Veru Inc.
Nasdaq:VERU

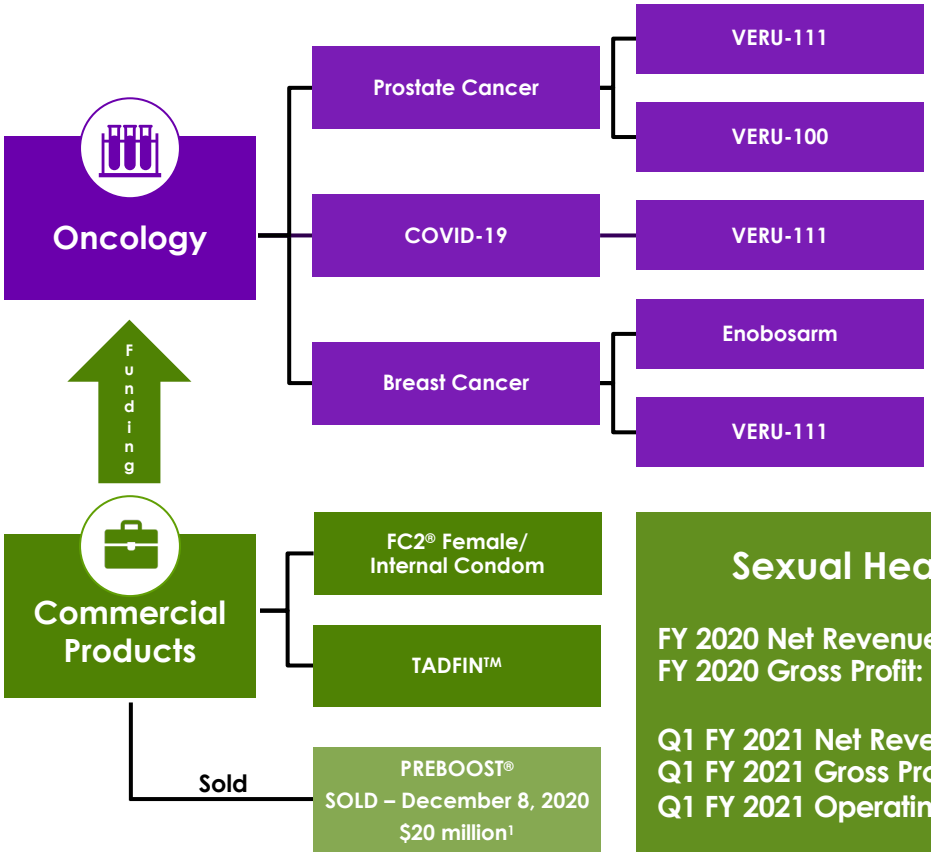
Oncology Biopharmaceutical Company Focused on Prostate Cancer and Breast Cancer

Veru Corporate Presentation
Oppenheimer 31st Annual Healthcare Conference
March 16-17, 2021

Forward looking statements

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

Oncology biopharmaceutical company
Focused on prostate cancer and breast cancer



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

Late stage COVID-19 antiviral and anti-inflammatory agent

5 registration clinical studies planned to commence in calendar year 2021

Focus is on large premium markets

Sexual Health Business

FY 2020 Net Revenues: $ 42.6 mm
FY 2020 Gross Profit: $ 30.8 mm

Q1 FY 2021 Net Revenues: $ 14.6 mm
Q1 FY 2021 Gross Profit: $ 10.8 mm
Q1 FY 2021 Operating Income $ 9.9 mm

Veru closes public offering (February 2021):
$115 million[2]
+
Existing cash on hand (as of December 31, 2021):
$30.9 million

[1] PREBOOST sale was $15 million in cash and $2.5 million to be paid at 12 months and another $2.5 million at 18 months
[2] Cash received from the public offering, net of underwriting discounts and commissions, was $108.1 million

Drug candidate pipeline[1]

Oncology biopharmaceutical company focused on prostate cancer and breast cancer

Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prostate Cancer					
VERU-111 Oral cytoskeleton disruptor	Metastatic castration resistant & AR targeting agent resistant prostate cancer prior to IV chemotherapy	Preclinical Complete	Phase 1b Complete	Phase 2 Active & Enrolled	VERACITY Phase 3 Planned Q1 2021 240 Patients
VERU-100 GnRH antagonist 3 month sc depot	Advanced prostate cancer androgen deprivation therapy	Preclinical Complete	Phase 2 Planned 1H 2021		Phase 3 Planned 2H 2021 ~100 Patients
Breast Cancer					
Enobosarm Selective AR targeted agonist	AR+/ER+/HER2- advanced breast cancer endocrine therapy	Preclinical Complete	Twelve Phase 1 Studies Complete	Six Phase 2 Studies Complete	ARTEST Phase 3 Planned Q2 2021 ~240 Patients
VERU-111 Oral cytoskeleton disruptor	Taxane resistant triple negative breast cancer	Preclinical Complete	Phase 2b Planned Q4 2021 ~200 Patients		

[1] Certain information herein represents objectives of the Company. Whether these objectives will be met as anticipated or at all depends on a variety of factors outside of the Company's control.

Experienced in clinical practice, drug development and commercialization

Mitchell Steiner, MD

FOUNDER, CHAIRMAN, PRESIDENT & CEO

CEO & President Aspen Park Pharm; President Urology OPKO Health, Inc.; CEO & Founder GTx, Inc.; Urology training-Johns Hopkins; Assistant Professor Urology Vanderbilt; Former Professor & Chairman of Urology University of Tennessee

Harry Fisch, MD

FOUNDER, CHIEF CORPORATE OFFICER & VICE CHAIRMAN

Chairman Aspen Park Pharmaceuticals and Millennium Sciences, Inc.; Urologist; Professor of Urology New York Presbyterian/ Weill Cornell

Gary Barnette, PhD

CHIEF SCIENTIFIC OFFICER

Sr. VP Scientific and Reg Affairs Camargo Pharm. Services; VP Clinical & Reg and Founder GTx, Inc.; Director Reg Affairs Solvay Pharma; Clinical Pharm/ Biopharmaceutics Reviewer FDA: PhD Basic Pharmaceutical Sciences West Virginia University

Gary Bird, PhD

PHARMA MANUFACTURING

VP Reg Affairs/Quality, Geno Inc; Partner, Pharma Consult Global; Dir. Corp Quality, GTx, Inc; Corp AdBiotechnology, Eli Lilly and Company; Special Assist. to Deputy Director, CBER, FDA; ChemRev,OGD, FDA; PhD- Enzymology & Entomology, Miss.St.U

Domingo Rodriguez, MD

EVP CLINICAL OPERATIONS

VP Global Development Operations Mallinckrodt Pharmaceuticals; VP Clinical Operations GTx; Area Director Medical Affairs BMS; Sales Marketing BMS/Bayer/Lilly; Medical School CETEC Dominican Republic

Kevin Gilbert, JD, CPA

EVP CORPORATE DEVELOPMENT

Corporate Development & Legal, Third Stream Bioscience; Attorney at McDermott, Will & Emery, Motorola, closed more than 100 transactions in 25 countries

Robert Getzenberg, PhD

EVP MEDICAL AFFAIRS

Exec Dean of Res, Nova Southeastern Univ SOM; Therapy Area Lead, GTx; Prof & Dir of Urol Res, Johns Hopkins Univ SOM; Prof & Dir of Urol Res, U Pitt SOM

Phil Kuhn, MBA

EVP STRATEGY AND COMMERCIALIZATION

Global Strategy and Commercial expertise in medical devices, diagnostics, and biologics; leadership roles at ISTO Biologics, Orthofix, Smith & Nephew, Boston Scientific, Johnson & Johnson, and Abbott

Prostate Cancer - Novel Medicines

VERU-111

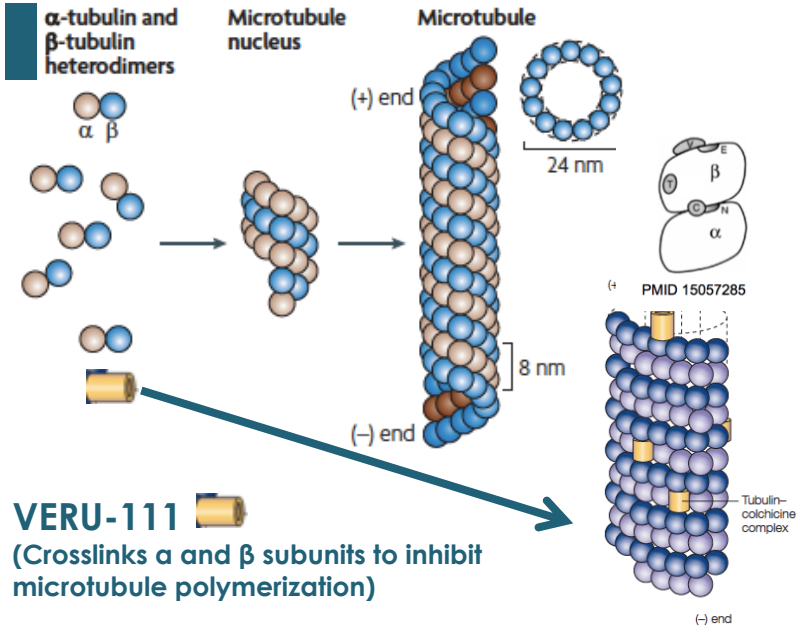
For the treatment of metastatic castration resistant prostate cancer

VERU-111 Target Product Profile
Targets the cytoskeleton: "Railroad tracks disruptor"

Preclinical Product profile[1-4, 6]

- Binds to "colchicine binding site" to crosslink a and β tubulin subunits to disrupt microtubule polymerization
- Downregulates intermediate filaments of cytoskeleton
- High oral bioavailability
- Not a substrate for multidrug resistance proteins (P-gp, MRPs, and BCRP)
- Not a substrate for CYP3A4
- Decreases production of βI, βIII and βIV tubulin isoforms
- Cleaves Poly (ADP-ribose) polymerase (PARP) protein
- 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

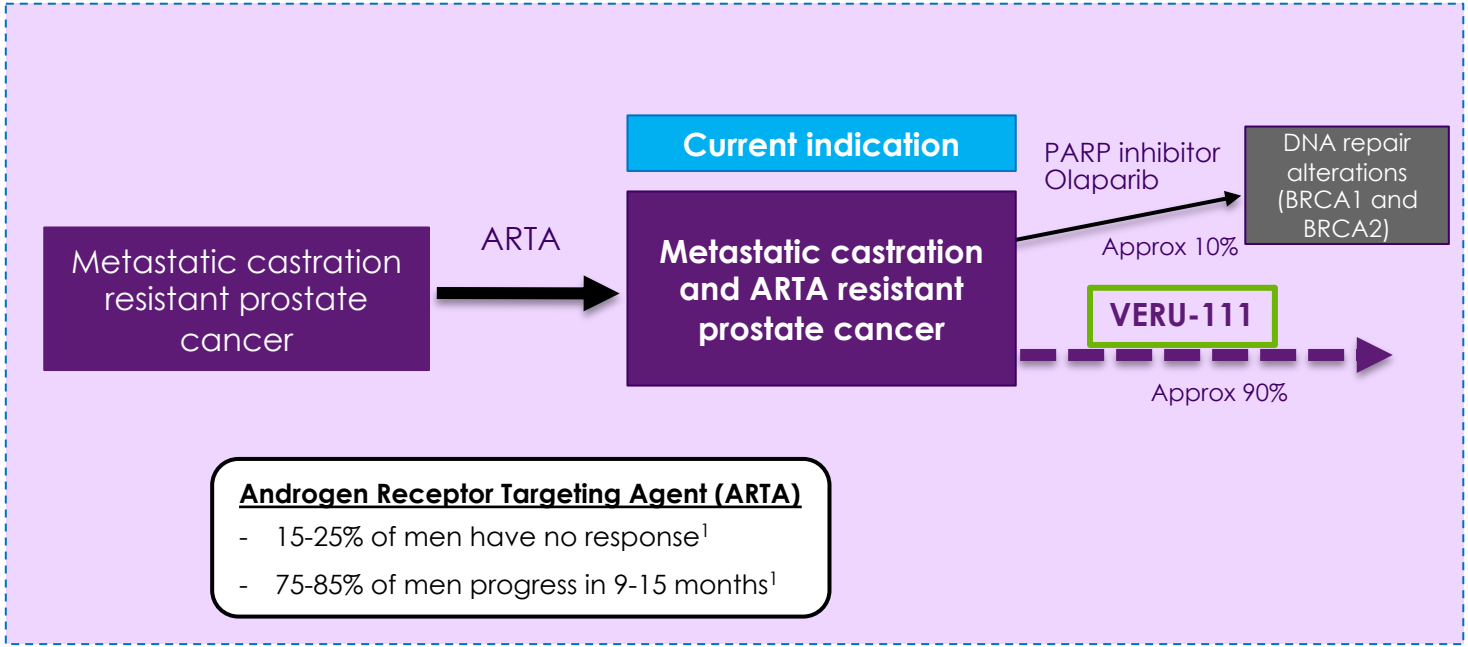
Targets cytoskeleton and disrupts microtubule assembly[5]



VERU-111
(Crosslinks a and β subunits to inhibit microtubule polymerization)

[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

VERU-111 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 targeting) and easy mode of administration remains an unmet need

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

Dose escalation Phase 1b clinical trial of VERU-111 in men with metastatic castration resistant prostate cancer following at least one prior AR targeting therapy and up to one taxane

- 7 US sites – Johns Hopkins Kimmel Comprehensive Cancer Center (lead center)
- 39 patients enrolled
- Inclusion criteria
  - 1 prior AR targeting therapy mandatory
  - Up to one line of taxane-based chemotherapy for mCRPC was allowed
- Trial design
  - Two part dosing schedule using standard 3+3 dose escalation strategy
    - Part 1- 7-day dose schedule – At each dose level, VERU-111 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 increased frequency to Day 1-14 daily dosing every 21 days (i.e. 14 days on, 7 days off). If 14-day dosing tolerated/safe, patients would take VERU-111 daily with continuous dosing until disease progression/toxicity.

VERU-111 clinical development
Phase 1b - 63 mg dose safety summary: almost all adverse events were grade 1 and 2

25 patients in the Phase 1b study have been dosed with 63 mg per day for at least one cycle

All Adverse Events Observed

	Incidence (%)
Diarrhea	17 (68%)
Nausea	8 (32%)
Decreased appetite	5 (20%)
Constipation	4 (16%)
Fatigue	4 (16%)
Vomiting	4 (16%)
Dysguesia	3 (12%)
Weight loss	3 (12%)
Abdominal cramping	2 (8%)
Anemia	2 (8%)
Edema in lower extremity	2 (8%)
Low WBC count	2 (8%)

All Drug Related Adverse Events

	Incidence (%)
Diarrhea	14 (56%)
Nausea	6 (24%)
Decreased appetite	3 (12%)
Fatigue	3 (12%)
Dysguesia	3 (12%)
Weight loss	3 (12%)
Vomiting	2 (8%)
Low WBC count	2 (8%)

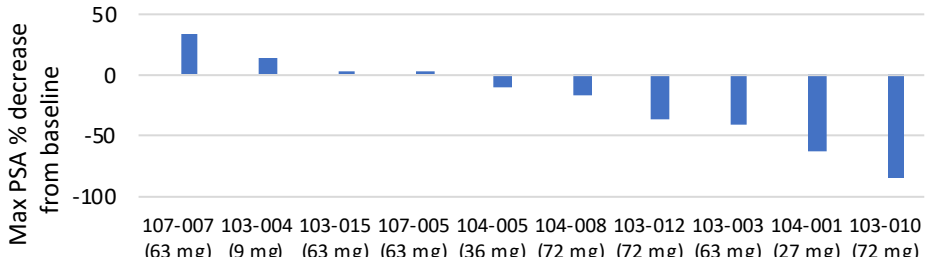
Only one patient experienced a Drug Related Grade ≥3 Adverse Events at the 63 mg dose. Fatigue resulting in a dose reduction to 54 mg. The fatigue resolved.

VERU-111 clinical development
Phase 1b efficacy

- **10 men reached at least four cycles of continuous dosing**
  - Disease (4 Bone;3 LN; and 3 LN+Bone)
  - Previous treatment- (5 Abi; 2 Enz; and 3 Abi+Enz)
- **PSA responses**
  - 6/10 had decrease in PSA
  - 4/10 had ≥ 30% decline in PSA
  - 2/10 had ≥ 50% decline in PSA
- **Best objective tumor responses**
  - 2 men had partial response (PR) (two additional objective responses occurred in subjects who did not reach 4 cycles)
  - 8 men had stable disease (SD)
- **Median radiographic progression free survival**
  - >12 months (range 6.0-23+ months)
- **3/10 men still on study as of 2/11**

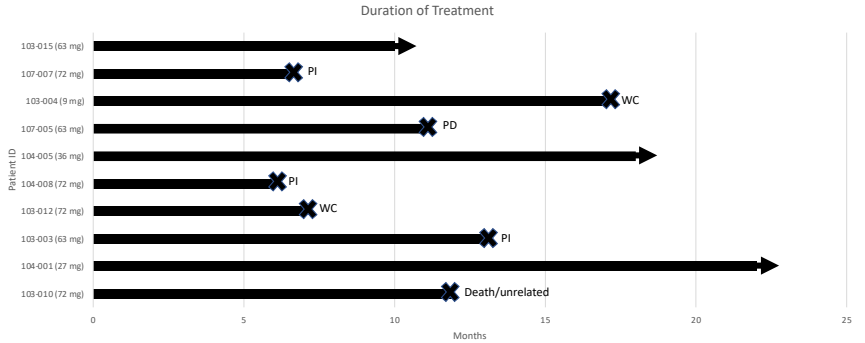
PSA waterfall plot

Ten men have reached ≥ 4 cycles of continuous dosing



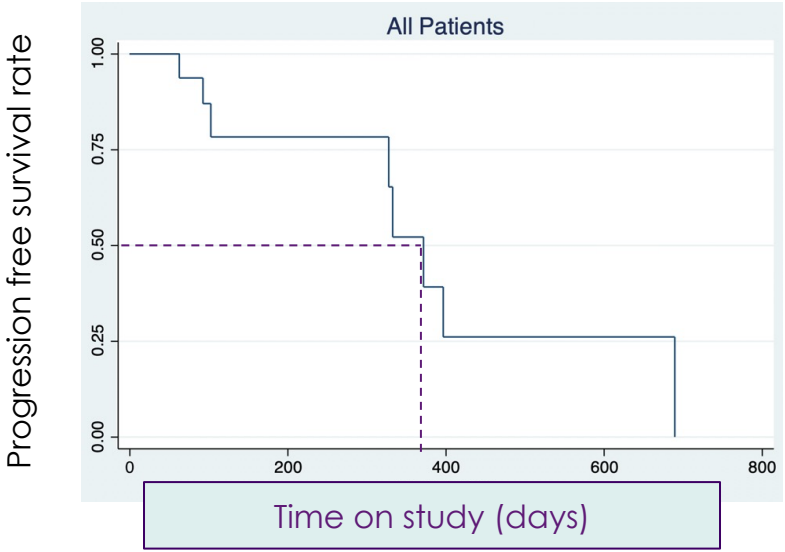
Swimmers' plot

Ten men have reached ≥ 4 cycles of continuous dosing



VERU-111 clinical development
Phase 1b efficacy analysis rPFS at recommended Phase 2 dose of 63mg

Radiographic progression free survival for all patients that received > 1 dose of VERU-111 63mg or higher (n=19)



Median radiographic progression free survival = 12.4 months

VERU-111 clinical development
Phase 1b case study patient 104-001

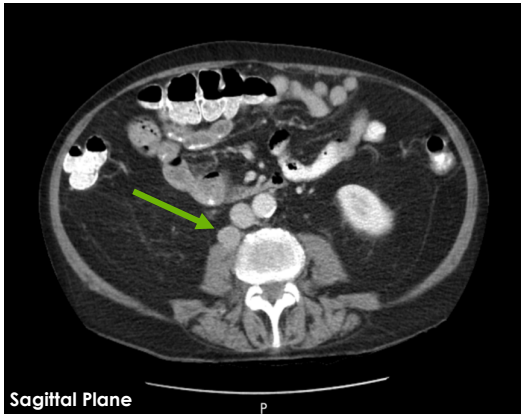
Patient: 104-001

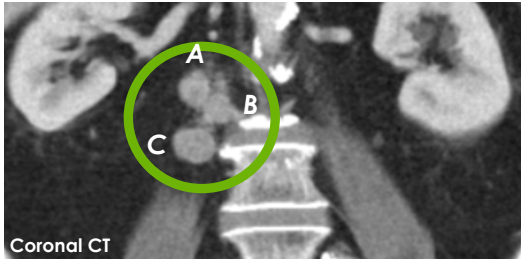
Gleason 9 mCRPC with lymph node only disease

Prior treatment included
- sipuleucel-T
- enzalutamide
- abiraterone

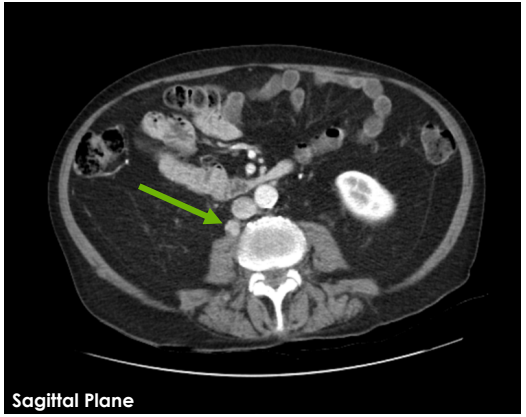
Still on study 21 months, -63% PSA from 21 day cycle initiation baseline

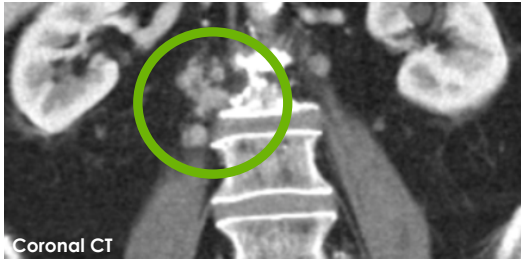
March 08, 2019: Screening CT scan
RP LN 1.7cm X 1.5cm
(measurable target lesion)





June 10, 2020: 15 months follow-up
RP LN 1.1cm X 1.0cm
(-33% decrease to nonpathologic node)





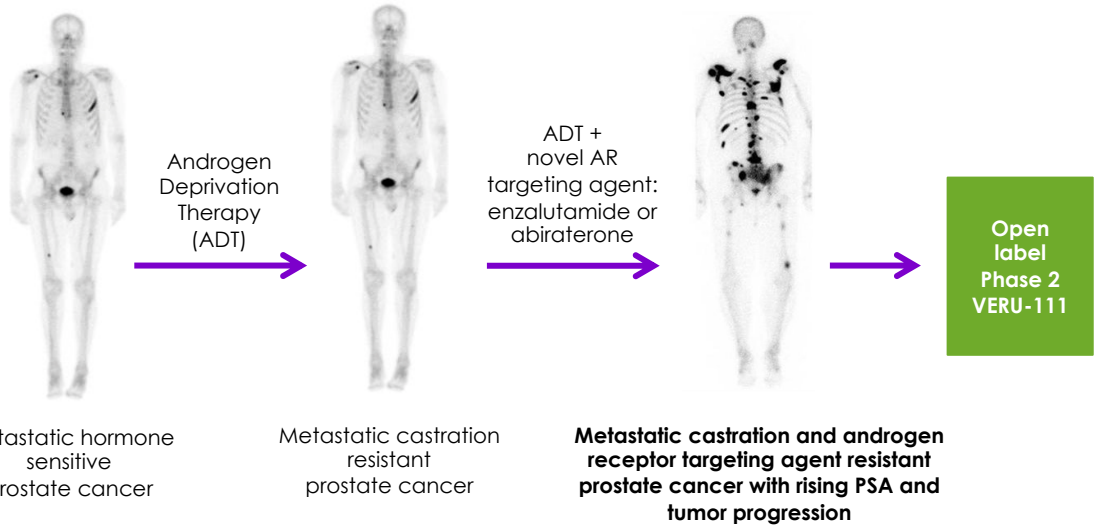
VERU-111 clinical development
Phase 1b conclusions

VERU-111 appears to be well tolerated in the Phase 1b portion of the study

- MTD (72 mg daily) was reached with the dose limiting toxicity being Grade 3 diarrhea
- Daily chronic drug administration is feasible and safe
- The recommended Phase 2 dose (RP2D) is 63mg oral daily dose for 21 days per cycle At the RP2D, there no reports of neutropenia or neurotoxicity or Grade 3 diarrhea
- Evidence of antitumor activity was observed including PSA reductions, objective tumor responses, and durable responses

VERU-111 clinical development
Phase 2 clinical study ongoing and completed enrollment of 41men in September 2020

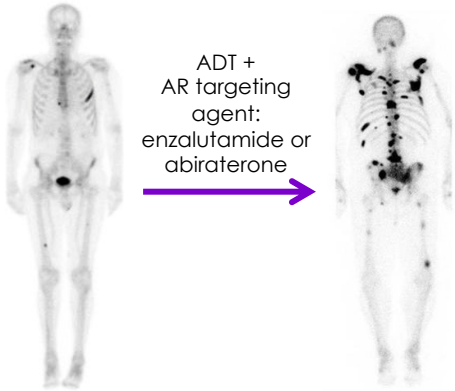
- **Conducted in 13 US clinical centers**
- **Population: Men who have metastatic castration resistant prostate cancer and who have also become resistant to an androgen receptor targeting agent, but prior to IV chemotherapy**
- **Trial design: Open label –**
  - 63mg/day, continuous daily dosing
  - If toxicity is observed, reduce dose to 54mg/day continuous daily dosing
- **Primary endpoint: radiographic progression free survival (rPFS)**



VERU-111 clinical development plan
VERACITY Phase 3 clinical trial design following FDA input – planned initiation 1Q 2021

- **Open label**
- **VERU-111 63mg daily oral continuous dosing for 21-day cycles versus an alternative androgen receptor targeting agent**
- **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 VERU-111 vs 3.5 months* for Alternative AR targeting agent
  - Sample size - 241 men
    - 2:1 randomization
    - 90% power, alpha=0.05, 10 months recruitment time, 12 month follow up after last patient first dose

Phase 3: Efficacy and safety of VERU-111 versus an alternative androgen receptor target agent (abiraterone or enzalutamide) in men with metastatic castration resistant prostate cancer who have developed cancer progression after receiving one androgen receptor targeting agent



Metastatic castration resistant prostate cancer

Metastatic castration and androgen receptor targeting agent resistant prostate cancer

*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

VERU-111 may have efficacy beyond prostate cancer
Antitumor activity of VERU-111 in preclinical models of other tumor types

- Triple negative breast cancer (taxane resistant)[1]
- Cervical cancer (taxane resistant)[2]
- Lung cancer (taxane resistant)[3]
- Ovarian cancer (taxane resistant)[4]
- Uterine cancer[5]
- Pancreatic cancer[6]
- Melanoma[7]
- Human promyelocytic leukemia (vincristine resistant)[8]

[1] Deng S et al Mol Cancer Ther 19:348-63, 2020 | [2]Kashyap VK et al Cancer Lett 470:64-74, 2020 | [3]Foyez M et al Data on file Veru, Inc. 2020 | [4,5] Data on file Veru, Inc. 2020 | [6]Kashyap V et al J Experimental and Clinical Can Res 38:29, 2019 | [7] Chen J et al J Med Chem 55:7285-7289, 2012; Hwang DJ et al ACS Med Chem Lett 6:993-997, 2015| [8] Data on file Veru, Inc. 2014 |

VERU-111 has strong global intellectual property protection

Licensed from the Ohio State Innovation Foundation in 2015

Composition of matter (molecule and polymorphs) issued or allowed patents

- 2 US latest expiry 2031 (with possible patent extension for NCE expiry 2036)
- 1 EU latest expiry 2029
- 2 Japanese latest expiry 2031
- 8 in other countries (not counting EU jurisdictions)
- 3 patent pending

Method of use VERU-111 for the treatment of prostate and breast cancer issued or allowed patents

- 3 US latest expiry 2031
- 1 EU latest expiry 2029
- 2 Japanese latest expiry 2031
- 8 in other countries (not counting EU jurisdictions)
- 16 patents pending

Other methods of use VERU-111

- 2 US latest expiry 2034
- 1 JP latest expiry 2034
- 6 ex-US and Ex-JP latest expiry 2034
- 24 patents pending (expected expiries of 2030-2042)

VERU-111 market

Prechemotherapy estimated annual market for oral agents for prostate cancer

2018
$6 billion global annual sales; $3.1 billion in the US [1]

Androgen receptor targeting agents for metastatic castration resistant prostate cancer

15-25% of men have no response[3] → $1.5 billion

75-85% of men progress in 9-15 months[3] → $3.4 billion

$4.9 billion global annual sales in Japan, the Americas, EMEA, Asia and Oceania [2,4]

[1] MME LLC, Prostate Cancer Market Revenues (2018); [2]Johnson & Johnson. 2019 Annual Report; [3]ES Antonarakis. *Clin Adv Hem Onc* 14:316-319 2016.; [4]Astellas Pharma Inc. 2019 Annual Report

VERU-100

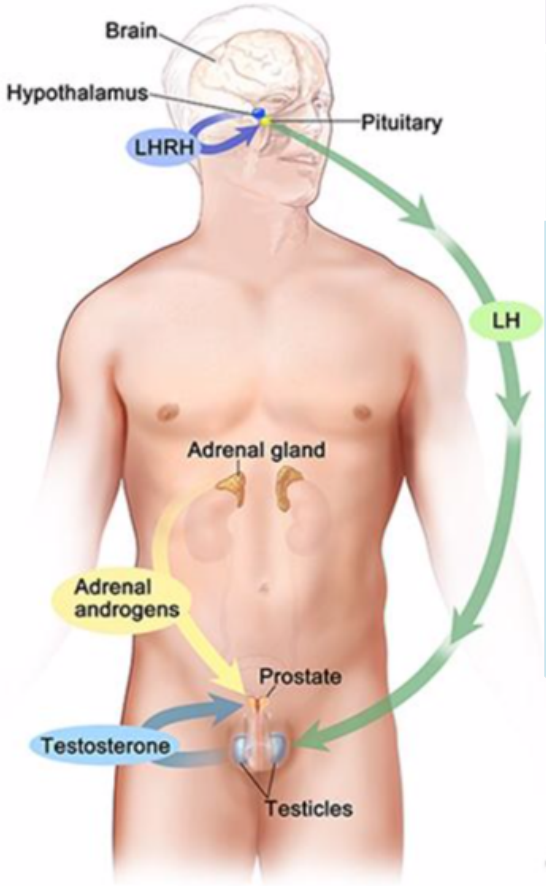
For the treatment of advanced prostate cancer

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
- CV safety concerns



GnRH antagonist

FIRMAGON® (degarelix) (SC)

- Painful injection as degarelix requires large loading and maintenance dose injected subQ
  - Loading 6mL (2X3 mL)
  - Maintenance 4 mL every month
- No long acting depot available; must be given every month

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

In prospective randomize Phase 3 study, GnRH antagonist has lower cardiovascular events compared to LHRH agonist

- **Prospective randomize Phase 3 study in 930 men with advanced prostate cancer comparing oral GnRH antagonist to LHRH agonist (leuprolide)[1]**
- **CV events lower with GnRH antagonist (relugolix) compared to LHRH agonist at 1 year**
  - Incidence of adverse cardiovascular events lowered by 54%
    - Leuprolide- 6.2% vs relugolix- 2.9%
  - In men with history of adverse CV events, new CV events lowered by 80%
    - Leuprolide- 17.8% vs relugolix- 3.6%

[1]Shore N N Eng J Med 382:2187-2196, 2020

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[2]

- Novel proprietary GnRH antagonist decapeptide formulation[1]
- 3 month slow release subQ depot (1cc SQ injection) with no loading dose
- 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
- Sustained suppression of FSH

Clinical development program as agreed upon by FDA

Open label Phase 2 scheduled for 1H 2021 n=35

Open label single registration Phase 3 scheduled for 2H 2021 n=100

[1]Developed in collaboration with Drug Delivery Experts, LLC (San Diego, California); [2]Veru Inc. VERU-100 Target Prescribing Information

Breast Cancer - Novel Medicines

Enobosarm

for the treatment of AR+ ER+ HER2 - advanced breast cancer

Endocrine therapies that target estrogen receptor axis are effective against ER+ breast cancer

Current Endocrine Therapies

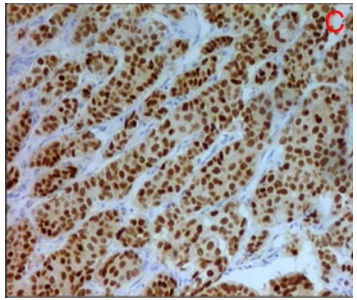
- Selective estrogen receptor modulators (tamoxifen and toremifene)
- ER antagonists and degraders (fulvestrant)
- Aromatase inhibitors (AI)
  - AROMASIN® (exemestane) - steroidal AI
  - ARIMIDEX® (anastrozole) and FEMARA ®(letrozole) - nonsteroidal AI
- CDK 4/6 inhibitors in combination with nonsteroidal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

Resistance to endocrine 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 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

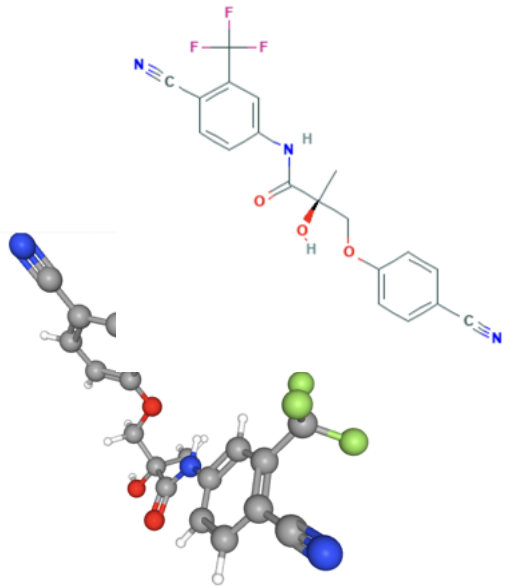
Theresa E. Hickey[1], Luke A. Selth[1,2,3], Kee Ming Chia[4], Geraldine Laven-Law[1], Heloisa H. Milioli[4], Daniel Roden[4], Shalini Jindal[1], Mun Hui[4], Jessica Finlay-Schultz[5], Esmaeil Ebrahimie[1], Stephen N. Birrell[1], Suzan Stelloo[6,11], Richard Iggo[1,7], Sarah Alexandrou[4], C. Elizabeth 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 | [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 and activating agent for the treatment for AR+ER+ advanced 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 or binding to other steroidal hormone receptors
  - 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]
  - Selective tissue activities translate to a favorable side-effect profile
    - Non-virilizing (no unwanted hair growth or acne)
    - No liver toxicity
    - No changes in hematocrit
- **Enobosarm suppresses AR+ER+ breast cancer in cell and patient-derived xenograft models of endocrine sensitive and resistant disease[7]**



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

Enobosarm has an extensive clinical experience

- **Enobosarm has been evaluated in 25 clinical trials comprising 2,091 subjects (348 subjects dosed at ≥ 9mg)**
- **6 Phase 2 studies in breast cancer (5) or breast disease (1)**
  - G200801 – Proof of concept 9 mg Enobosarm in AR+ ER+ metastatic breast cancer
  - G200802 - Efficacy and safety of 9 mg and 18 mg (randomized) Enobosarm in AR+ ER+ metastatic breast cancer
  - G200901 – Efficacy of 18 mg Enobosarm in heavily pretreated metastatic AR+ TNBC
  - [1]City of Hope Investigator Initiated – Efficacy of 18 mg Enobosarm in combination with pembrolizumab in AR+ TNBC
  - [2]Emerald –A window of opportunity study to assess the biological effects in AR+/ER+ early breast cancer
  - [3]Australia Investigator Initiated – Enobosarm + anastrozole in premenopausal women with high mammographic density
- **12 Phase 1 studies for NDA and label completed**
  - QT – no QT effects
  - Drug interactions- no significant drug-drug interactions
  - Food effect- no food effect
  - Renal impairment- no significant effects
  - Hepatic impairment- no significant effects
  - Major metabolites analysis and route of elimination- renal elimination and only metabolite is Enobosarm glucuronide
  - Cytochrome P450 3A4- Enobosarm is not an inhibitor

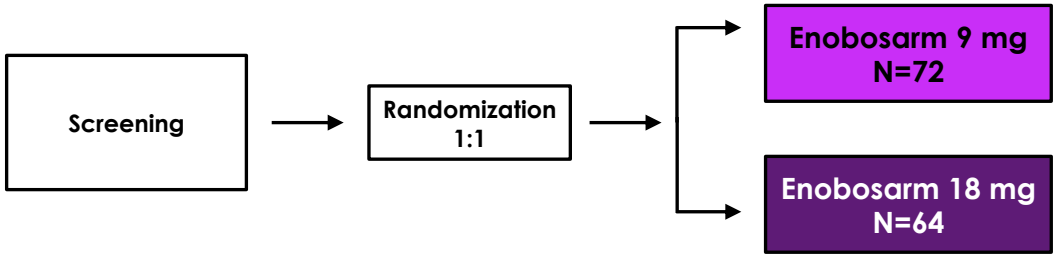
[1]Lee-Bitar JS et al J Clin Onco 37: supplement abstract 1069 2019 NCT02971761 | [2]EudraCT number 2016-000543-13 | [3] Clinicaltrials.gov NCT03264651

Efficacy and safety of Enobosarm, a selective androgen receptor agonist, to target AR in women with advanced AR+/ER+ breast cancer – final results from an international Phase 2 randomized study (G200802)

Carlo Palmieri[1], Hannah Linden[2], Stephen Birrell[3], Elgene Lim[4], Lee S Schwartzberg[5], Hope S Rugo[6], Patrick Cobb[7], Kirti Jain[8], Charles Vogel[9], Joyce A O'Shaughnessy[10], Stephen Johnston[11] , Robert H Getzenberg[12], Mitchell Steiner[12], Adam Brufsky[13] and Beth Overmoyer[14]

[1]The Clatterbridge Cancer Center NHS Foundation Trust, Liverpool, United Kingdom; [2]University of Washington/ Seattle Cancer Care Alliance, Seattle, WA;[3]Wellend Health/Burside Hospital, Toorak Gardens, Australia; [4]University of New South Wales, Australia and Garvan Institute of Medical Research, Darlinghurst, Australia; [5]The West Clinic, Memphis, TN; [6]University of California San Francisco, San Francisco, CA;[7]Cancer Centers of Montana, Billings, MT;[8]Ashland Bellefonte Cancer Center, Ashland, KY; [9]University of Miami Sylvester Comprehensive Cancer Center, Miami, FL;[10]Baylor University Medical Center, Texas Oncology, US Oncology, Dallas, TX; [11]Royal Marsden NHS Foundation Trust, London, United Kingdom; [12]Veru Inc, Miami, FL;[13]Magee-Womens's Hospital, University of Pittsburgh Medical Center, Pittsburgh, PA;[14]Dana Farber Cancer Institute, Boston, MA

Phase 2 clinical trial (G200802) design
Targeting AR+ER+ 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 9mg or 18mg 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)
Patient demographics

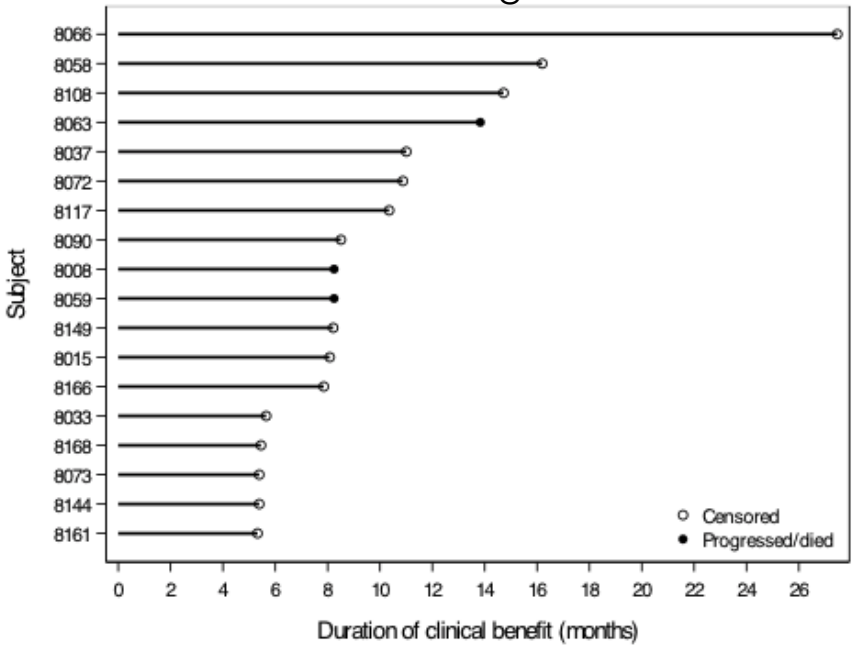
	9 mg cohort	18 mg cohort
Age (median), years (range)	60.5 (35-83)	62.5 (42-81)
Caucasian (%)	98.0	94.2
Initial presentation of Stage IV metastatic breast cancer	12%	26.9%
Median months since initial diagnosis (range)	110.0 (19-435)	86.0(15-323)
Median months since metastatic diagnosis (range)	34.3 (1-167)	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)

Evaluable Population

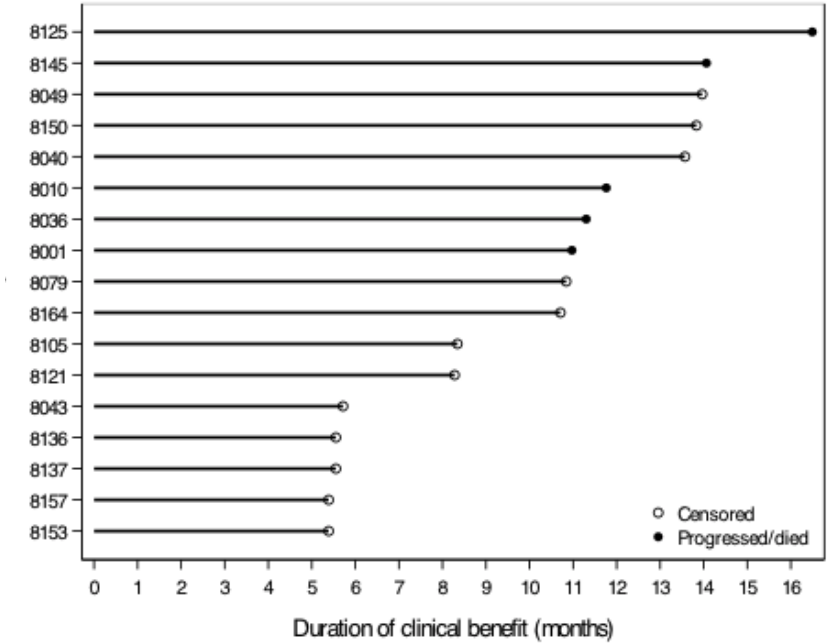
	9mg cohort	18mg cohort
Number of evaluable patients	50	52
Primary endpoint: CBR at 24 weeks	**32% (95% C.I. 19.5%;46.7%)**	**29% (95% C.I. 17.1%;43.1%)**
Median rPFS (range)	>5.6 months (0->27.5)	4.2 months (0-16.5)

Phase 2 clinical trial (G200802):
Duration of CBR is approximately 12-14 months

9 mg



18 mg

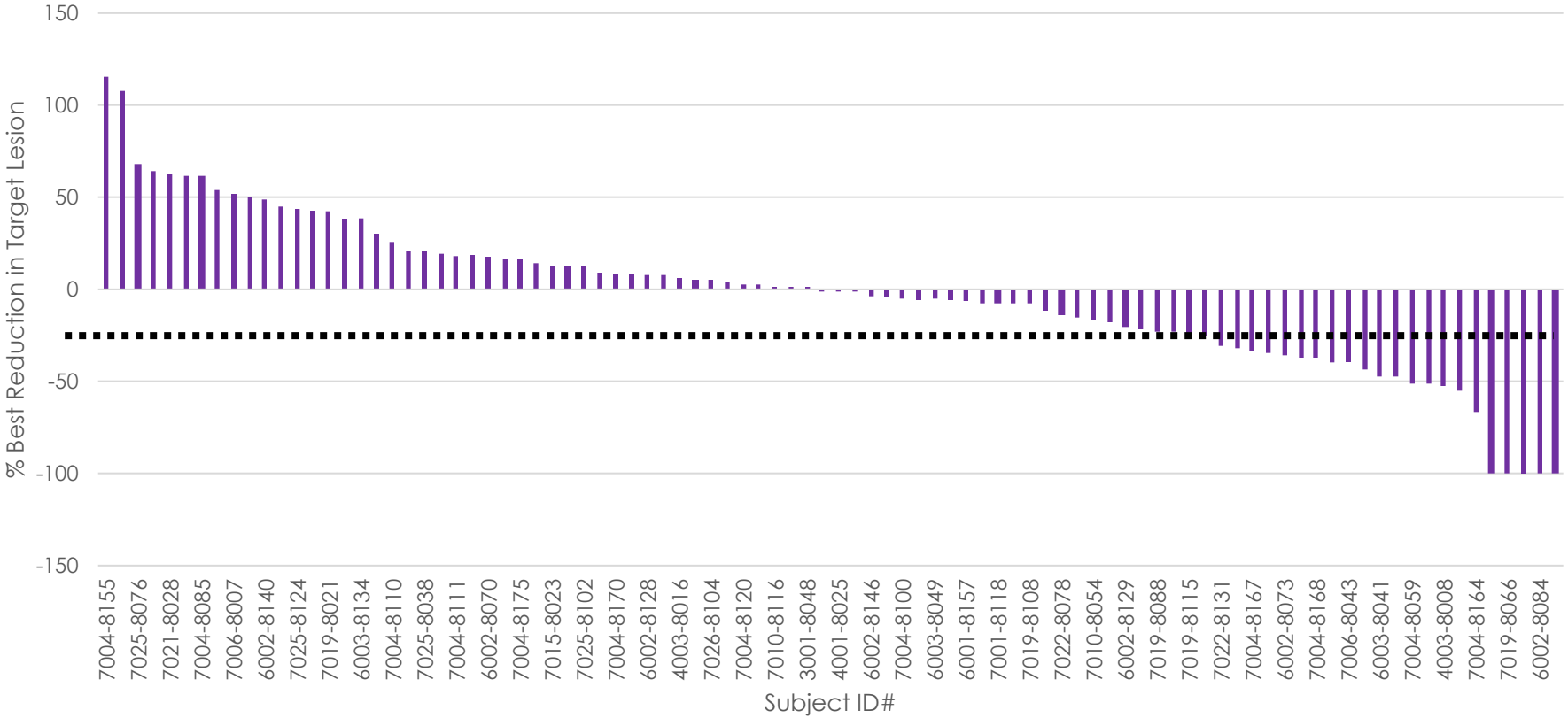


Please note that the x-axis is different

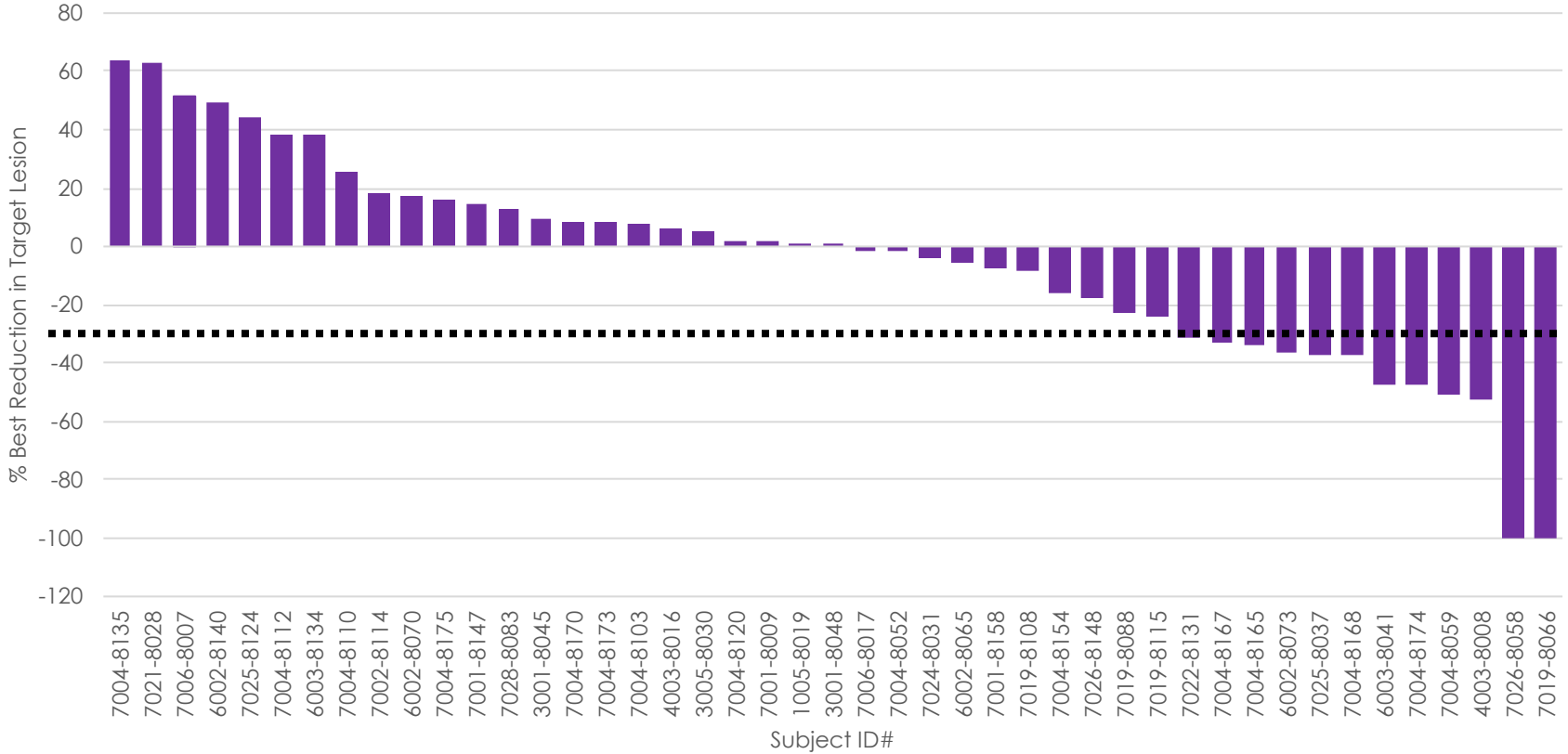
Efficacy results- RECIST 1.1 best overall tumor responses (BOR) by central read at any time during the study in patients with measurable disease at baseline

- 9 mg cohort (n=34)
  - 2 (5.9%) complete responses
  - 8 (23.5%) partial responses
  - **ORR = 29.4% (10/34)**
- 18 mg cohort (n=37)
  - 3 (8.1%) complete responses
  - 6 (16.2%) partial responses
  - **ORR= 24.3% (9/37)**

Phase 2 clinical trial (G200802)
Best overall % target lesion reduction – Enobosarm (9 and 18 mg) G200802



Phase 2 clinical trial (G200802)
Best overall % target lesion reduction – Enobosarm 9mg



Phase 2 clinical trial (G200802)
QOL assessment

- EuroQol-visual analogue scale (EQ-VAS) scores were obtained at baseline and during the study (week 24 and EOT)
- For the entire instrument there was 8.6 (14.69) (p=0.002) for 9mg and 7.3 (16.67) (p=0.011) for 18mg decrease in score (improvement) from baseline to the end of treatment visit (EOT)

QOL Measurement % patients reporting improvement @ week 24	9 mg cohort	18 mg cohort
Mobility	40%	50%
Anxiety/depression	50%	29%
Pain discomfort	50%	31%

Phase 2 clinical trial (G200802)
Safety summary all patients ITT

Enobosarm was well tolerated; majority of events were Grade 1 and 2

	Enobosarm 9 mg N=75	Enobosarm 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	Enobosarm 9 mg N=75	Enobosarm 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%)

Phase 2 clinical trial (G200802)
Conclusions- AR targeted therapy shows efficacy and safety in AR+ ER+ breast cancer

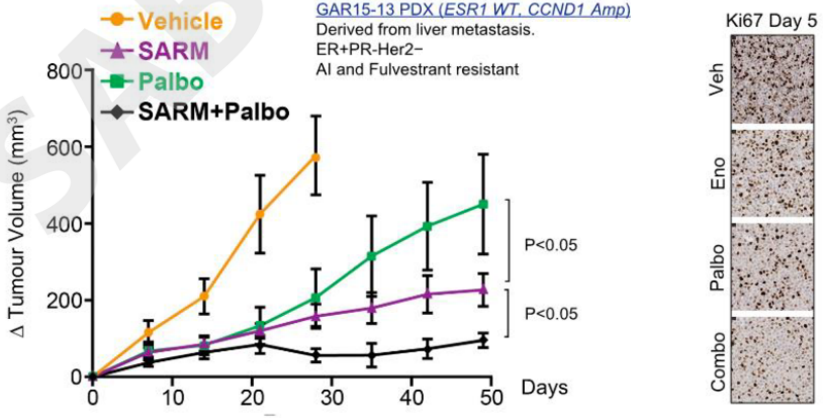
- **Enobosarm AR targeted treatment demonstrated clinical benefit with objective tumor responses in women with heavily pretreated estrogen receptor targeted resistant AR+ ER+ metastatic breast cancer**
- **Quality of life measurements demonstrated overall improvement including mobility, anxiety/depression 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**
  - 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 in metastatic breast cancer**

Role of enobosarm and CDK4/6 inhibitors in estrogen receptor targeting agent resistant AR+/ER+ metastatic breast cancer- preclinical models (Patient derived xenografts)[1,2]

- CDK4/6 inhibitor suppressed growth of ER targeting agent resistant breast cancer[1,2]
- Enobosarm monotherapy had greater inhibition of ER targeting agent resistant breast cancer than a CDK4/6 inhibitor[1,2]
- Enobosarm + CDK4/6 inhibitor had greater inhibition of ER targeting agent resistant breast cancer than either alone[1,2]
- Enobosarm suppressed breast cancer cells that were resistant to both CDK 4/6 inhibitor and estrogen receptor targeting agent[2]
- Enobosarm and CDK4/6 inhibitor further suppressed breast cancer cells that were resistant to both CDK4/6 inhibitor and estrogen receptor targeting agent –enobosarm restored CDK 4/6 inhibitor sensitivity[2]

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

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



SARM= enobosarm
Palbo=CDK4/6 inhibitor

[1] Lim E et al. 2019 SABCS presentation | [2] Hickey TE et al. Nature Medicine 2020

Phase 2 clinical study (G200802)
Evaluable patients (AR+) with CDK 4/6 inhibitor resistance in the metastatic setting

- **Objective tumor responses**
  - 30% overall
- **CBR at 24 weeks**
  - 50% overall
- **Mean rPFS**
  - 7.3 months overall (9mg + 18mg)
  - 10.0 months 9mg dose

CDK 4/6 inhibitor resistant subjects with measurable disease

9 mg patient ID	Outcome	18 mg patient ID	Outcome
7004-8120		6003-8133	
7019-8066	CR	7001-8001	PR
7026-8083		7001-8118	SD
7019-8087	CR	7004-8100	
7019-8106	SD	7022-8078	

Assumptions for Phase 3 Design
Summary of efficacy for two Phase 2 clinical trials (G200801 and G200802)

G200801 and G200802 efficacy summary for 9mg

	Phase 2 801 (n=22)	Phase 2 802 (n=50)
CBR at 6 months	35.3% (90% CI:16.6%,58%)	32% (95% C.I. 19.5%;46.7%)
Duration in subjects that reach 6 months	11 months	12 months (5.8-27 months)
rPFS	>5.6 months	>5.6 months (0-27 months)

Active Control Assumption
rPFS for exemestane was **2.3 months** in E2112 Phase 3 Study[1]

- Heavily pretreated population with average of 3 endocrine therapies and 85-88% received chemotherapy prior to study entry
- 12% of subjects had CDK4/6 inhibitor in Phase 2 clinical trial (G200802)

[1]Yeruva, S.L.H., Zhao, F., Miller, K.D. *et al.* E2112: randomized phase III trial of endocrine therapy plus entinostat/placebo in patients with hormone receptor-positive advanced breast cancer. *npj Breast Cancer* 4, 1 (2018). https://doi.org/10.1038/s41523-017-0053-3

Enobosarm, AR targeted endocrine therapy pivotal Phase 3 open label, randomized ARTEST clinical trial- anticipated to start Q2 2021

ARTEST Clinical Trial Design

Phase 3 open label, multicenter, multinational, randomized, active control pivotal study to evaluate the efficacy and safety of oral enobosarm 9mg monotherapy or enobosarm 9mg + CDK4/6 inhibitor combination therapy vs active control (exemestane or SERM) in AR+ ER+ HER2- metastatic breast cancer

ARTEST Indication

Treatment of AR+ER+HER2- metatstatic breast cancer in subjects who have failed a nonsteroidal aromatase inhibitor (AI), fulvestrant, and CDK4/6 inhibitor therapies

ARTEST Patient Population

Subjects with AR+ ER+ metastatic or recurrent locally advanced breast cancer, not amenable to curative treatment by surgery or radiotherapy, with objective evidence of disease progression

Must have had received a nonsteroidal AI inhibitor, fulvestrant, and CDK 4/6 inhibitor for metastatic disease

- Previously responded to hormone Tx for metastatic disease ≥ 6 months
- No prior chemotherapy (not including immunotherapies or targeted therapies) for the treatment of metastatic breast cancer

ARTEST Endpoints

Primary endpoint:

- Radiographic progression free survival (rPFS)

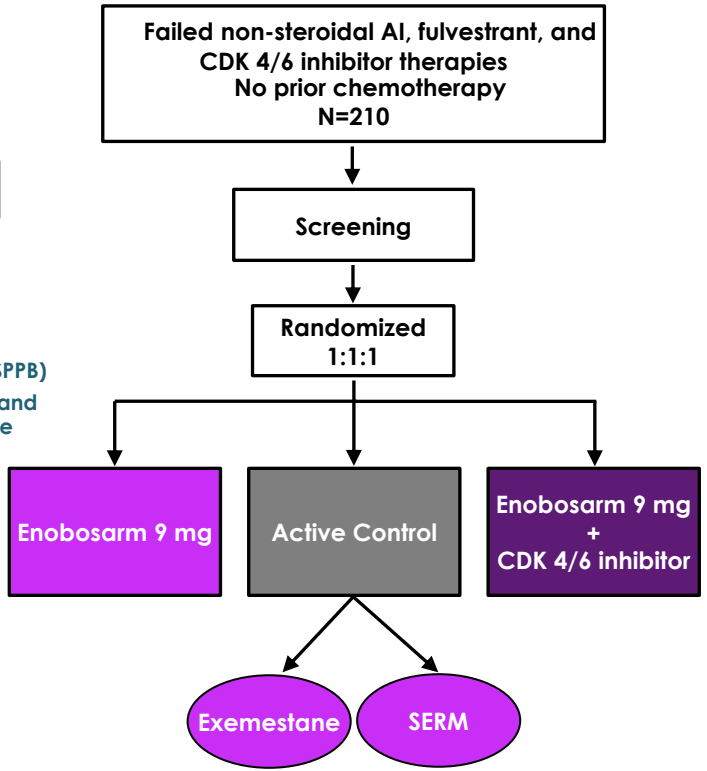
Secondary endpoints:

- Overall response rate (CR+PR)
- Change in Short Physical Performance Battery (SPPB)
- Change in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ)
- Duration of response
- Overall survival

ARTEST Assumptions

- Total sample size: 210 subjects 90% power alpha=0.05
- Active control group (exemestane or SERM): estimated mean rPFS = 3.5 months
- Enobosarm arm: estimated mean rPFS=7 months

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



Combination of pembrolizumab + enobosarm in AR+ 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

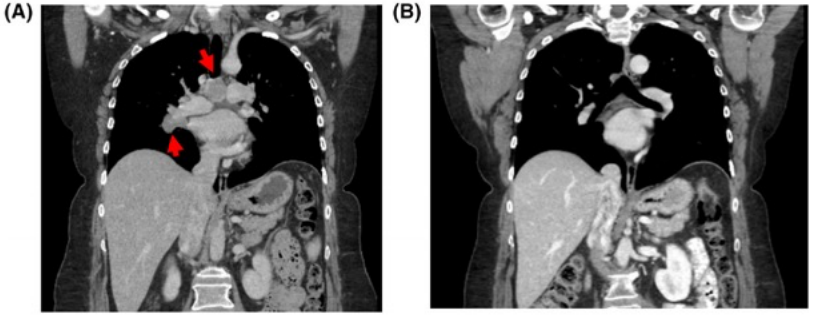


Figure 2. CT imaging of exceptional response. **(A):** Baseline CT on July 24, 2017, showed subcarinal and right hilar conglomerate lymph adenopathy (the red arrows pointing the target lesions). **(B):** The bulky subcarinal adenopathy and right hilar is no longer seen on August 24, 2018. Patient continues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

Enobosarm has strong global intellectual property protection

Licensed from the University of Tennessee Research Foundation in 2020

Composition of matter (molecule and polymorphs) issued or allowed patents

- 5 US latest expiry 2029 (with patent extension for NCE expiry 2034)
- 3 EU latest expiry 2028
- 5 Japanese latest expiry 2028
- 9 Composition of matter in other countries (not counting EU jurisdictions)
- 20 Polymorph in other countries (not counting ER jurisdictions)
- 2 patents pending

Method of use "Enobosarm for the treatment of breast cancer" issued or allowed patents

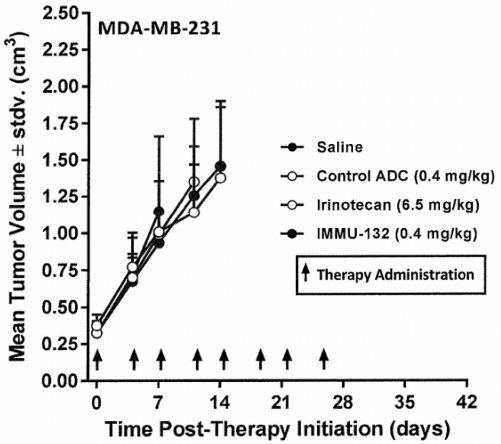
- 7 US latest expiry 2034
- 1 EU latest expiry 2033
- 3 Japanese latest expiry 2033
- 10 in other countries
- 8 patents pending

VERU-111

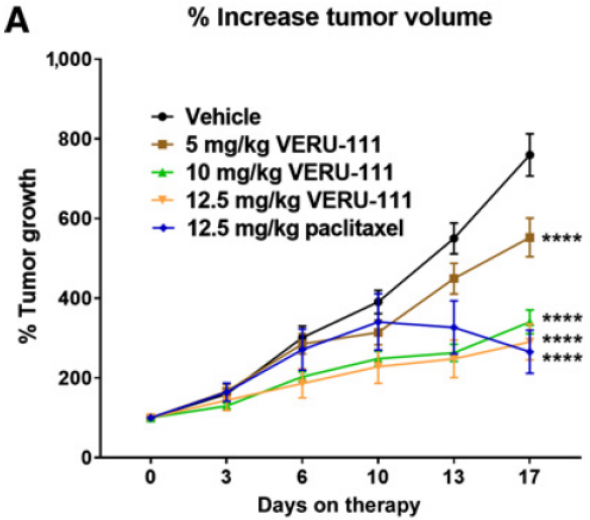
for the treatment of taxane resistant triple negative breast cancer

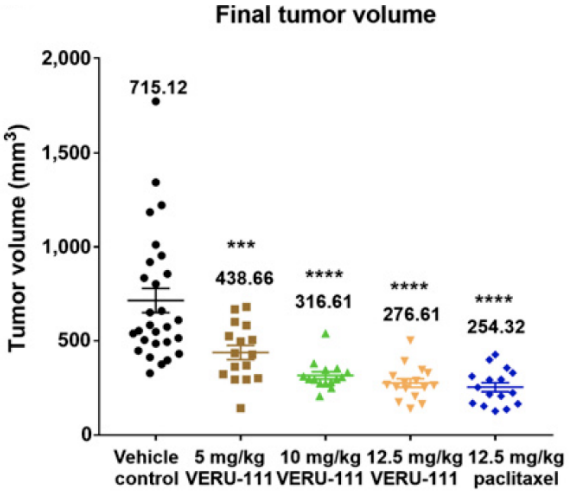
Comparison of IMMU-132 (TRODELVY) and VERU-111 in MDA-MB-231 triple negative breast cancer animal model

TRODELVY (IMMU-132) has no activity in MDA-MB-231 TNBC Animal Model[1]



Oral VERU-111 has antitumor activity in MDA-MB-231 TNBC Animal Model[2]

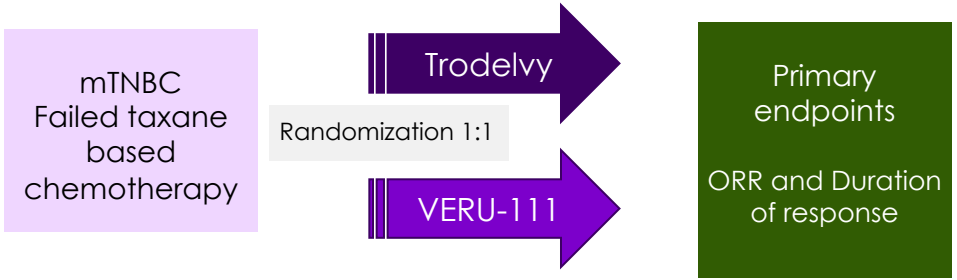




[1]US patent US2018/0271992 A1 | [2] Deng et al, Mol Can Therapeutics, 29:348-363, 2020

Phase 2b clinical study:
VERU-111 for taxane resistant triple negative breast cancer

Phase 2b pivotal taxane resistant triple negative breast cancer



Trial study design

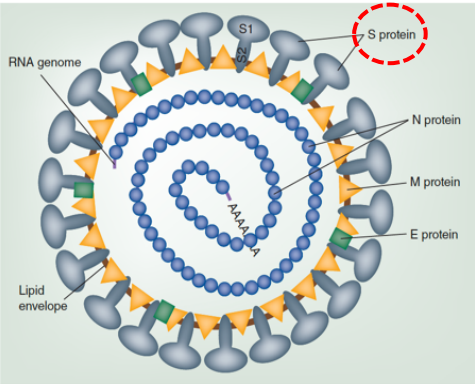
- Confirmed metastatic TNBC who failed taxane based chemotherapy
- Randomized open label study
  - VERU-111 versus TRODELVY
- 212 subjects
- Primary endpoint
  - ORR
  - Duration of response
- Other endpoints
  - rPFS
  - Safety
- If clinically meaningful, will seek accelerated approval

VERU-111
18mg

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

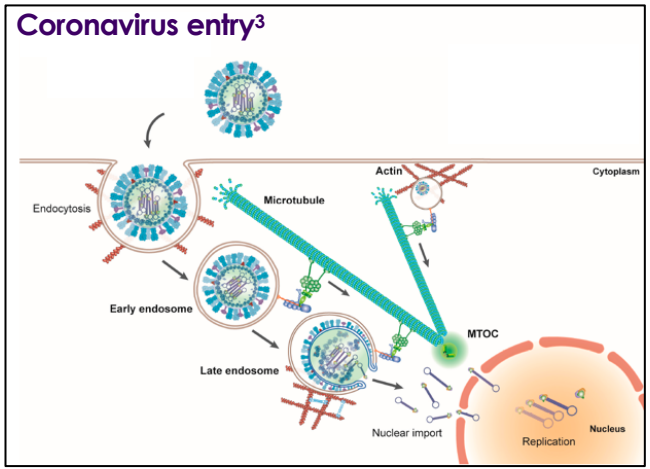
Coronavirus's spike (S) protein is the key structure that interacts with microtubules in the cytoskeleton during intracellular trafficking[4]

SARS-CoV-2 structure[4]

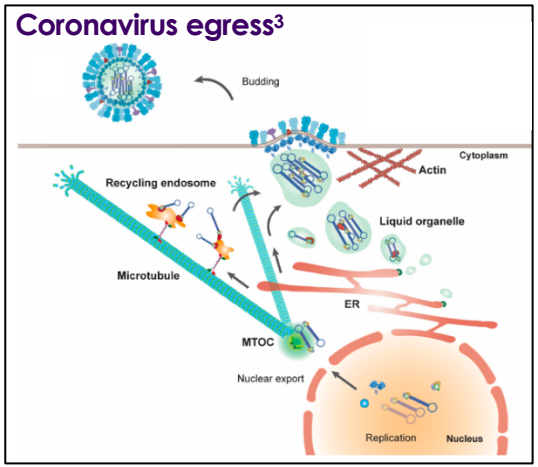


- **Virus's most critical task is to hijack the host's internal transportation system, the microtubules in the cytoskeleton[1,3]**
- **VERU-111 disrupts the microtubule trafficking system**
  - Antiviral
  - Anti-inflammatory

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

VERU-111: Phase 2 clinical trial design for COVID-19

Double-Blind, Placebo-Controlled, Phase 2 Study of VERU-111 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 VERU-111 and 20 Placebo groups)
- Hospitalized subjects with documented evidence of COVID-19 infection with 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

		VERU-111	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 VERU-111 18 mg

Endpoints - patients that received >1 dose of drug

Primary Endpoint	Placebo	VERU-111	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	VERU-111	Relative Reduction	p-value
Deaths (ITT)	6/20 (30%)	1/19 (5.3%)	82%	p=0.044
Treatment failures, i.e. death or respiratory failure at Day 29 in >60 years of age	4/8 (50%)	1/11 (9%)	82%	p=0.0456
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=0.0405
Mean days in ICU +/- SE	9.55±11.54 (n=20)	3.00±7.16 (n=18)	69%	p=0.0412

Endpoints – patients that received standard of care (remdesivir and/or dexamethasone)	Placebo	VERU-111	Relative Reduction	p-value
Days in ICU	8.83±13.07 (n=18)	1.43±3.96 (n=14)	84%	p=0.0240
Days on mechanical ventilation	6.00±10.57 (n=18)	0 (n=14)	100%	p=0.0427

Safety outcomes for VERU-111 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 VERU-111 in adverse events observed in the study

Any adverse event that occurred in ≥ 2 patients on study

Preferred Term	VERU-111 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

Next steps clinical development of VERU-111 for high risk COVID-19 patients

- **End of Phase 2 meeting with FDA February 2021**
  - FDA agrees that Phase 2 clinical findings suggest a clinically meaningful benefit for use of VERU-111 in hospitalized COVID-19 patients at high risk for ARDS
  - FDA agrees to advance VERU-111 into Phase 3 clinical study in hospitalized high risk COVID-19 patients to confirm the potential benefit and risk
  - Single, double-blind, placebo control Phase 3 clinical trial to support approval (full NDA approval or EUA)
- **Met with BARDA for possible funding in February 2021**
- **Veru has enough VERU-111 to supply Phase 3 clinical trial**

COVID-19 Phase 3 clinical development clinical trial will start in April 2021

Double-Blind, Placebo-Controlled, Phase 3 Study of VERU-111 for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Hospitalized Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)

- N=300 with a 2:1 randomization
- Dosing: daily dosing up to 21-days or until discharge from hospital
- Treatment arms: VERU-111 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 ≥5
- Primary endpoint: proportion of patients alive at Day 29 (mortality)
- Key secondary endpoints: Respiratory failure, days in ICU, days on mechanical ventilation, days in the hospital, and viral load

Sexual Health Division

NDA submitted 2/21 for TADFIN™ capsule (tadalafil 5mg + finasteride 5mg combo) to improve compliance & safety

Co-administration of CIALIS (tadalafil 5 mg) and PROSCAR (finasteride 5 mg) is currently approved for the initial treatment of symptoms of BPH for up to 26 weeks[1]

- Drug-drug interaction and co-administration studies are completed for combination indication[2]

Each component is approved for:

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

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

Pre-NDA meeting on Proprietary TADFIN™ capsule

- **Single dose randomized two period, crossover study in 33 healthy males over the age 45 years**
  - Process of getting 12 month stability data on commercial batches
- **Pre-NDA meeting held May 23, 2019**
  - NDA may be submitted after 12 months of stability data on manufactured/commercial drug batches
- **NDA submitted in February 2021**

Market Potential

US and global markets expected to be >$200 million through telemedicine and salesforce channels[3]

[1] Cialis (tadalafil) FDA Package Insert | [2]Casabé A et al. J Urol 191:727-733 2014 | [3]IQVIA Data (2018) Assumption: $120 per prescription

FC2® Female/internal Condom business revenues are growing

FC2 Female/Internal Condom is the only FDA approved female use product to prevent pregnancy and transmission of sexually transmitted infections

- 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]

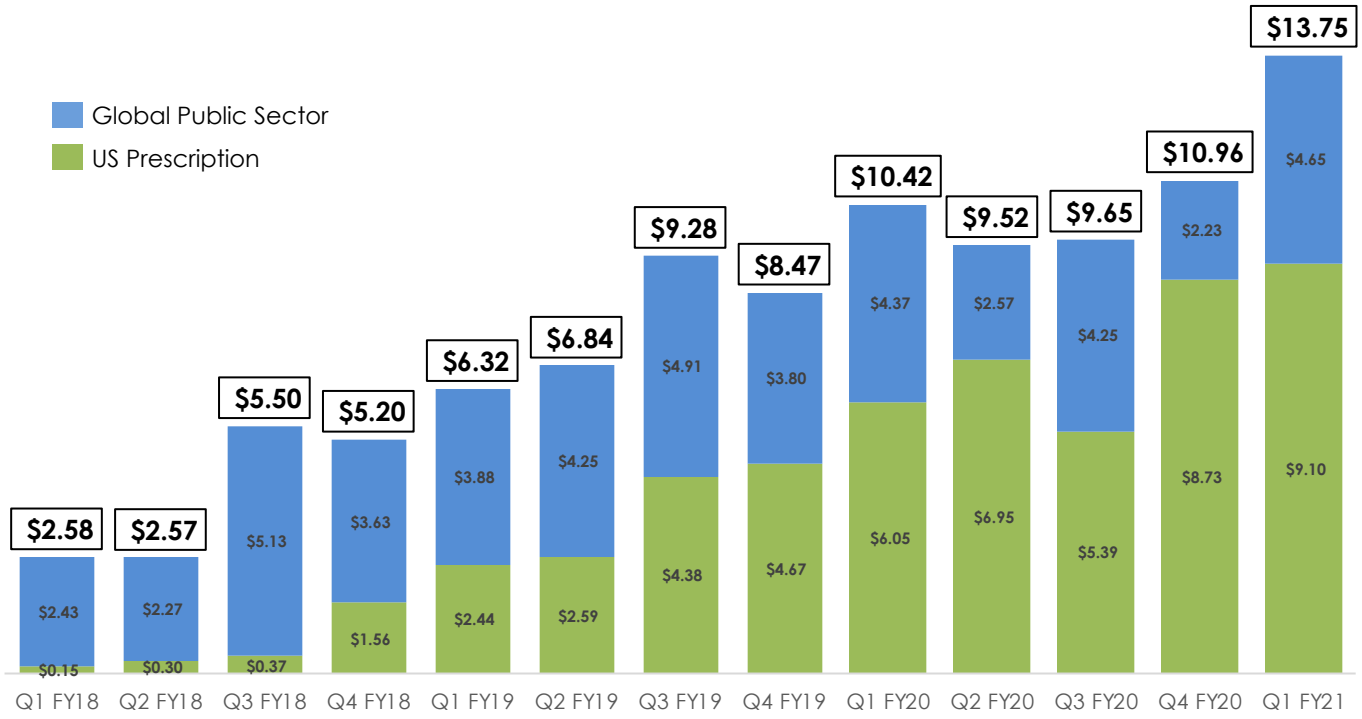
Rapidly growing US prescription business for high margin revenues

- Prescription business is growing via existing and anticipated new contracts with additional telemedicine partners

[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

FC2 global public sector & FC2 US prescription revenues (Millions USD)



FC2 Revenues

FY 2018: $ 15.9 mm
FY 2019: $ 30.9 mm
FY 2020: $ 40.6 mm

FC2 US Prescription 12-Pack Units Sold

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

Financial highlights

Results of Operations

FY 2020 Net Revenues	$ 42.6 mm
FY 2020 Gross Profit	$ 30.8 mm
FY 2020 Operating Loss	$ 14.7 mm
FY 2020 Adjusted Operating Loss[1]	$ 0.6 mm
Q1 FY 2021 Net Revenues	$ 14.6 mm
Q1 FY 2021 Gross Profit	$ 10.8 mm
Q1 FY 2021 Operating Income	$ 19.2 mm
Q1 FY 2021 Adjusted Operating Income[2]	$ 0.8 mm

Balance Sheet as of December 31, 2020

Cash	$ 30.9 mm
Receivables	$ 4.2 mm
PREBOOST Payment Due	$ 5.0 mm[4]
US/UK NOL carryforward	$ 41.7/$61.3mm
Common Shares Outstanding[3]	~ 71.9 mm

Record quarter for revenue growth from sexual health business $14.6 million with profitable operating income in Q1 FY 2021

PREBOOST sale for $20 million[4]

Veru closes public offering of $115 million in February 2021[5,6]

[1] Represents a non-GAAP financial measure calculated by subtracting a $14.1 mm non-cash impairment charge related to intangible assets from Operating Loss, a GAAP measure
[2] Represents a non-GAAP financial measure calculated by subtracting a $18.4 mm gain on PREBOOST sale from Operating Income, a GAAP measure
[3] An aggregate of 10.5 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 71.9 million common shares above
[4] 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
[5] Cash received from the public offering, net of underwriting discounts and commissions, was $108.1 million
[6] Veru issued 7,419,354 shares of common stock in the public offering

Drug candidate pipeline[1]

Oncology biopharmaceutical company focused on prostate cancer and breast cancer

Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prostate Cancer					
VERU-111 Oral cytoskeleton disruptor	Metastatic castration resistant & AR targeting agent resistant prostate cancer prior to IV chemotherapy	Preclinical Complete	Phase 1b Completed	Phase 2 Active & Enrolled	VERACITY Phase 3 Planned Q1 2021 200-300 Patients
VERU-100 GnRH antagonist 3 month sc depot	Advanced prostate cancer androgen deprivation therapy	Preclinical Complete	Phase 2 Planned 1H 2021		Phase 3 Planned 2H 2021 ~100 Patients
Breast Cancer					
Enobosarm Selective AR targeted agonist	AR+/ER+/HER2- advanced breast cancer endocrine therapy	Preclinical Complete	Twelve Phase 1 Studies Complete	Six Phase 2 Studies Complete	ARTEST Phase 3 Planned Q2 2021 ~240 Patients
VERU-111 Oral cytoskeleton disruptor	Taxane resistant triple negative breast cancer	Preclinical Complete	Phase 2b Planned Q4 2021 ~200 Patients		

[1] Certain information herein represents objectives of the Company. Whether these objectives will be met as anticipated or at all depends on a variety of factors outside of the Company's control.

Milestones

5 registration clinical studies expected to be initiated in calendar year 2021[1]

Prostate cancer

VERU-111

- Phase 2 trial: completely enrolled and ongoing metastatic castration & androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy-ongoing
- Planned Phase 3 trial: Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemo to start Q1 calendar year 2021

VERU-100

- Initiate Phase 2 trial in 1H 2021 and start Phase 3 registration study 2H 2021

Breast Cancer

Enobosarm

- Initiate Phase 3 clinical study enobosarm for AR+/ER+/HER2- breast cancer Q2 2021

VERU-111

- Initiate Phase 2b clinical trial taxane resistant triple negative breast cancer Q4 2021

COVID-19

VERU-111

- Initiate Phase 3 trial in 2Q of 2021

[1] Certain information herein represents objectives of the Company. Whether these objectives will be met as anticipated or at all depends on a variety of factors outside of the Company's control.