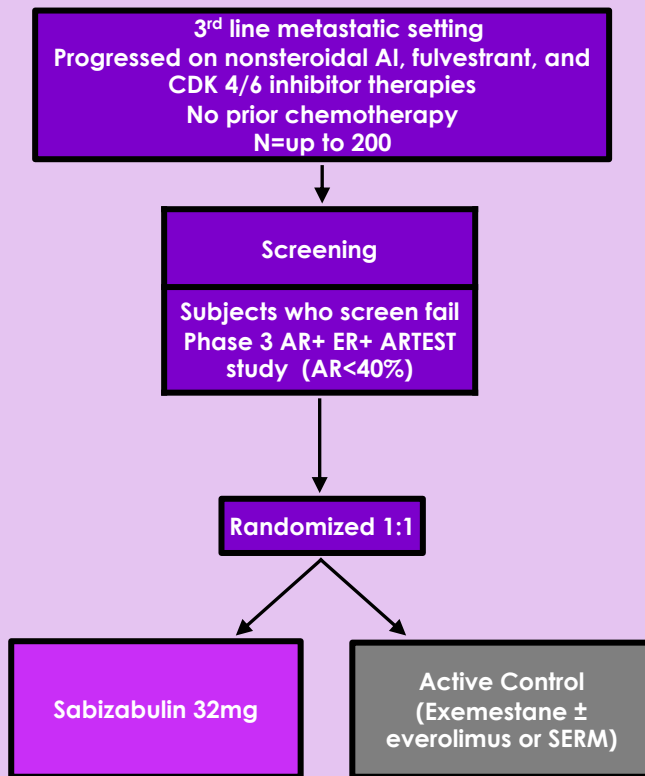
ARTEST Patient Population

- ER+ HER2-metastatic, 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

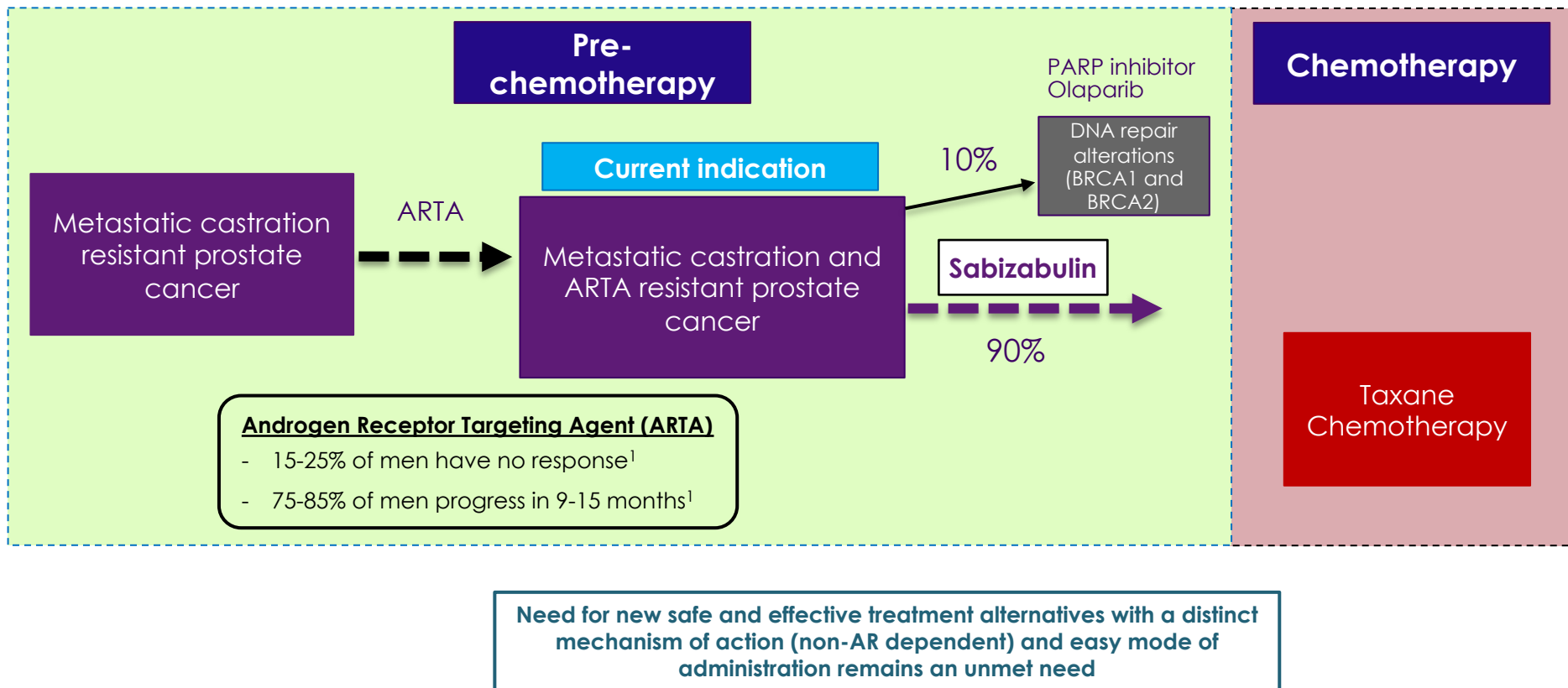
- **Primary endpoint:**
 - Median radiographic progression free survival (rPFS)
- **Secondary endpoints:**
 - Overall response rate (CR+PR)
 - Duration of response
 - Overall survival
 - Change in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ)
 -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

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



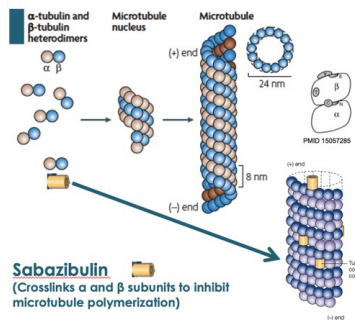
Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prostate Cancer						
Sabizabulin	Oral cytoskeleton disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV-chemo	Phase 3 VERACITY: 245 Patients			
			Ongoing			
VERU-100	Long-acting GnRH antagonist peptide subcutaneous 3-month depot injection	Advanced hormone sensitive prostate cancer	Phase 2: ~35 Patients			
			Ongoing			
Zuclomiphene citrate	Oral, non-steroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	Phase 2b			
			Planned			

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



Sabizabulin is an oral agent that targets and disrupts the cytoskeleton

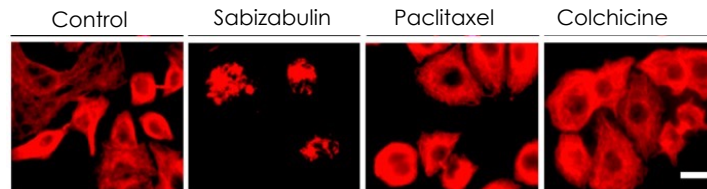
AR independent Targets cytoskeleton to crosslink and inhibit microtubule assembly¹



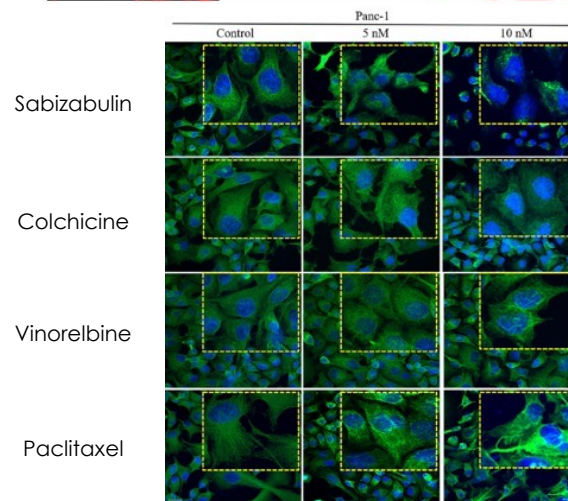
- Targets the “colchicine binding site” on β -tubulin and unique site on α -tubulin to crosslink α and β subunits to inhibit microtubule polymerization (low nM concentration)
- Not a substrate for multidrug resistance proteins (P-gp, MRPs, and BCRP)
- Favorable toxicity profile no neurotoxicity and no 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

Human
Lung cancer cells
A549/TxR⁹



Human
Pancreatic
cancer cells
Panc-1⁸



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 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 had evidence of significant and durable objective tumor responses- cytotoxic activity?	
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 5 men on study ¹)

¹Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose as of February 2021 and had measurable disease

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

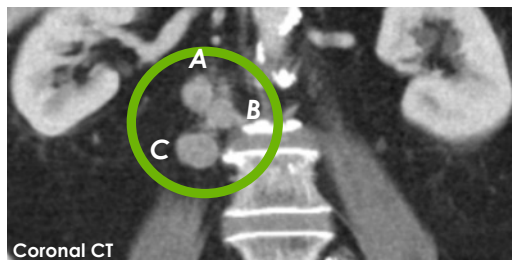
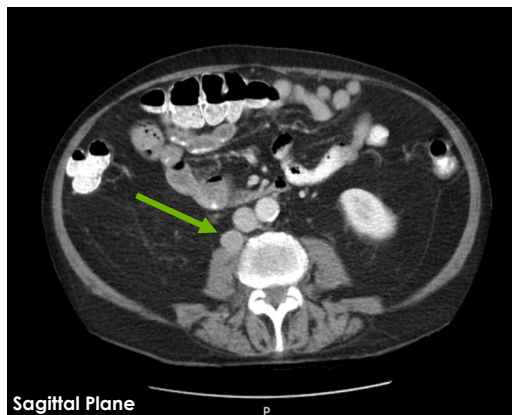
¹ Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose

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

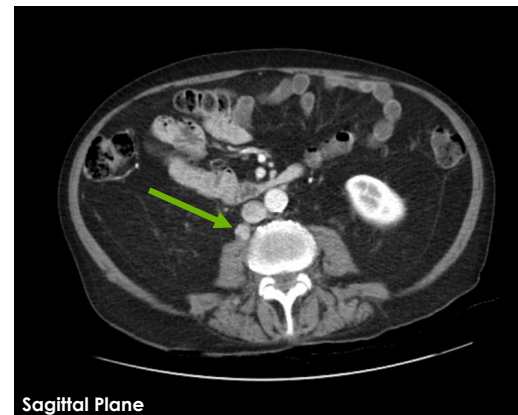
March 08, 2019: Screening CT scan

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)

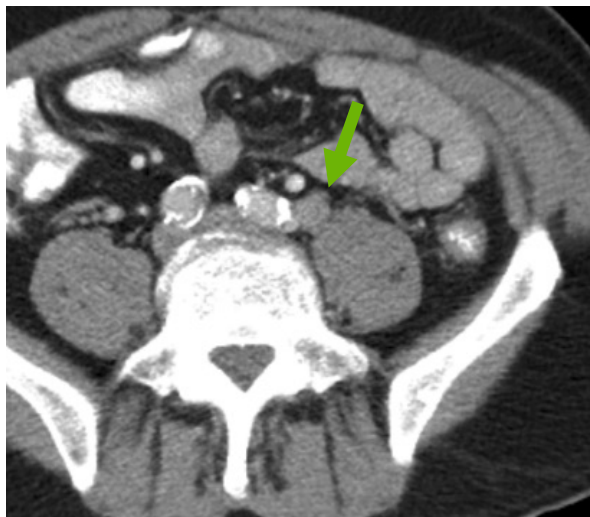


Patient: 104-017

- 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

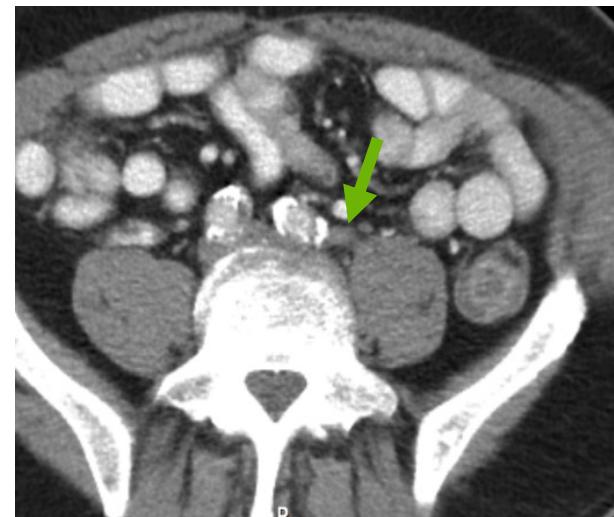
July 8, 2020: Screening CT scan

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 63 mg 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 32 mg for the Treatment of Metastatic Castration-Resistant Prostate Cancer in Patients Whose Prior Treatment Progressed on at Least One Androgen Receptor Targeting Agent – Lead PI – Robert Dreicer, MD, University of Virginia

• Efficacy endpoints

• Primary endpoints

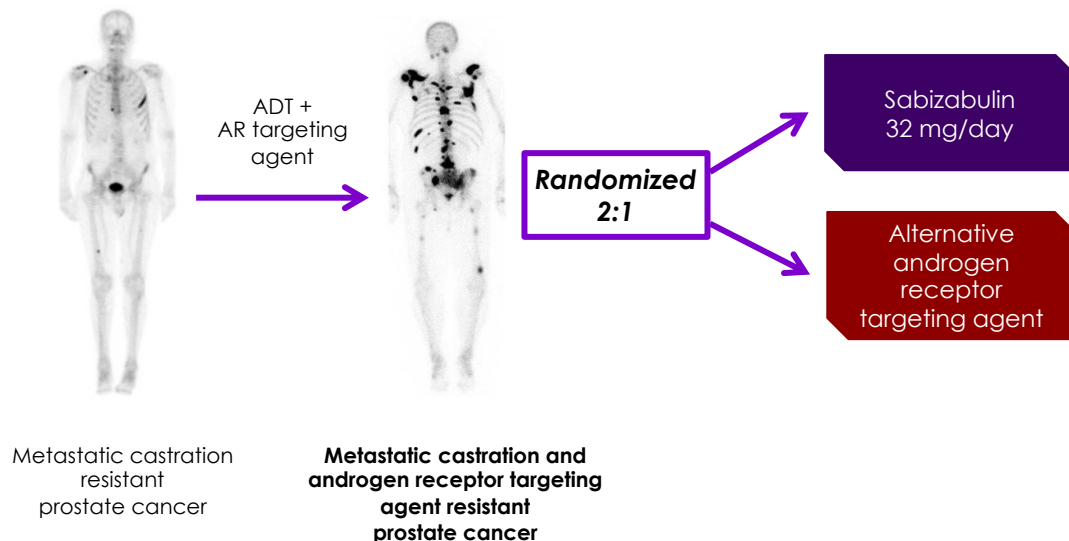
- Radiographic progression free survival (rPFS)

• 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

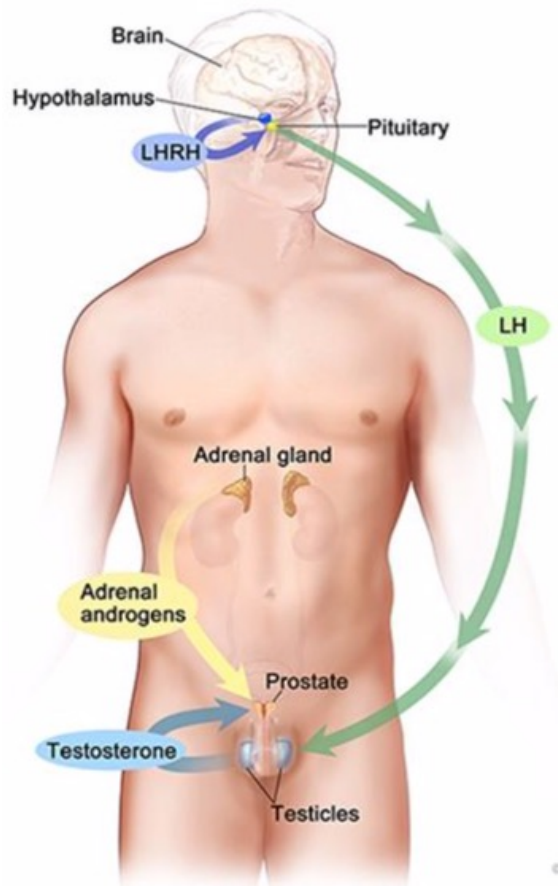
Quest for a better androgen deprivation therapy: VERU-100

Current commercial limitations

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)

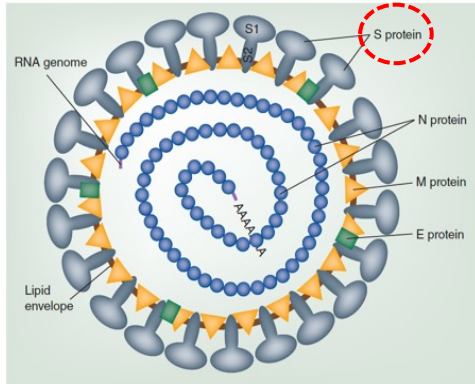


Sabazibulin 9 mg

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

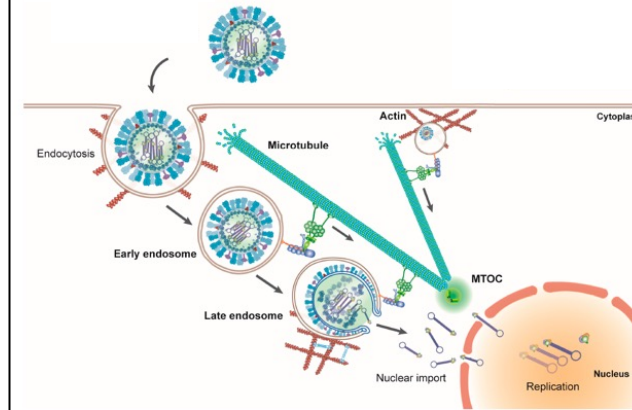
Coronavirus's spike(S) protein is the key structure that interacts with microtubules in the cytoskeleton during intracellular trafficking⁴

SARS-CoV-2 structure⁴

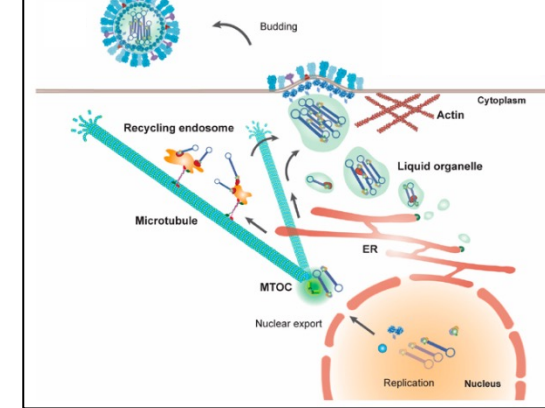


- Virus's most critical task is to hijack the host's internal transportation system, the microtubules in the cytoskeleton¹⁻³
- Sabizabulin disrupts the microtubule trafficking system
 - Antiviral
 - Anti-inflammatory

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

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

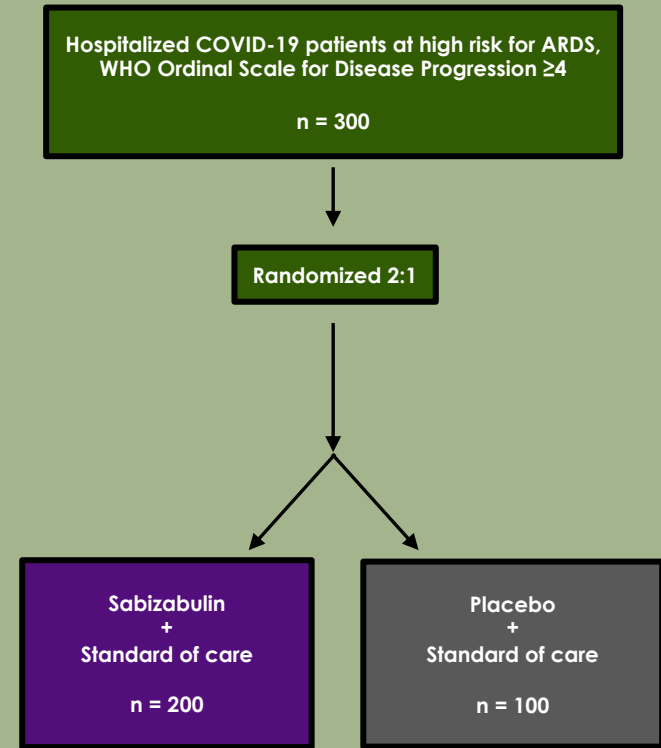
- There were no treatment related adverse events observed on the study
- There were no treatment related serious adverse events observed on the study
- There is no imbalance against sabizabulin in adverse events observed in the study

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, Mexico, Brazil, Argentina, Colombia, and Bulgaria
- Clinical results expected 1H 2022






ENTADFI[®]
(tadalafil and finasteride)
capsules

UREV
Sexual Health Division



ENTADFI™ capsule (finasteride and tadalafil), a new treatment for BPH with low potential for adverse sexual side effects, approved in 12/2021¹⁻³

UREV
Sexual Health



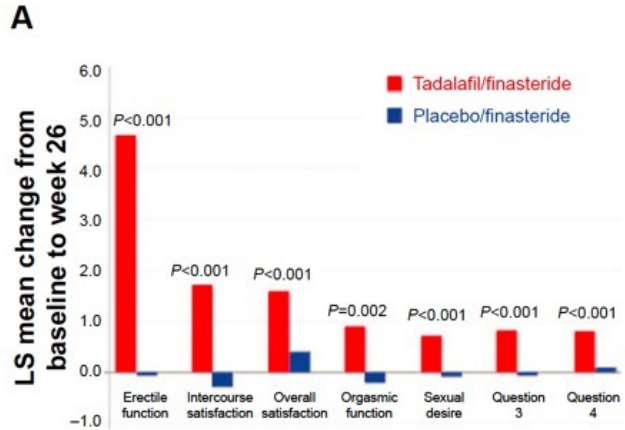
Only BPH treatment that prevents BPH progression with low potential for adverse sexual side effects

US and global markets expected to be >\$200 million

Company has partnered with GoodRx and plans to launch product in early 2022 through telemedicine sales channel as well as seek additional partners in US and ROW

¹ Cialis (tadalafil) FDA Package Insert | ²Casabé A et al. J Urol 191:727-733, 2014. | ³Glina S et al. J Sex Med 12:129-1238, 2015.

ED symptom score²
Men with baseline ED



ED symptom score²
Men without baseline ED

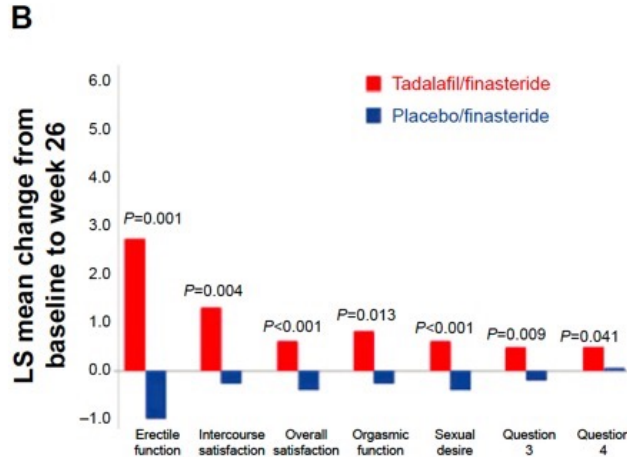


Figure 2 Comparison of treatment results with regard to IIEF scores reported by Glina et al.²⁷

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

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 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

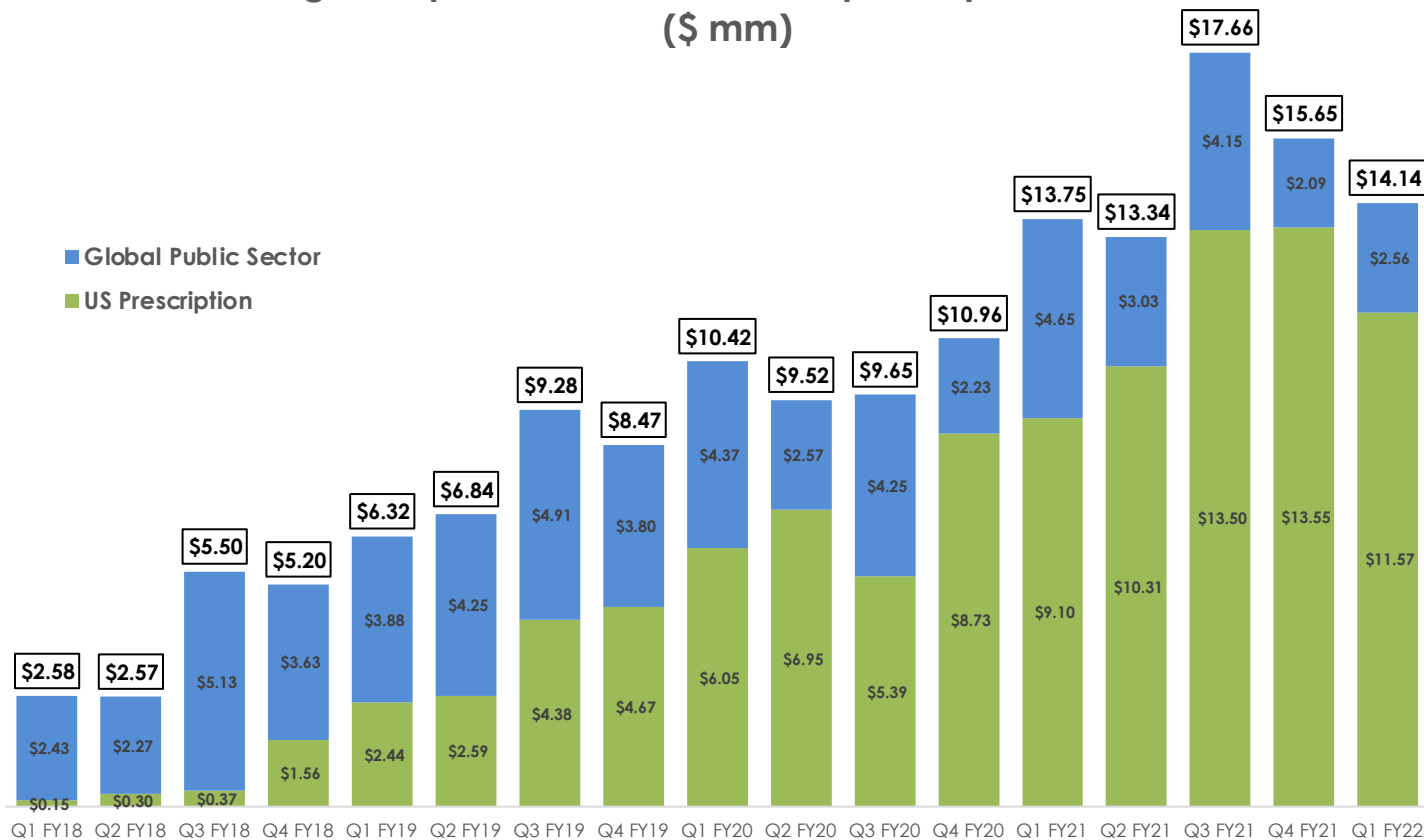
FC2 business profitable from FY 2006-present¹



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
 FY 2021: \$ 60.4 mm

FC2 US Prescription 12-Pack Units Sold

FY 2018: 24,000
 FY 2019: 159,000
 FY 2020: 342,000
 FY 2021: 570,000

Veru Net Revenues

FY 2021 Net Revenues	\$ 61.3 mm
FY 2020 Net Revenues	\$ 42.6 mm
FY 2019 Net Revenues	\$ 31.8 mm
FY 2018 Net Revenues	\$ 15.9 mm

Veru – First Quarter Results of operations

Q1 FY 2022 Net Revenues	\$ 14.1 mm
Q1 FY 2022 Gross Profit	\$ 11.8 mm
Q1 FY 2022 Operating Loss	\$ (5.0) mm

UREV – Sexual Health Results of operations

FC2 FY 2020 Net Revenues	\$ 40.6 mm
FC2 FY 2021 Net Revenues	\$ 60.4 mm

Veru – Balance Sheet as of December 31, 2021

Cash	\$ 116.1 mm
Receivables	\$ 8.1 mm
PREBOOST Payment Due	\$ 2.5 mm ²
US/UK NOL carryforward	\$ 38.6/\$63.5 mm
Common Shares Outstanding ¹	~ 80.0 mm



Record revenue FY
from sexual health
business \$61.3 million



Veru closes public
offering of \$115 million
in February 2021^{3,4}



PREBOOST sale for
\$20 million²

¹ An aggregate of 12.8 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 80.0 million common shares above

² 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

³ Cash received from the public offering, net of underwriting discounts and commissions, was \$108.1 million

⁴ Veru issued 7,419,354 shares of common stock in the public offering

Program	Mechanism	Indication	2021	2022	2023	2024
Breast Cancer						
Enobosarm	Selective androgen receptor targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	<div><div>Phase 3 FPI</div><div>Phase 3 data</div><div>NDA</div></div> <div>Phase 3 ARTEST study – Fast Track</div>			
Sabizabulin 32 mg	Oral cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)	<div><div>Phase 2b Initiation</div><div>Phase 2b data</div></div>			
Enobosarm + abemaciclib combination	Selective androgen receptor targeting agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	<div><div>Lilly clinical collaboration and supply agreement</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 targeting agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	<div><div>Phase 2 Initiation</div></div>			
Prostate Cancer						
Sabizabulin 32 mg	Oral targeted cytoskeleton disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV-chemo	<div><div>Phase 3 FPI</div><div>Phase 3 data</div><div>NDA</div></div> <div>Phase 3 VERACITY study</div>			
VERU-100	Long-acting GnRH antagonist peptide subcutaneous 3-month depot injection	Advanced hormone sensitive prostate cancer	<div><div>Phase 2 FPI</div><div>Phase 2 data</div><div>Phase 3 Initiation</div><div>Phase 3 data</div></div>			
Zuclopimphene citrate	Oral, non-steroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	<div><div>Phase 2b Initiation</div></div>			
Virology						
Sabizabulin 9 mg	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS	<div><div>Phase 3 FPI</div><div>Phase 3 data</div><div>EUA/NDA</div></div> <div>Phase 3 COVID study- Fast Track</div>			