

# Oncology Biopharmaceutical Company Focused on Prostate Cancer and Breast Cancer

Veru Corporate Presentation – January 2021

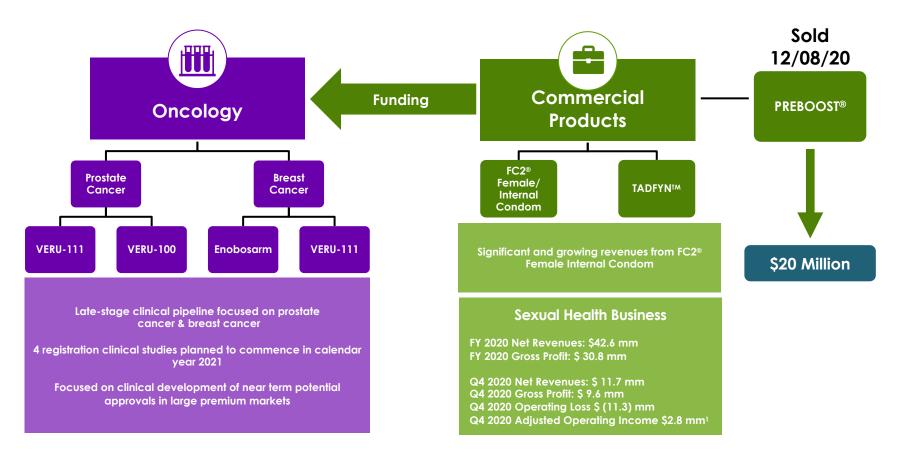
### Forward looking statements



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 forwardlooking 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 and costs for clinical studies and regulatory submissions, clinical study results, including potential benefits and absence of adverse events, and 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; 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; 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

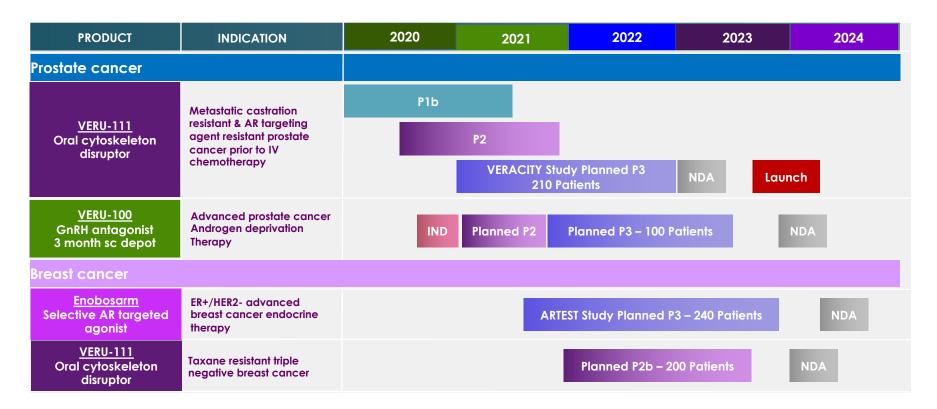




### **Pipeline & Milestones**

### Oncology biopharmaceutical company focused on prostate cancer and breast cancer Verl





### 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; Therap Area Lead, GTx; Prof & Dir of Urol Res, Johns Hopkins Univ SOM; Prof & Dir of Urol Res, U Pitt SOM

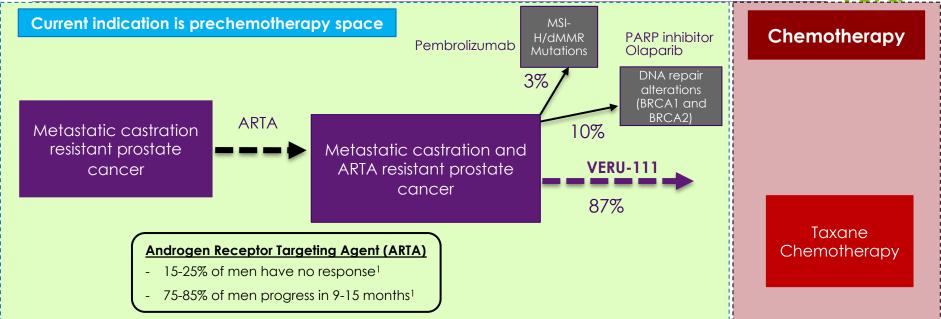
# Phil Kuhn, MBA EVP STRATEGY AND COMMERCIALIZATION

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



### 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

# **VERU-111**

For the treatment of metastatic castration resistant prostate cancer

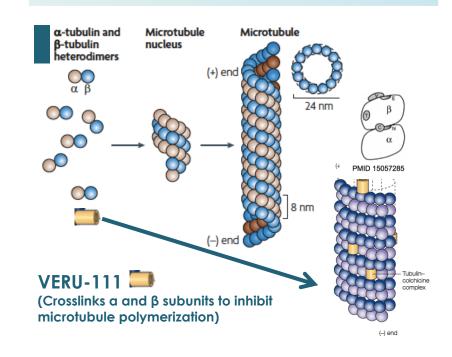
# VERU-111 targets the cytoskeleton: "Railroad tracks disruptor" Binds to a & β tubulin subunits of microtubules to disrupt cytoskeleton



### Preclinical Product profile 1-4, 6

- Binds to "colchicine binding site" to crosslink a and β tubulin subunits to inhibit microtubule polymerization (low nM concentration)
- 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<sup>5</sup>





Phase 1b 3+3 design Open label N = 39

Population: Metastatic castration and androgen receptor targeting agent resistant prostate cancer ± 1 taxane

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

- 7 US sites Johns Hopkins Kimmel Comprehensive Cancer Center (lead center)
  - 39 patients total enrolled across all sites
    - 1 prior AR targeting therapy mandatory
    - Up to one line of taxane-based chemotherapy for mCRPC was allowed
  - Two part dosing schedule using standard 3+3 dose escalation strategy
- Phase 1b
  - 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 Phase 1b Patient Demographics**



Characteristics	
Subjects	39
Age	74 yo median (61-92)
Gleason sum	8 (5-10)
Race	
Caucasian	28 (72%)
African American	8 (21%)
Hispanic	3 (8%)
ECOG score	
0	21 (54%)
1	16 (41%)
2	2 (8%)

Metastatic Disease	
Bone only	21 (55%)
LN only	6 (16%)
Bone and LN	8 (21%)
Visceral	1 (3%)
Visceral and bone	1 (3%)
Prior therapies	
Abiraterone	14 (36%)
Enzalutamide	8 (20%)
Abiraterone and enzalutamide	17 (44%)
Taxane	9 (23%)



# Safety results for Phase 1b clinical trial conducted in 7 US centers

- Dose escalated from 4.5mg to 81mg
- MTD was determined to be 72mg; 3 of 11 men had reversible Grade 3 diarrhea
- Recommended Phase 2 dose is 63mg for continuous 21-day cycle
  - No Grade 3 diarrhea reported at doses ≤ 63mg
  - No reports of neutropenia or neurotoxicity at doses ≤ 63mg
- Most common adverse events (mostly Grade 1 & 2)
  - Nausea
  - Vomiting
  - Diarrhea
  - Fatigue

### VERU-111 clinical development: Phase 1b efficacy (antitumor activity)



### 10 men reached at least four 21-day cycles of continuous dosing

- Disease (4 Bone; 3 LN; and 3 LN+Bone)
- Previous Tx- (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

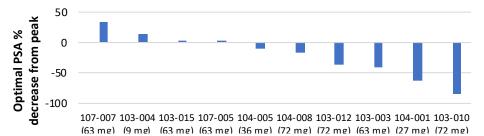
- 2 men had partial responses (PR) (two additional objective responses occurred in subjects who did not reach 4 cycles)
- 8 men had stable disease (SD)

### Median duration of treatment without progression

- >11 months (range 6.0-22+ months)
- 3/10 men still on study as of 1/21

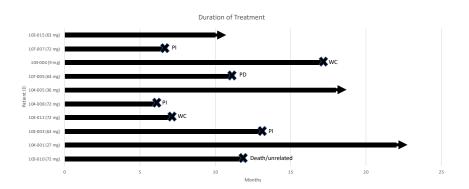
### Efficacy signals:

Ten men have reached ≥ 4 21-day cycles of continuous dosing



### Swimmers Plot

Patients that completed at least 4 21-day cycles



### VERU-111 Phase 1b clinical study: Case study patient 104-001



### Patient: 104-001

Gleason 9 mCRPC node only disease

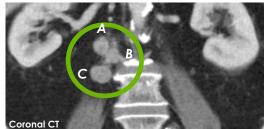
Prior treatment included

- sipuleucel-T
- enzalutamide
- abiraterone

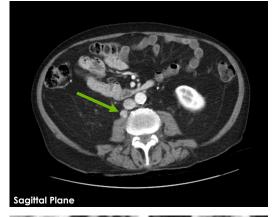
Still on study 21 months, -63% PSA from 21 day cycle initiation baseline

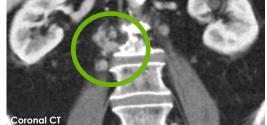
March 08, 2019: Screening CT scan RP LN 1.7cm X 1.5cm (measurable target lesion)





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







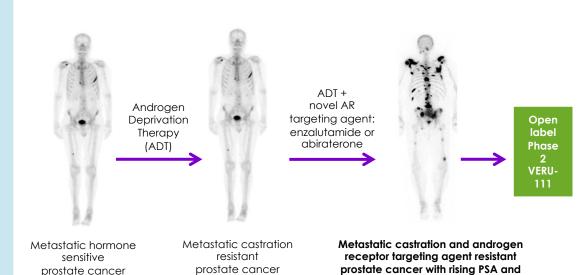
### VERU-111 appears to be well tolerated in the Phase 1b portion of the study

- 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 Phase 2 clinical study ongoing and completed enrollment of $\approx$ 40 men in September 2020



- Conducted in 14 US clinical centers
- Population: Men who have metastatic castration resistant prostate cancer and who have also become resistant to an androgen receptor targeting agent (ARTA), but prior to IV chemotherapy
- Completed enrollment in September 2020-41 subjects
- Trial design: Open label
  - Start with 63mg/day, continuous daily dosing
  - If unacceptable toxicity is observed, reduce dose to 54mg/day continuous daily dosing
- Primary endpoint: rPFS



tumor progression

### VERU-111 clinical development plan: Pivotal Phase 3 clinical trial design following FDA input – initiating 1Q 2021



### **VERACITY Phase 3 trial design**

#### Open label

VERU-111 63mg daily oral continuous dosing for 21day cycles versus an alternative androgen receptor targeting agent

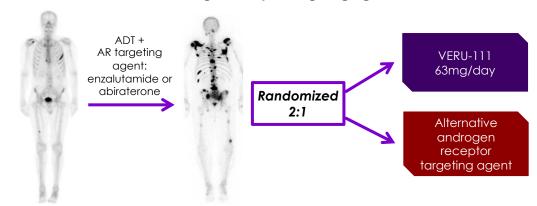
#### Efficacy endpoints

- 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- 9 months for VERU-111 vs 5 months\* for Alternative AR targeting agent
- Sample size 210 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 with rising PSA and tumor progression

\*Based on Olaparib study<sup>1</sup> and CARD study<sup>2</sup> 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  $\mid$   $^{2}$  de Wit R et al. NEJM 381:2506-18 2019

### VERU-111 Phase 1b clinical development: Efficacy Analysis at recommended Phase 2 dose of 63mg



### Patient characteristics:

- Pre-taxane
- Treated with at least one dose of 63 mg per day or higher
- In all patients (n=16):
  - Median duration of treatment without progression = 5.8+ months (range 0-21+ months)
- Excluding patients that discontinued due to AE (n=11):
  - Median duration of treatment without progression = 9.8+ months (range 2-21+ months)
- Patients that remain on study (n=7):
  - Median duration of treatment without progression of 10.5+ months (range = 4.2-21+ months)



# 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



\$4.9 billion global annual sales in Japan, the Americas, EMEA, Asia and Oceania <sup>2,4</sup>

<sup>4</sup>Astellas Pharma Inc. 2019 Annual Report

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

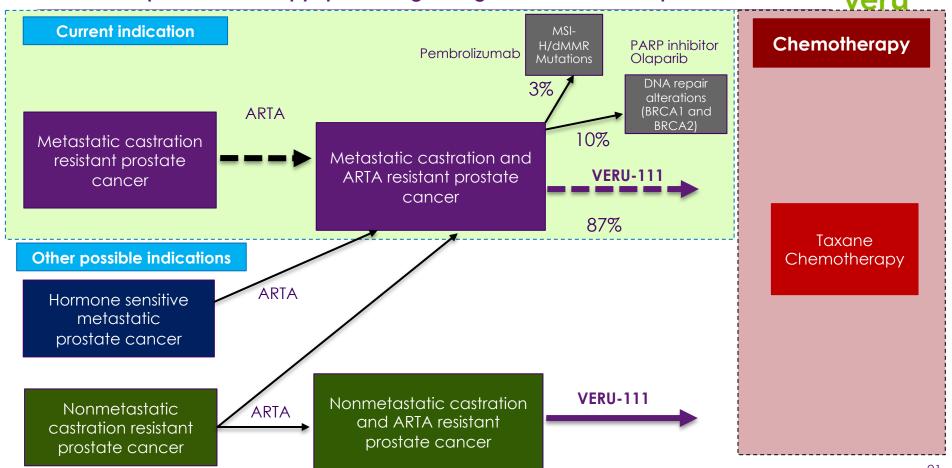


- Triple negative breast cancer (taxane resistant)<sup>1</sup>
- Cervical cancer (taxane resistant)<sup>2</sup>
- Lung cancer (taxane resistant)<sup>3</sup>
- Ovarian cancer (taxane resistant)<sup>4</sup>
- Uterine cancer<sup>5</sup>
- Pancreatic cancer<sup>6</sup>
- Melanoma<sup>7</sup>
- Human promyelocytic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

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

### VERU-111 prostate cancer treatment paradigm:

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



### 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
- 7 in other countries (not counting EU jurisdictions)
- 1 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)
- 14 patents pending

#### Other methods of use VERU-111

- 2 US latest expiry 2034
- 6 ex-US latest expiry 2034
- 23 patents pending (expected expiries of 2030-2040)

# **VERU-100**

For the treatment of advanced prostate cancer

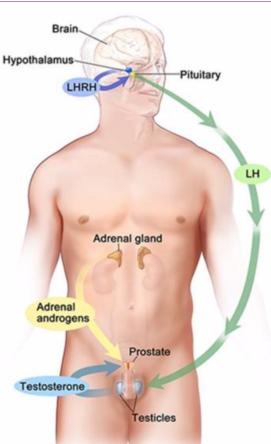
### Quest for a better androgen deprivation therapy Current commercial limitations



### 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<sup>1</sup>
- Up to 17% of men do not achieve castration<sup>1</sup>
- 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

<sup>&</sup>lt;sup>1</sup> 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<sup>2</sup>

- Novel proprietary GnRH antagonist decapeptide formulation<sup>1</sup>
- 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

# 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)<sup>1</sup>
- 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%

# VERU-100 for the treatment of advanced prostate cancer Clinical development program as agreed upon by FDA



- Nonclinical studies to support Phase 2 and Phase 3 completed
- Clinical supply GMP manufacturing completing

### Single Phase 2 Scheduled for 1H 2021 n=35

Open label multicenter dose finding study in men with advanced prostate cancer

### Single registration Phase 3 Scheduled for 2H 2021 n=100

Open label multicenter registration study in men with advanced prostate cancer

### ADT market for advanced prostate cancer is well established



Total global sales of ADT drugs in 2018 was \$2.6 billion (IQVIA 2018)

VERU-100 could have peak sales of \$750 million with 28% global market share

Year	Total	
	US	Ex-US
2018	\$1,150M <sup>1</sup>	\$1,484 M <sup>1</sup>

### Intellectual property

Formulation patents expire in 2038





# Enobosarm

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

### Endocrine therapies that target estrogen receptor axis 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) nonsteroidal Al
- ARIMIDEX® (anastrozole) and FEMARA ®(letrozole) steroidal Als

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

Resistance to endocrine therapies eventually occurs which requires alternative treatment approaches including chemotherapy<sup>1, 2</sup>

# A selective AR agonist targeting the androgen receptor may be the next important class of endocrine therapy in breast cancer

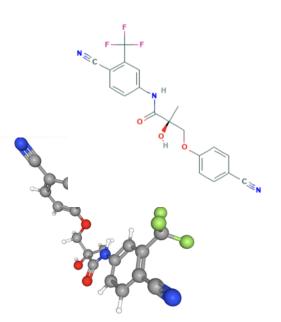


- Historically, androgens have been used in breast cancer treatment but their virilizing effects, increase in hematocrit, and liver toxicity have limited their clinical application
- AR is the most abundantly expressed sex hormone receptor in breast cancers
  - 70-95% of breast cancers are AR+<sup>2-6</sup>
  - High concordance rate (70%) between AR positivity in primary and metastasis<sup>7</sup>
  - In normal and cancerous breast tissue, androgens inhibit cellular proliferation 1-3
  - AR positivity is an independent predictor of beneficial breast cancer outcome<sup>2,3,5,6</sup>
- The development of novel strategies to target the AR as a treatment for women with ER-positive breast cancer that have become resistant to drugs that target the ER is warranted<sup>3</sup>

# Enobosarm, first-in-class, novel oral selective AR targeted treatment for AR+ER+ advanced breast cancer



- Enobosarm is a non-steroidal, selective androgen receptor agonist<sup>1, 2</sup>
  - Once-a-day oral daily dosing
  - Selectivity for 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<sup>3,4,5</sup>
  - Anabolic on muscle to improve muscle mass and physical function<sup>2,6</sup>
  - 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
- Extensive clinical and safety database
- Enobosarm inhibits AR+ER+ breast cancer in cell and patient-derived xenograft models of endocrine sensitive and resistant disease<sup>7</sup>



Chemical structure of Enobosarm

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

# Enobosarm, first-in-class, novel oral selective AR targeted treatment for AR+ER+ advanced breast cancer has extensive clinical experience



- 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
  - ¹City of Hope Investigator Initiated Efficacy of 18 mg Enobosarm in combination with pembrolizumab in AR+ TNBC
  - <sup>2</sup>Emerald –A window of opportunity study to assess the biological effects in AR+/ER+ early breast cancer
  - 3Australia 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

### Phase 2 clinical trial (G200801): AR+ER+ advanced breast cancer



### Phase 2 Trial design (G200801)

- Single arm Phase 2 proof of concept study with 9mg daily dose
- Efficacy primary endpoint- To assess the clinical benefit rate (CBR) (CR+ PR + SD) in subjects with AR+ ER+ advanced breast cancer treated with Enobosarm at 24 weeks
- Evaluate safety
- Assess biomarkers- serum PSA, bone turnover markers, and CA 27-29

### Patient population - 22 enrolled

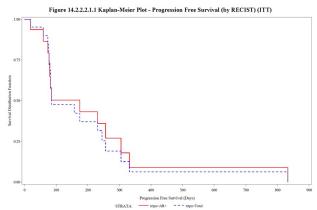
- AR+ ER+ metastatic breast cancer
- Previously responded to adjuvant Tx for ≥3 years, or most recent hormone Tx for metastatic disease ≥ 6 months
- Heavily pretreated 68% had previous chemotherapy and average previous lines of endocrine therapy was 3 (range 1-5)
- 80% (17 of 22) subjects were confirmed AR+

### Phase 2 clinical trial (G200801): AR+ER+ metastatic breast cancer

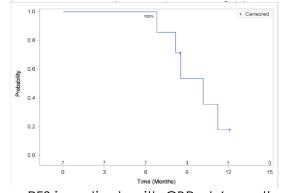


### **Efficacy results**

- Median time on drug 86 days (2-363 days)
- Clinical benefit rate at 6 months =35.3% (90% CI:16.6%,58%)
  - One patient had decrease in lung lesion from 25mm to 17mm on day 84, but also had evidence of liver progression
- Progression free probability was 57.7% at Day 84 and 50.5% at Day 168 (5.6 months)
  - 6 month Kaplan-Meier estimate for PFS was 43.8%
- Median rPFS in subjects that had a CBR (duration of response)= 11 months



PFS in all patients



PFS in patients with CBR at 6 months

### Phase 2 clinical trial (G200801): AR+/ER+ metastatic breast cancer



### Safety

- Enobosarm was well tolerated
- 21 subjects experienced 87 mostly mild to moderate intensity treatment-related AEs
  - 2 AEs (fatigue and generalized weakness and bone pain)
  - 2 AR+ subjects had SAEs of severe bone pain
- 2 subjects had elevated ALT and AST levels
  - Only one ALT elevation exceeded 3x ULN
  - No dose was changed
  - In both subjects, ALT and AST levels recovered to normal while on drug

### Study conclusions

- First study of Enobosarm 9mg oral daily dose as AR targeted therapy in a heavily pretreated population of women with AR+ ER+ metastatic breast cancer
  - Demonstrated clinical benefit
  - Safe and well tolerated with no significant virilizing effects, no liver toxicity, and no polycythemia

## Phase 2 clinical trial (G200802): AR+/ER+ metastatic breast cancer presented at San Antonio Breast Cancer Symposium December 2020

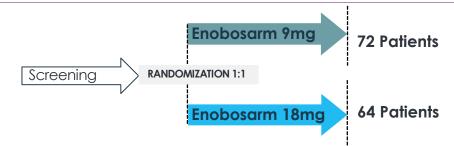


Efficacy and safety of Enobosarm, a selective androgen receptor agonist, to target AR in women with advanced AR+/ER+ breast cancer – final results from an international Phase 2 randomized study (G200802)

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

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

## Phase 2 clinical trial (G200802): AR+ER+ metastatic breast cancer who previously responded to endocrine treatment, heavily pretreated population



### 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)
- Assess biomarkers- serum PSA, CTCs

### Patient population- 136 postmenopausal 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 evaluable
- Previously responded to adjuvant endocrine Tx for ≥3 years, or most recent endocrine Tx for metastatic disease ≥ 6 months

### Phase 2 clinical trial (G200802): baseline 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)	
Central 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	

### Phase 2 clinical trial (G200802): Efficacy summary

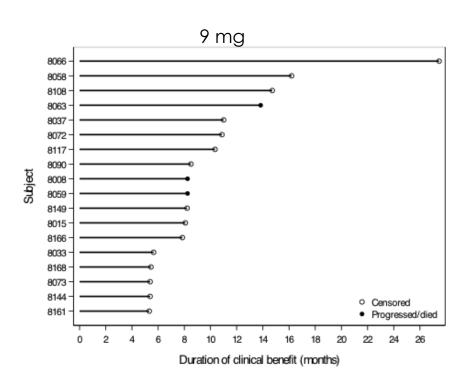


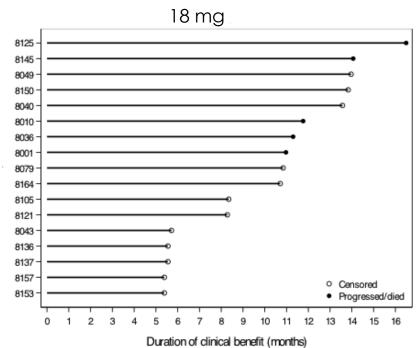
### **Evaluable Population**

	9mg cohort	18mg cohort
Number of evaluable patients	50	52
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 clinical benefit in patients with clinical benefit at week 24







### Phase 2 clinical trial (G200802): best overall tumor responses



- Efficacy results- RECIST 1.1 best overall tumor responses by central read at any time during the study in patients with measurable disease at baseline
  - 9 mg cohort (n=34)
    - 1 (2.9%) complete response
    - 11 (32.4%) partial response
    - 35.3% (12/34)
  - 18 mg cohort (n=39)
    - 3 (7.7%) complete response
    - 7 (17.9%) partial response
    - 25.6% (10/39)

### 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) and 7.3 (16.67) (p=0.011) 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



### Enobosarm was well tolerated; majority of events were Grade 1 and 2 Summary of safety (all patients - ITT)

	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): AR+ER+ metastatic breast cancer Conclusions- AR targeted therapy shows efficacy in ER resistant 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
  - CBR at 6 months of 32% (9 mg) and 29% (18 mg)
  - Best overall tumor response of 35.3% (9 mg)and 25.6% (18 mg)
  - Median progression free survival (PFS) of 5.6+ (9 mg) and 4.2 (18 mg) months
    - Imbalance in patients that presented with Stage 4 tumor stage breast cancer (12% 9mg and 26.9% 18mg)
- Quality of life measurements demonstrated overall improvement including mobility, anxiety/depression and pain
- Enobosarm appears safe and well tolerated without virilizing effects, increase in hematocrit, or liver toxicity
  - Most adverse events are grade 1 and 2
- The 9 mg dose 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 targeting the AR in metastatic breast cancer



### G200801 and G200802 efficacy summary for 9mg

	Phase 2 801 (n=22)	Phase 2 802 (n=50)
CBR at 6 months	35.3% (90% Cl: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<sup>1</sup>

- 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 2 802 study

### Reached agreement with FDA to advance Enobosarm, AR targeting endocrine therapy, to pivotal Phase 3 open label, randomized clinical trial



Indication- treatment of ER+/HER2- advanced breast cancer in subjects who have failed a nonsteroidal aromatase inhibitor(NSAI), fulvestrant, and CDK4/6 inhibitor endocrine therapy

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 in metastatic advanced ER+/HER2- breast cancer

#### **Patient population**

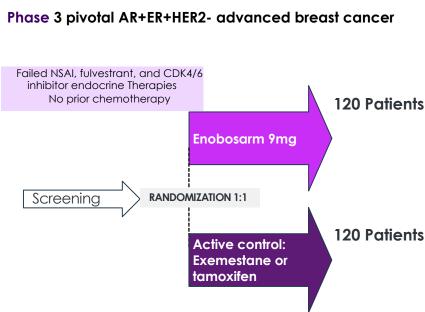
- Subjects with ER+ metastatic or recurrent locally advanced breast cancer, not amenable to curative treatment by surgery or radiotherapy, with objective evidence of disease progression
- Must have had received a nonsteroidal AI inhibitor, fulvestrant, and CDK 4/6 inhibitor for metastatic disease
  - 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

#### **Endpoints**

- Primary endpoint- radiographic progression free survival (rPFS)
- Secondary endpoints-
  - Clinical benefit rate at 6 month (CR+PR+SD)
  - 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

#### **Assumptions**

- Total sample size: 240 subjects 90% power alpha=0.05
- Active control group (exemestane or tamoxifen): estimated mean rPFS = 3.5 months
- Enobosarm arm: estimated mean rPFS=7 months



Primary endpoint- radiographic progression free survival (rPFS) of subjects receiving 9mg Enobosarm versus active-control in subjects ER+ breast cancer

After the patients in the exemestane or tamoxifen treatment arm fail (show rPFS), they may cross over to Enobosarm 9mg

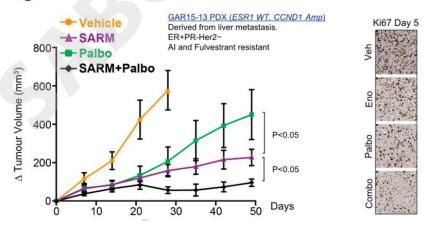
### Role of enobosarm and CDK4/6 inhibitors in estrogen receptor targeting agent resistant metastatic breast cancer- preclinical models (Patient derived xenografts)<sup>1,2</sup>



- CDK4/6 inhibitor inhibits growth of ER targeting agent resistant breast cancer<sup>1,2</sup>
- Enobosarm monotherapy has greater inhibition of ER targeting agent resistant breast cancer than a CDK4/6 inhibitor<sup>1,2</sup>
- Enobosarm + CDK4/6 inhibitor had greater inhibition of ER targeting agent resistant breast cancer than either glone<sup>1,2</sup>
- Enobosarm suppressed breast cancer cells that are resistant to both CDK 4/6 inhibitor and estrogen receptor targeting agent<sup>2</sup>
- Enobosarm and CDK4/6 inhibitor further suppressed breast cancer cells that are resistant to both CDK4/6 inhibitor and estrogen receptor targeting agent –enobosarm restores CDK 4/6 sensitivity<sup>2</sup>

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

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



SARM= enobosarm and Palbo=CDK4/6 inhibitor

Lim E et al. 2019 SABCS presentation | 2 Hickey TE et al. Nature Medicine 2020 (IN PRESS)

### 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
- 10 in other countries (not counting EU jurisdictions)
- 3 patents pending

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

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

### Market opportunity:

### Current annual market for an endocrine treatments for advanced breast cancer drugs



- Injectable –FASLODEX® (fulvestrant) revenues
  - Global \$1 billion market in 20181
  - US \$537 million market in 2018<sup>1</sup>

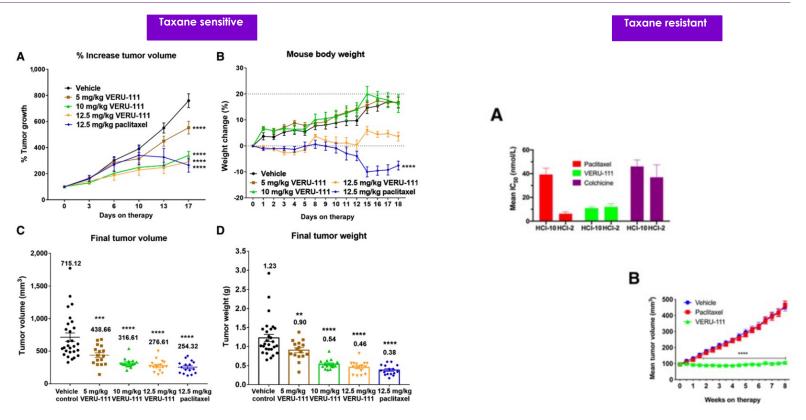
- Oral agent CDK4/6 inhibitors in combination with endocrine therapies (Al or fulvestrant) 2019 global revenues total \$6 billion<sup>2</sup>
  - IBRANCE® (palbociclib)-\$4.96 billion
  - VERZENIO® (abemaciclib)-\$0.579 billion
  - KISQALI® (ricociclib)-\$0.480 billion

# VERU-111

for the treatment of taxane resistant triple negative breast cancer

## Preclinical studies in TNBC MDA-MB-231 and taxane resistant HCl-10-Luc2 TNBC xenografts: VERU-111 for taxane resistant triple negative breast cancer<sup>1</sup>



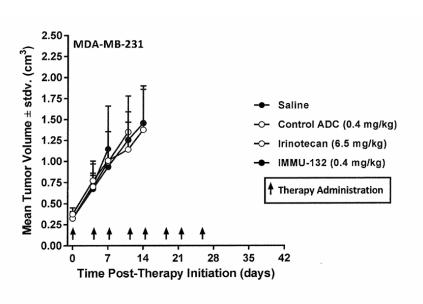


<sup>&</sup>lt;sup>1</sup> Deng S et al. Mol Cancer Ther 19:348-63, 2020

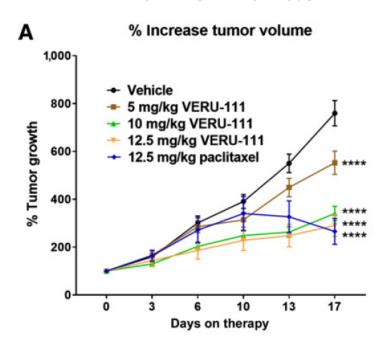
## Comparison of IMMU-132 (TRODELVY) and VERU-111 in MDA-MB-231 triple negative breast cancer animal model



### TRODELVY (IMMU-132) has no activity in MDA-MB-231 TNBC Animal Model<sup>1</sup>



### Oral VERU-111 has antitumor activity in MDA-MB-231 TNBC Animal Model<sup>2</sup>



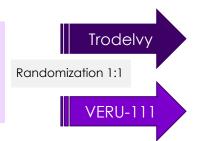
<sup>&</sup>lt;sup>1</sup>US patent US2018/0271992 A1 | <sup>2</sup> Deng et al, Mol Can Therapeutics, 29:348-363, 2020

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



### Phase 2b pivotal taxane resistant triple negative breast cancer

mTNBC Failed taxane based chemotherapy



Primary endpoints ORR and Duration of response

### Trial study design

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



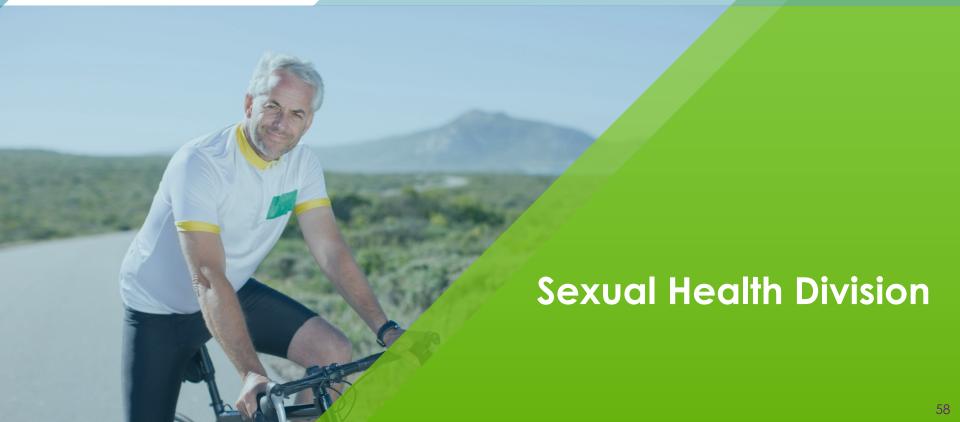
### VERU-111 as a potential treatment for SARS-CoV-2: Clinical development plan



# 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)<sup>1</sup>

- Approximately 40 subjects will be 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 will be enrolled.
- Subjects will receive study drug for up to 21 days.
- The primary efficacy endpoint of the study will be the proportion of patients that are alive and without respiratory failure at Day 29.
- Secondary endpoints include measured improvements on the WHO Disease Severity Scale (8 point ordinal scale)<sup>2</sup>
- Enrollment completed December 2020





## TADFYN<sup>TM</sup> capsule (tadalafil 5mg + finasteride 5mg combo) to improve compliance & safety









### **TADFYN**<sup>™</sup>

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<sup>1</sup>

 Drug-drug interaction and co-administration studies are completed for combination indication<sup>2</sup>

#### 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) dailysymptoms of male pattern hair loss

The solution: proprietary TADFYN<sup>TM</sup> tablet formulation: Increases convenience and compliance

## Pre-NDA meeting on Proprietary TADFYN<sup>TM</sup> 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 expected to be submitted in Q1 2021

#### **Market Potential**

US and global markets expected to be >\$200 million through telemedicine and salesforce channels<sup>3</sup>

### 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<sup>1</sup>

## Rapidly growing US prescription business for high margin revenues

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



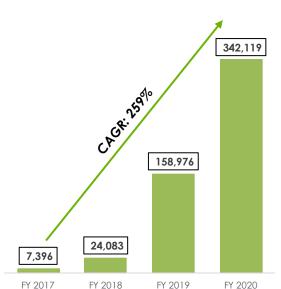
### Financial highlights: Prescription sales (12 pack units) & FC2 trends



FC2 Prescription Quarterly Sales
12-Pack Units

FC2 Prescription Yearly Sales
12-Pack Units





#### **Commercial Products**



## 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 <sup>3</sup>	\$ 0.6 mm
Q4 2020 Net Revenues	\$11.7 mm
Q4 2020 Gross Profit	\$ 9.6 mm
Q4 2020 Operating Loss	\$(11.3) mm
Q4 2020 Adjusted Operating Income <sup>3</sup>	\$ 2.8 mm

### Balance Sheet as of September 30, 2020

Cash	\$ 13.6 mm
PREBOOST Sale (12/08/20) <sup>2</sup>	\$ 20.0 mm
Receivables	\$ 5.2 mm
US/UK NOL carryforward	\$ 41.7/\$61.3mm
Common Shares Outstanding <sup>1</sup>	~ 69.9 mm

<sup>&</sup>lt;sup>1</sup>An aggregate of 11.0 million stock options, stock appreciation rights, and warrants are outstanding and are, or could potentially be, dilutive in excess of the 69.9 million common shares above



Record year for revenue growth from sexual health business \$42.6 million with profitable operating income in Q4 FY  $2020^{3}$ 



**PREBOOST** sale for \$20 million<sup>2</sup>



**Expecting robust and growing** revenues from FC2 in FY2021



Company expects to have sufficient resources to fund clinical development of all the currently planned oncology drug programs without the need for a new equity financing through end of FY 2022

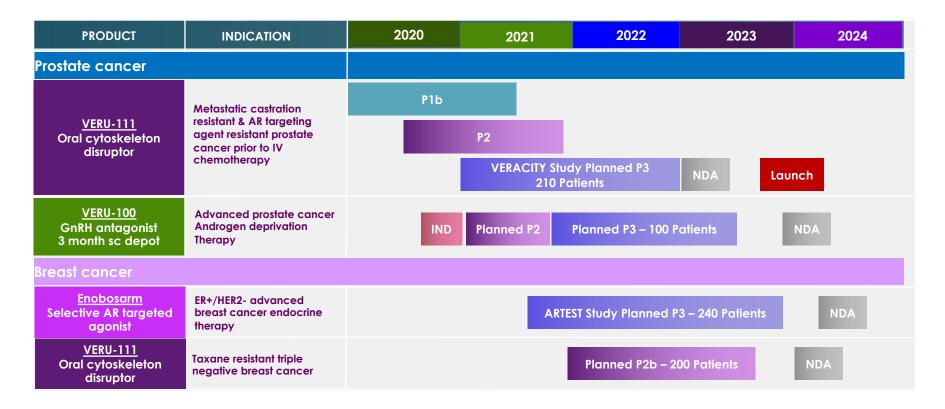
<sup>&</sup>lt;sup>2</sup> PREBOOST sale is \$15 million in cash and \$2.5 million in receivables at 12 months and \$2.5 million in receivables at 18 months

<sup>&</sup>lt;sup>3</sup> Excludes the effect of a \$14.1 mm non-cash impairment charge related to intangible assets

### **Pipeline & Milestones**

### Oncology biopharmaceutical company focused on prostate cancer and breast cancer Verl





### Veru projected milestones



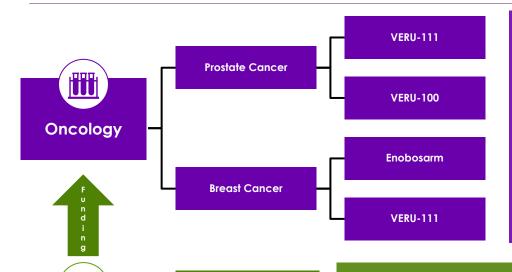
PRODUCT	INDICATION	2019	2020	2021	2022	2023
SEXUAL HEALTH DIVISION*						
TADFYN <sup>TM</sup> (tadalafil/finasteride)	ВРН	ВЕ		NDA US launch	l	
THE FEMALE HEALTH COMPANY DIVISION						
FC2	Dual birth control & STI prevention			Marketed		

Represent Management's current expectations and are not a guarantee of future results.

<sup>\*</sup>Tamsulosin DRS granules and XR capsules and Solifenacin granules development programs are currently on hold

#### Veru - FY 2021





FC2® Female/

Internal Condom

**TADFYN**<sup>TM</sup>

**PREBOOST®** 

SOLD - 12/8/20

\$20 million

### 4 registration clinical studies expected to be initiated in calendar year 2021

#### **Prostate Cancer**

- VERU-111: Phase 2 trial: completely enrolled and ongoing metastatic castration & androgen receptor targeting agent resistant prostate cancer prior to IV chemo
- VERU-111: Planned Phase 3 trial: Metastatic castration & androgen receptor targeting agent resistant prostate cancer prior to IV chemo to start Q1 calendar year 2021
- **VERU-100**: Initiate Phase 2 trial in the early 2021 and start Phase 3 registration study 2nd half 2021

#### **Breast Cancer**

- **Enobosarm**: Initiate Phase 3 clinical study enobosarm 3rd line ER+HER2-breast cancer Q2 2021
- VERU-111: Initiate Phase 2b clinical trial taxane resistant triple negative breast cancer Q3 2021

#### **Sexual Health Business Growing**

Sales of commercial legacy product will continue to deliver strong sales revenue to support investment in the development of clinical cancer drugs

- PREBOOST: Sold to Roman Health Ventures for \$20 mm<sup>1</sup>
- **FC2:** Increase sales in global public sector and US prescription business
- TADFYN: Target submission for BPH NDA early 2021 with launch expected 2nd half 2021

Company expects to have sufficient resources to fund clinical development of all the currently planned oncology drug programs without the need for a new equity financing through end of FY 2022

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

Sold

Commercial

**Products**