Veru Inc.
Nasdaq:VERU

Oncology Biopharmaceutical Company Focused on Breast Cancer and Prostate Cancer

Veru Corporate Presentation

H.C. Wainwright BioConnect Conference
January 10-13, 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.

Oncology biopharmaceutical company
Focus on breast cancer and prostate cancer with a sexual health division

Veru
Drug Pipeline

Breast Cancer	Enobosarm	Sabizabulin 32mg
Prostate Cancer	Sabizabulin 32mg	VERU-100
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 2020 Net Revenues:	$ 40.6 mm
FC2 FY 2021 Net Revenues:	$ 60.4 mm
Sexual Health Business FY 2021 Operating Income:	$ 44.0 mm

Veru Financials

Cash: $122.4 mm
Receivables: $8.8 mm

(as of September 30, 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 Q4 FY 2021 Net Revenues:	$ 15.6 mm
Veru Q4 FY 2021 Gross Profit:	$ 12.3 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 agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 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: 200 Patients — Planned Q1 2022			
Enobosarm + abemaciclib combination	Selective androgen receptor agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	Phase 3 ENABLAR-2: 180 Patients — Planned Q1 2022			
Sabizabulin + enobosarm	Oral targeted cytoskeleton disruptor + Selective androgen receptor targeted agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	Phase 2b: 111 Patients — Planned Q1 2022			
Prostate Cancer						
Sabizabulin	Oral targeted 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			
Zuicomiphene citrate	Oral, non-steroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	Phase 2b — Planned			
Virology						
Sabizabulin	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS	Phase 3: 300 Patients — Ongoing			

Endocrine therapies that block estrogen are effective against ER+ breast cancer

Current Endocrine Therapies

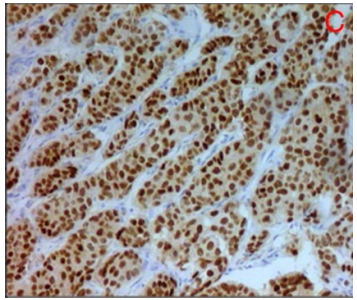
- Selective estrogen receptor modulators (tamoxifen and toremifene)
- ER antagonists and degraders (fulvestrant)
- Aromatase inhibitors (AI)
  - AROMASIN® (exemestane) - steroidal AI
  - ARIMIDEX® (anastrozole) and FEMARA ®(letrozole) - nonsteroidal AI
- CDK 4/6 inhibitors in combination with nonsteroidal AI or fulvestrant

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

[1]Alluri et al., Breast Cancer Res 16:494, 2014 | [2]Basile D et al. Cancer Treatment Reviews 61:15-22, 2017

Androgen receptor is the most abundantly expressed sex hormone receptor in breast cancers with up to 95% of breast cancers[2-6]

- **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 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**
- **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 warranted[3]**



Ductal infiltrating breast carcinoma 3+ AR nuclear positivity[7]

nature medicine ARTICLES
https://doi.org/10.1038/s41591-020-01168-7
Check for updates

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

Theresa E. Hickey[1], Luke A. Selth[1,2,3], Kee Ming Chia[4], Geraldine Laven-Law[1], Heloisa H. Milioli[4], Daniel Roden[4], Shalini Jindal[1], Mun Hui[4], Jessica Finlay-Schultz[5], Esmaeil Ebrahimie[1], Stephen N. Birrell[1], Suzan Stelloo[6,11], Richard Iggo[1,7], Sarah Alexandrou[4], C. Elizabeth Caldon[4], Tarek M. Abdel-Fatah[8], Ian O. Ellis[8], Wilbert Zwart[6], Carlo Palmieri[9], Carol A. Sartorius[5], Alex Swarbrick[4], Elgene Lim[4], Jason S. Carroll[10] and Wayne D. Tilley[1,3]

The role of the androgen receptor (AR) in estrogen receptor (ER)-α-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.

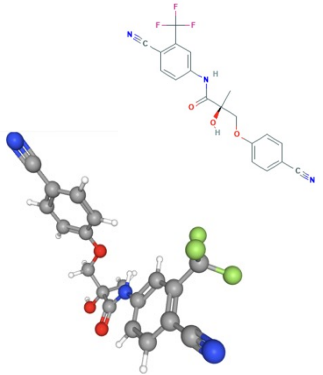
[1]Birrell et al, J Steroid Biochem Mol Biol 52:459-67, 1995 | [2]Peters et al, Cancer Res 69: 6131-40, 2009 | [3]Hickey et al, Nature Medicine 2021 | [4]Moinfar et al, Cancer 98:703–11, 2003 | [5]Hu et al, Clin Cancer Res 17:1867–74, 2011 | [6]Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | [7]Bronte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

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

[1] Narayanan R et al. Mol Cell Endocrinol 2017 | [2] Dalton JT et al. Curr Opin Support Palliat Care 7:345-351, 2013 | [3]Kamrakova M et al Calcif Tissue Int 106:147-157,2020 | [4]Hoffman DB et al. J Bone Metaab 37:243-255, 2019 | [5]KearbeyJD et al Pharm Res 26:2471-2477, 2009 | [6]Dobs AS et al. Lancet Oncol 14:335-45, 2013 | [7]Hickey et al., Nature Medicine 2021

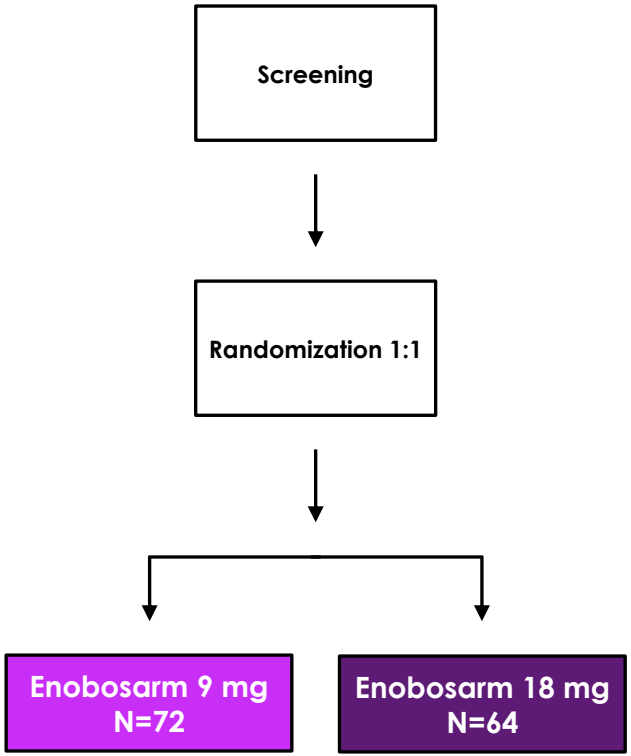
Phase 2 clinical trial (G200802) design
Targeting AR+ ER+ HER2- metastatic breast cancer in a heavily pretreated population[1]

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



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

Phase 2 clinical trial (G200802) - Post-hoc AR expression subset analysis
Efficacy outcomes correlate with degree of AR staining (9mg +18mg cohorts combined)

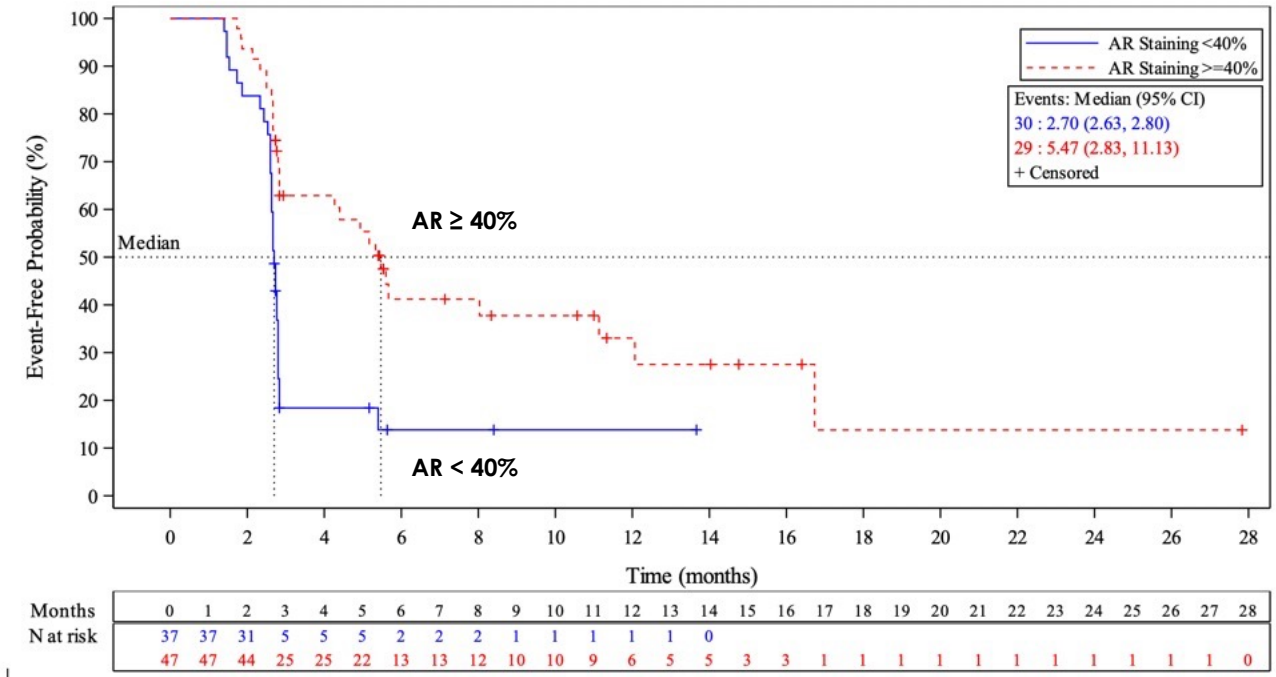
Post-hoc AR expression subset analysis:

- 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)
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)- Conclusions
AR targeted therapy shows efficacy and safety in AR+ER+HER2- metastatic breast cancer

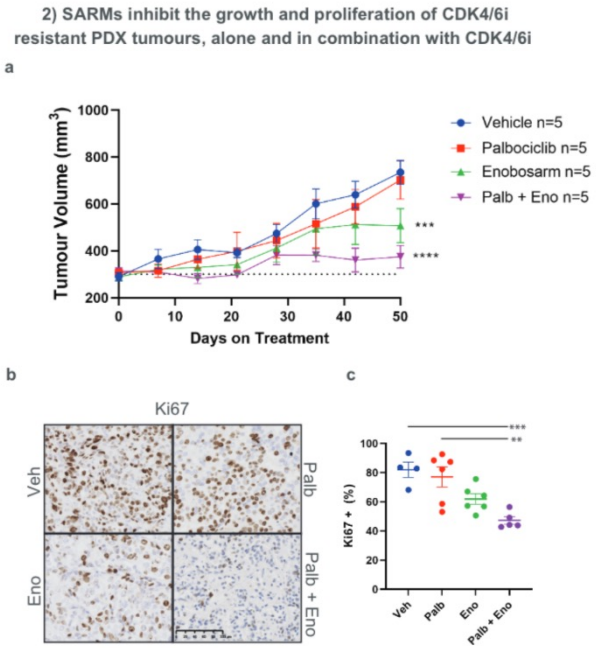
- **Enobosarm AR targeted treatment demonstrated clinical benefit with objective tumor responses in women with heavily pretreated estrogen blocking agent resistant AR+ ER+ HER2- metastatic breast cancer**
- **The presence of AR and expression of AR ≥ 40% enriched for subjects most likely to respond to 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**

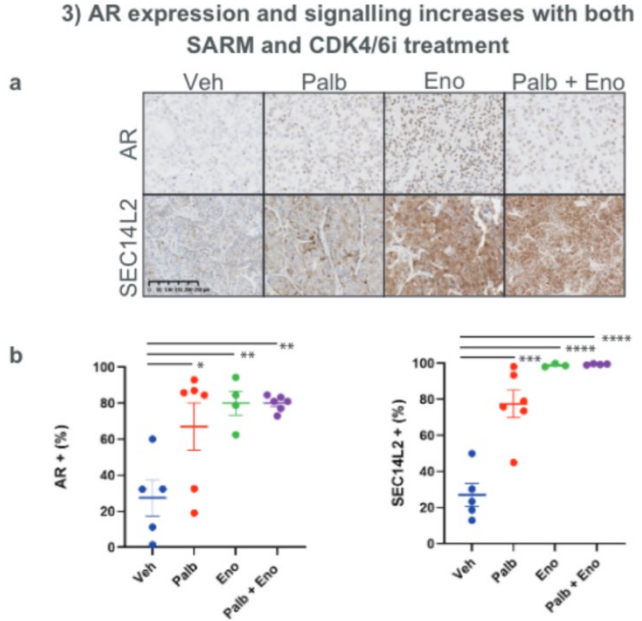
Enobosarm and/or CDK4/6 inhibitor against CDK4/6 inhibitors and estrogen blocking agent resistant AR+ER+HER2- metastatic breast cancer- the real story ?

Preclinical models (Patient derived xenografts)[1]

Both CDK4/6 inhibitor and enobosarm upregulate AR expression in estrogen blocking agent and CDK4/6 inhibitor resistant metastatic breast cancer!

CTPx4353: PDX, originated from liver metastasis, patient relapsed on fulvestrant, palbociclib and aromatase inhibitor





*3 a) Representative IHC images of AR and SEC14L2 expression in CTPx4353 tumours. b) Percentage of cells positive for AR and SEC14L2; * p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001*

[1] Freelander A et al. 2021 SABCS presentation

Phase 2 (G200802) study
Evaluable patients (AR+) with palbociclib resistance in the metastatic setting

- **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

Phase 3 registration, open label, randomized ARTEST clinical trial (V3002401)(NCT#04869943) 3rd line metastatic setting – AR staining ≥ 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 ± 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 ≥ 40% AR nuclei staining from breast cancer sample

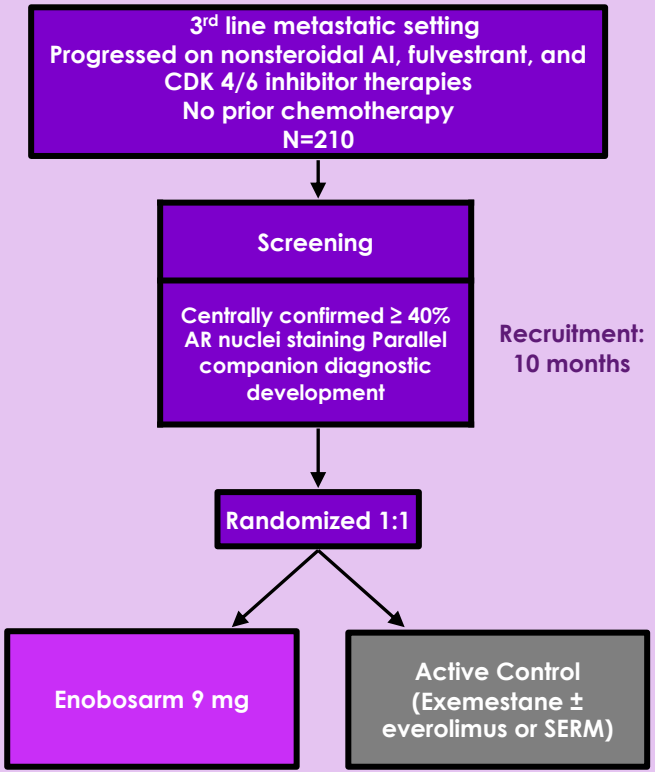
ARTEST Efficacy Endpoints

- 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
- α = 0.05
- 99% power
- 20% drop out rate
- 123 events
- Active control group (exemestane± everolimus or a SERM): estimated median rPFS = 3 months[1-3]
- Enobosarm arm: estimated median rPFS=6 months

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



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

Phase 3 (V2000701) ENABLAR-2 study- 2nd line metastatic setting- AR staining ≥ 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 Q4 2021

Palbociclib resistance after first line metastatic Tx

Progressed on Nonsteroidal AI + Palbo or Fulvestrant + Palbo

Stage 1
n=up to 6

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

Stage 2
1:1 rando
n = 180

Combination group

Abemaciclib, CDK 4/6 inhibitor + Enobosarm

Control Group

Alternative estrogen blocking agent*

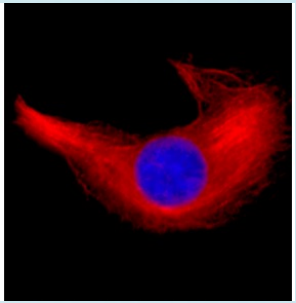
- **Primary endpoint**
  - Median radiographic progression free survival (rPFS) in subjects with ≥ 40% AR staining
- **Key Secondary endpoints:**
  - Overall response rate (CR+PR)
  - Change in Short Physical Performance Battery (SPPB)
  - DEXA- body composition muscle and bone

- **Statistical assumptions**
  - Total sample size: 180
  - a = 0.05
  - 97% power
  - 20% drop out rate
  - 121 events
  - Control group estimated median rPFS=5 months[1]
  - Combo group: estimated median rPFS=9 months

[1] Ibrance FDA Package Insert (2019)

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 a-tubulin to crosslink a 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 cancer[11], Pancreatic cancer[12], Melanoma[13], 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 progressed on nonsteroidal aromatase inhibitor, fulvestrant, and CDK4/6 inhibitor therapy (3rd line metastatic setting)

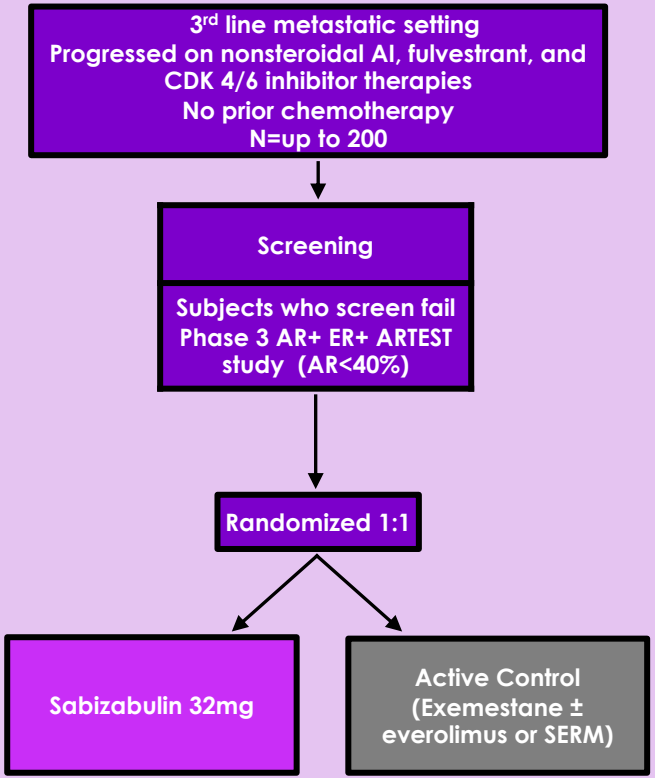
ARTEST Patient Population

- **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



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

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

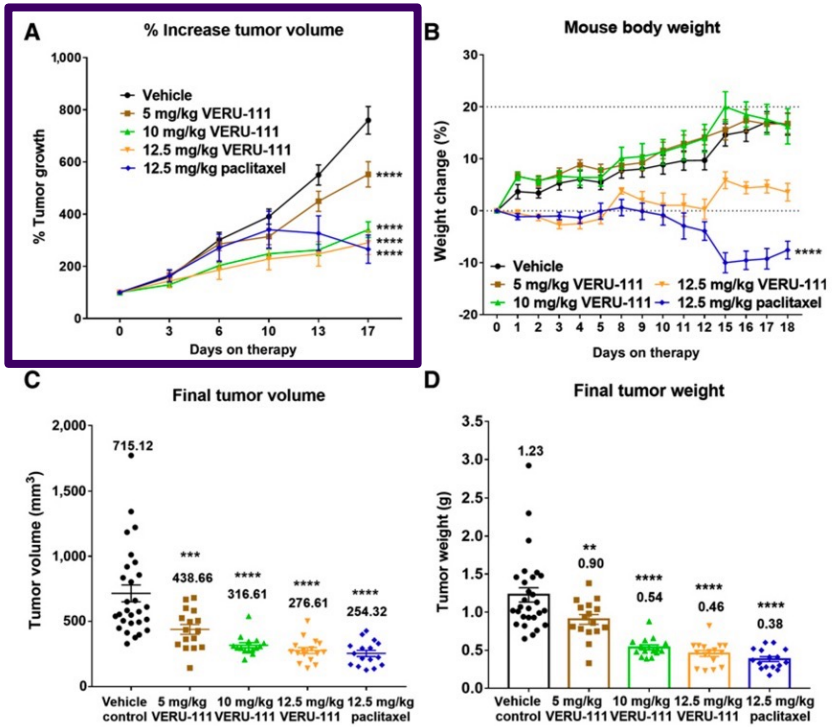
Sabizabulin 32mg

for the treatment of chemotherapy resistant metastatic triple negative breast cancer

Preclinical studies show that sabizabulin has efficacy against taxane resistant triple negative breast cancer[1]

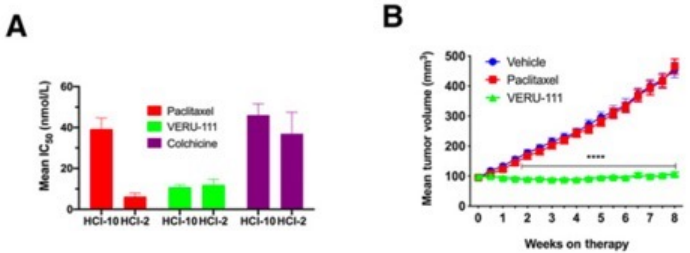
Taxane sensitive

Sabizabulin (VERU-111) has antitumor activity in MDA-MB-231 TNBC Model[1]

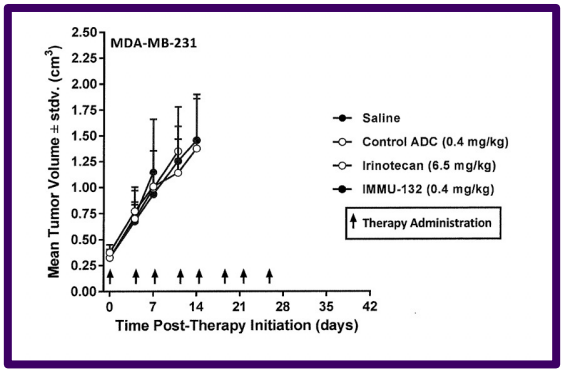


Taxane resistant

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



TRODELVY (IMMU-132) has no activity in MDA-MB-231 TNBC Animal Model[2]



[1] Deng S et al. Mol Cancer Ther 19:348-63, 2020 | [2]US patent US2018/0271992 A1

Combination of pembrolizumab + enobosarm in AR+ metastatic triple negative breast cancer

- **Preclinical models of AR+ TNBC show enobosarm has antitumor activity in animal models[1]**
- **Phase 2 clinical trial[2]**
  - 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 [a]Medical Oncology and Therapeutics Research, [b]Biostatistics, [c]Immune-Oncology, and [d]Pathology, City of Hope Comprehensive Cancer Center and Beckman Research Institute, Duarte, California, USA; [e]Pathogen and Microbiome Division, Translational Genomics Research Institute North, Flagstaff, Arizona, USA

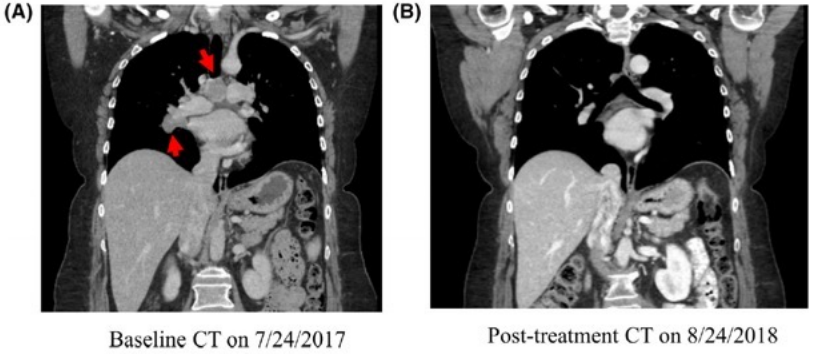


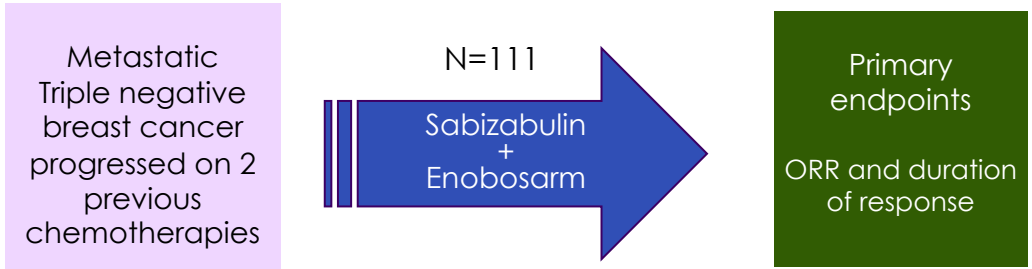
Figure 2. CT imaging of exceptional response. **(A):** Baseline CT on July 24, 2017, showed subcarinal and right hilar conglomerate lymph adenopathy (the red arrows pointing the target lesions). **(B):** The bulky subcarinal adenopathy and right hilar is no longer seen on August 24, 2018. Patient continues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

Phase 2b clinical study (V2011801): Sabizabulin + enobosarm for metastatic triple negative breast cancer with tumor progression after receiving at least 2 chemotherapies

Trial study design

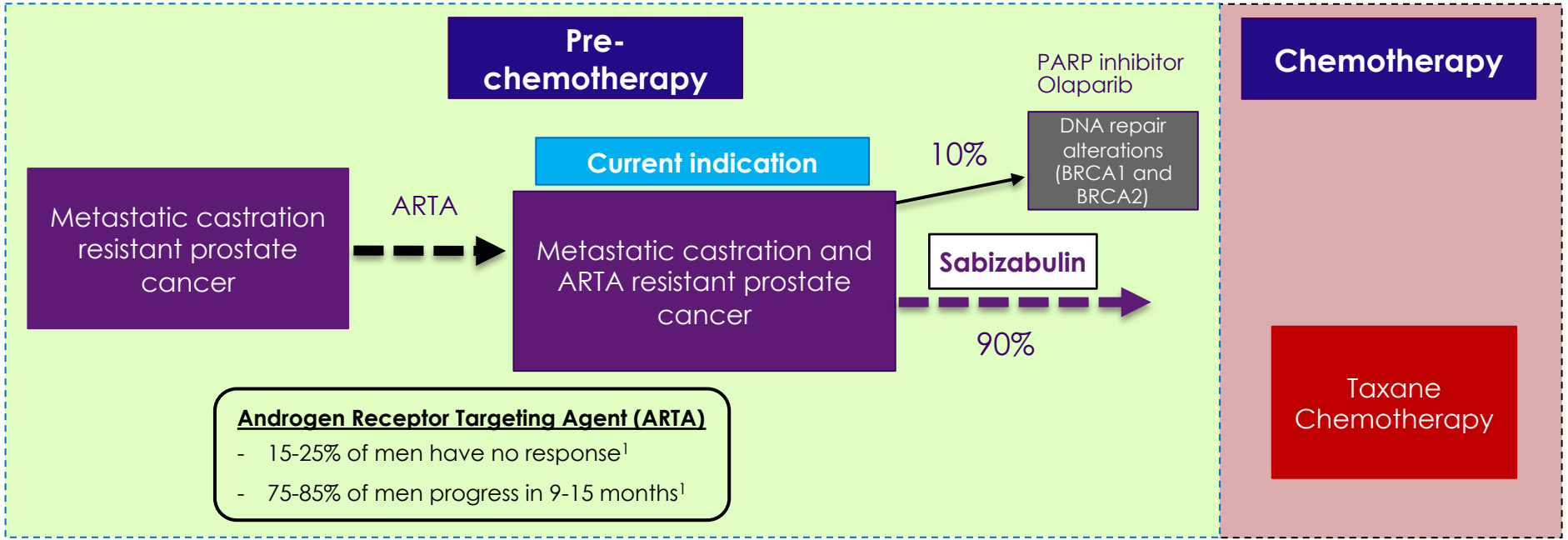
- Patients previously treated with a least 2 systemic chemotherapies for metastatic triple negative breast cancer
- Safety run-in of sabizabulin 32mg + enobosarm 9mg
- Single arm, open label study
  - Oral Sabizabulin 32 mg + enobosarm 9mg
- Expected to initiate Q1 2022 - 111 subjects
- Primary endpoint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



Prostate Cancer – Novel Medicines

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prostate Cancer						
Sabizabulin	Oral targeted 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	
Zulcomiphene 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



Need for new safe and effective treatment alternatives with a distinct mechanism of action (non-AR dependent) and easy mode of administration remains an unmet need

[1]ES Antonarakis. *Clin Adv Hem Onc* 14:316-319 2016.

Sabizabulin clinical development
Phase 1b (expansion cohort) and Phase 2 clinical study design- ONGOING STUDY

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

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 2[1]
- 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 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 5 men on study[1])

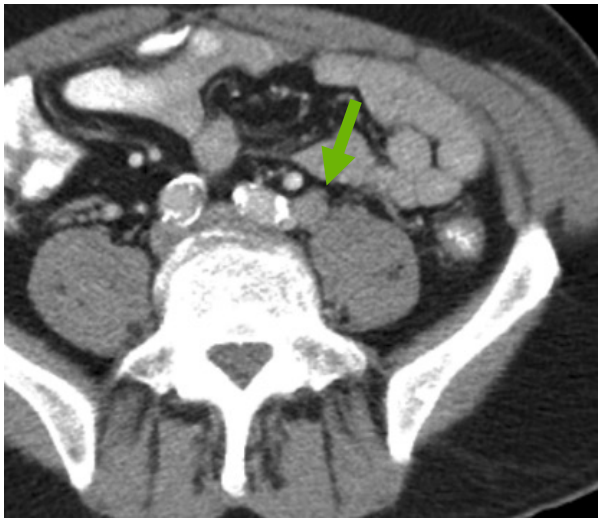
[1]Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose as of February 2021 and had measurable disease

Sabizabulin clinical development
Phase 2 case study patient 104-017

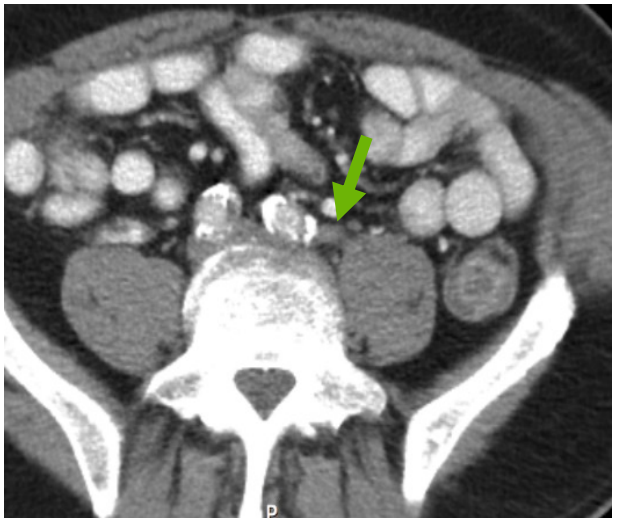
Patient: 104-017

- 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 1b/2 clinical development:
Conclusions

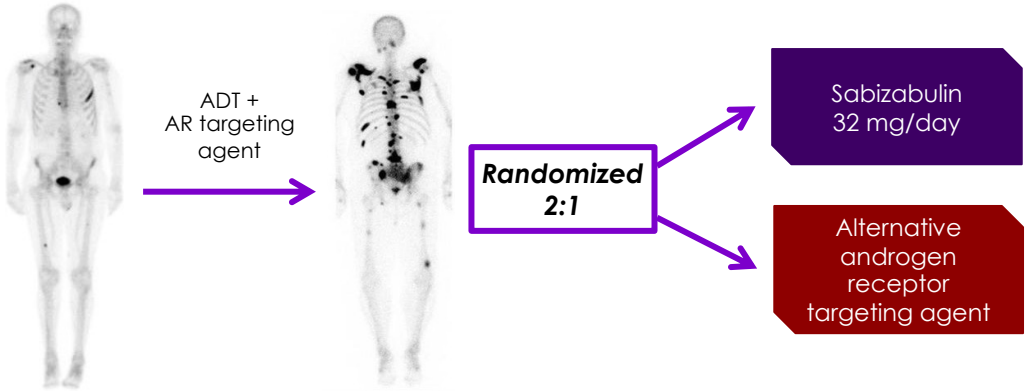
Sabizabulin was well tolerated with evidence of significant and durable objective tumor responses

- 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

Phase 3 VERACITY clinical trial (V3011102) (NCT#-04844749)
Enrolling in approximately 45 clinical sites

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 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
    - a = 0.05
    - 98% power
    - Drop out= 30%
    - 10 months recruitment time, 12 month follow up after last patient first dose



*Based on Olaparib study[1] and CARD study[2] an alternative androgen receptor targeting agent is expected to have a median rPFS of 3.6-3.7 months in this similar population

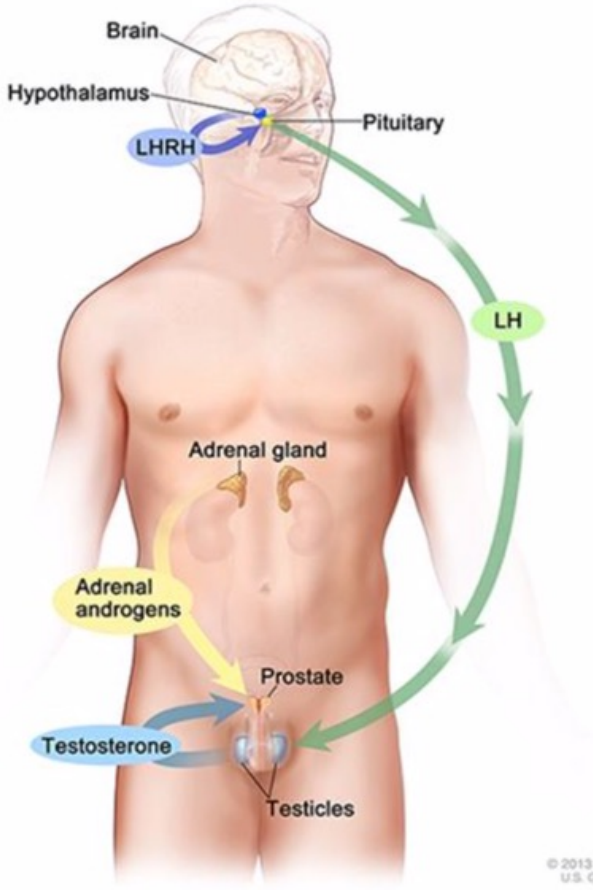
[1] de Bono J et al. NEJM April 28,2020 | [2] de Wit R et al. NEJM 381:2506-18 2019

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 levels[1]
- Up to 17% of men do not achieve castration[1]
- 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 profile[1]

- 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

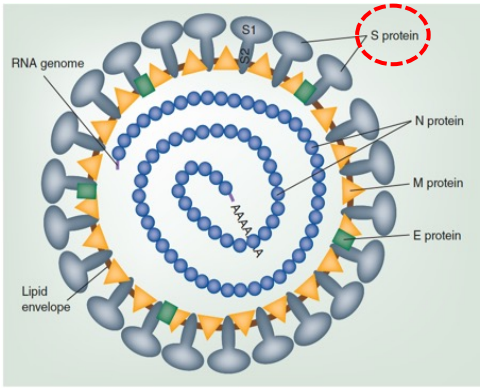
[1]Developed in collaboration with Drug Delivery Experts, LLC (San Diego, California)

Sabazibulin 9 mg

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

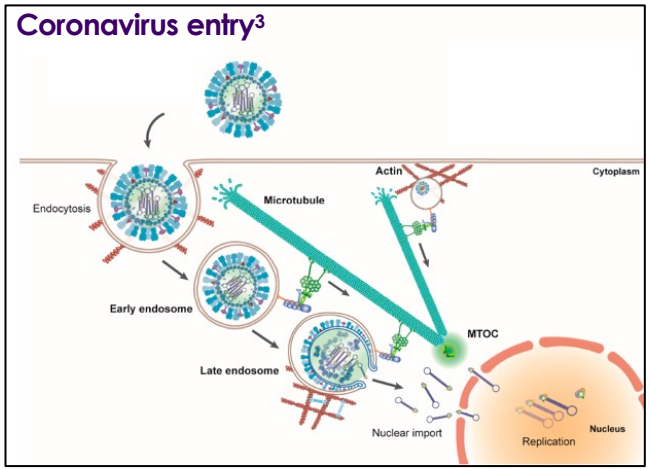
Coronavirus's spike(S) protein is the key structure that interacts with microtubules in the cytoskeleton during intracellular trafficking[4]

SARS-CoV-2 structure[4]

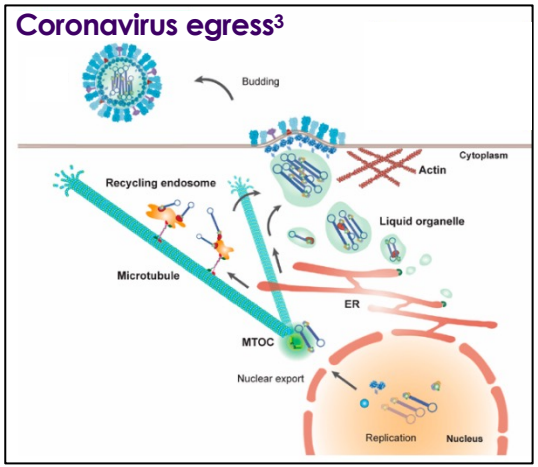


- **Virus's most critical task is to hijack the host's internal transportation system, the microtubules in the cytoskeleton[1-3]**
- **Sabizabulin disrupts the microtubule trafficking system**
  - Antiviral
  - Anti-inflammatory

Coronavirus entry[3]



Coronavirus egress[3]



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

Sabizabulin: Phase 2 clinical trial design for COVID-19

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)

Phase 2 clinical trial of sabizabulin 18 mg

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±11.54 (n=20)	3.00±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±13.07 (n=18)	1.43±3.96 (n=14)	84%	p=0.02
Days on mechanical ventilation	6.00±10.57 (n=18)	0 (n=14)	100%	p=0.04

Safety outcomes for Sabizabulin 18mg from Phase 2 clinical trial

Safety

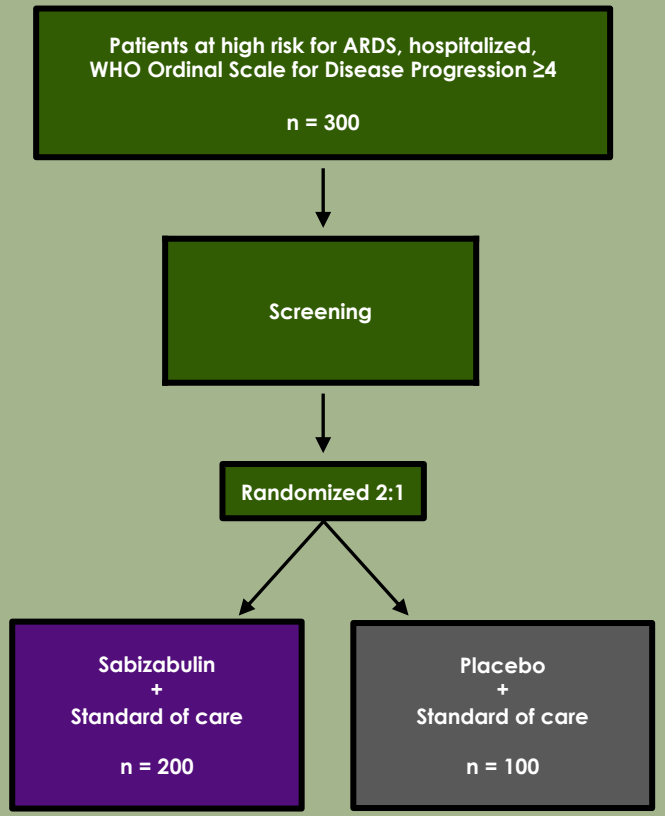
- There were no treatment related adverse events observed on the study
- There were no treatment related serious adverse events observed on the study
- There is no imbalance against sabizabulin in adverse events observed in the study

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



veru

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 12/2021[1-3]

ENTADFI®
(tadalafil and finasteride)
capsules

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 | [2]Casabé A et al. J Urol 191:727-733, 2014. | [3]Glina S et al. J Sex Med 12:129-1238, 2015.

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

UREV Sexual Health

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-present[1]

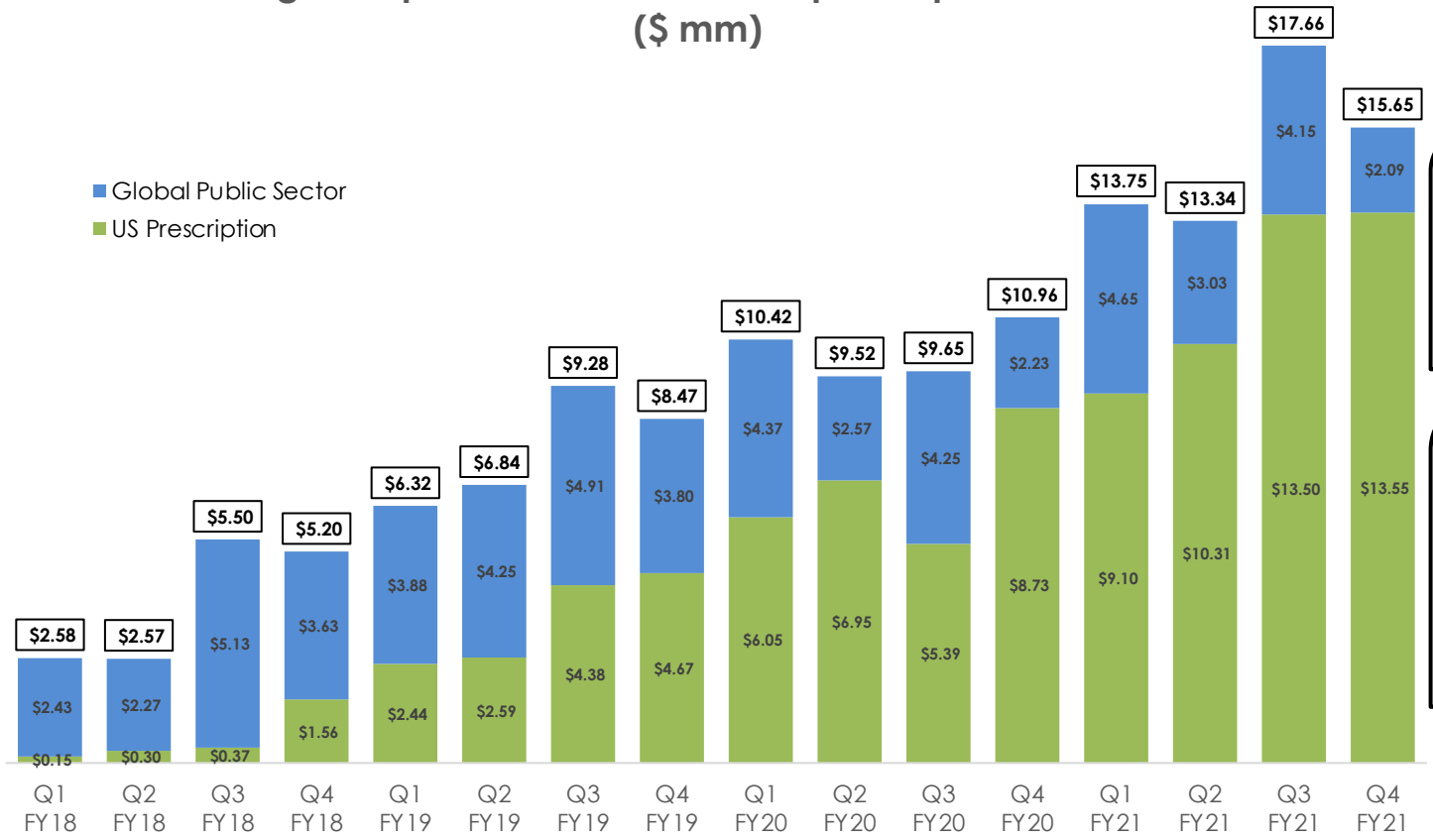
Medical Device

[1]For 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® revenues

UREV
Sexual Health

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

Financial highlights

Veru – Fiscal year 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 – Fiscal Year Results of operations	
FY 2021 Net Revenues	$ 61.3 mm
FY 2021 Gross Profit	$ 47.9 mm
FY 2021 Operating Income	$ 13.0 mm

UREV – Women's 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 September 30, 2021	
Cash	$ 122.4 mm
Receivables	$ 8.8 mm
PREBOOST Payment Due	$ 5.0 mm[2]
US/UK NOL carryforward	$ 39.1/$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 million[2]

[1] An aggregate of 10.7 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

Milestones

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