Veru Inc.
Nasdaq:VERU

Biopharmaceutical Company Focused on Infectious Disease and Oncology

Veru Corporate Presentation
Oppenheimer 33rd Annual Healthcare Conference
March 13th – 17th, 2023

Forward looking statements

The statements in this presentation that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding: whether and when the Company will submit a new EUA application, or receive an emergency use authorization or any approval from FDA or from any regulatory authority outside the U.S., for sabizabulin for certain COVID-19 patients; whether the protocol for any proposed confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients will meet its proposed primary or secondary endpoints; the proposed timing, size and scope of any such Phase 3 study; whether any potential planned interim analyses of such Phase 3 study will show sufficient efficacy and safety and whether any such interim results would be sufficient to support stopping the study early and submitting a new EUA or an NDA on any accelerated timeline; when the Company expects to disclose the details of the design and timing of this potential Phase 3 confirmatory study; whether the FDA will accept any results of such trial as sufficient for a new EUA or an NDA submission and, if any such application is submitted, whether the FDA will ultimately authorize or approve such application; how long the FDA will be able to continue to issue EUAs under its current emergency authorization under the U.S. Department of Health and Human Services; whether the current mortality rate of COVID-19 in the U.S. will continue, increase or decrease; whether the market for COVID-19 treatments will be sufficient to support commercialization or continued development; whether sabizabulin will be a potentially life-saving drug for COVID-19 patients in the U.S. or elsewhere in the world; the degree to which the FDA continues to work with the Company to develop sabizabulin; the results or consequences and the expected timing of the Company's efforts to avail itself of the FDA's formal dispute resolution process regarding the FDA's recent declination of an EUA for sabizabulin; the design, timing, enrollment and potential efficacy demonstrated by a new trial of sabizabulin in influenza patients at high risk of ARDS; whether the FDA or Company's clinical trial partner, Eli Lilly & Company, will agree with the plans to combine the ARTEST and ENABLAR-2 Phase 3 studies; the expected time for enrollment and data readout for the new planned ENABLAR-2 study; whether and when the Company will resume development of the Veru-100 and zuclomiphene assets; whether the current and future clinical development efforts of the Company and any of their results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company's other drug candidates; whether the drug candidates will be approved for the targeted line of therapy; whether ENTADFI will be commercialized successfully, the Company will grow sales of ENTADFI or the Company will be able to successful partner with any other entity to grow sales of ENTADFI; whether the telemedicine customers for FC2 will return to historical ordering patterns or increase their purchases of FC2 at all; whether the Company will be able to raise money successfully and in sufficient amounts in the equity markets, and whether the Company's current cash will be sufficient to fund its planned or expected operations. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company's product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA or other regulatory authorities and any determinations made by the FDA or any other regulatory authority, including the risk that the Company may not be able to obtain an EUA from the FDA or similar authorizations from other regulatory authorities on a timely basis or at all; any agreements or positions taken by the FDA in a pre-EUA meeting which may not bind the FDA or prevent it from later taking a different position, asking for more data or delaying or denying the application; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company lacks experience in scaling up or commercializing a drug product and may not be able to successfully commercialize sabizabulin as a COVID-19 treatment; the Company may be unable to manufacture sabizabulin as a COVID-19 treatment in sufficient quantities or at sufficient yields; the risk that the Company is unable to obtain favorable pricing for sabizabulin as a COVID-19 treatment in the U.S. or elsewhere or is unable to obtain reimbursement from governmental or commercial health insurance payors; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; the Company's ability to protect and enforce its intellectual property; the potential 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; 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; the concentration of accounts receivable with our largest customers and the collection of those receivables; 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; 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 from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the fiscal year ended September 30, 2022 and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

Biopharmaceutical company
Focus on infectious disease and oncology with a sexual health division (UREV)

Veru
Drug Pipeline

Sabizabulin

Infectious disease

- COVID-19 ARDS
- Influenza ARDS

Enobosarm

Oncology

- 2nd line metastatic breast cancer
- Bone only metastatic breast cancer

Late-stage clinical pipeline focused on infectious diseases and oncology

UREV
Sexual Health Division

ENTADFI® (tadalafil and finasteride) capsules

FDA launched for BPH late 2022

FC2 Female Condom (internal condom)

FC2 Female Condom (internal condom)

FC2 FY 2021 Net Revenues: $ 60.4 mm

FC2 FY 2022 Net Revenues: $ 39.4 mm

Current drug candidate pipeline
Biopharmaceutical company focused on infectious disease and oncology

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Infectious disease: Acute respiratory distress syndrome						
Sabizabulin	Oral microtubule disruptor	Hospitalized COVID-19 patients at high risk for ARDS	Fast Track Designation Phase 3: 204 Patients Completed			
Oncology						
Enobosarm	Selective androgen receptor targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	Fast Track Designation Phase 3 ARTEST: 210 Patients Ongoing			
Enobosarm + abemaciclib combination (Lilly)	Selective androgen receptor targeting agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	Fast Track Designation Phase 3 ENABLAR-2: 186 Patients Lilly clinical collaboration and supply agreement Ongoing			
Sabizabulin	Oral microtubule disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV-chemo	Phase 3 VERACITY: 245 Patients Ongoing			
VERU-100	Long-acting GnRH antagonist peptide subcutaneous 3-month depot injection	Advanced hormone sensitive prostate cancer	Phase 2: ~45 Patients Ongoing			

Restructuring clinical development programs to streamline our most advanced drug candidates into high value indications with near term clinical data

- **Focus on drug candidates which are highly differentiated in indications with large market opportunities and potential for *Phase 3 clinical trial* near term data in 2024**
  - Potential treatment with a mortality benefit in viral acute respiratory distress syndrome (ARDS)
    - Sabizabulin, novel indirect antiviral and broad anti-inflammatory agent, for viral acute respiratory distress syndrome indications in infectious disease
  - Potential to be first new hormone therapy for metastatic breast cancer not targeting the ER, but AR with the potential to also improve QOL and bone loss
    - Enobosarm, novel androgen receptor targeted agent, in ER+HER2-metastatic breast cancer indications in oncology
- **Reserve sabizabulin for infectious disease indications only; stop development of sabizabulin in the prostate cancer VERACITY study**
- **Pause Phase 2 assets VERU-100 and zuclomiphene**

Plan of action- sabizabulin for viral ARDS

- Reserve sabizabulin for infectious disease indications
- Pursue confirmatory Phase 3 clinical study for hospitalized COVID-19 patients at high risk for ARDS (n=408 patients) with a planned interim analysis clinical data targeted for 2024
- Plan Phase 3 clinical study for hospitalized influenza patients at high risk for ARDS

Coronavirus pandemic is in its 4th year as we transition to a still deadly endemic
Society fears death from COVID-19 infection

Risk of death from COVID-19 is unacceptably high:
Need new drugs like sabizabulin IN hospital !

OUT of hospital: general population

Prevent COVID-19

Vaccines

Treat mild-moderate COVID-19

Antivirals

- PAXLOVID®
- Molnupiravir

- Treatment window: Symptoms less than 5 days

IN hospital: death rate for COVID-19 is up to 21-67%

Treat moderate-severe COVID-19

Antiviral Remdesivir

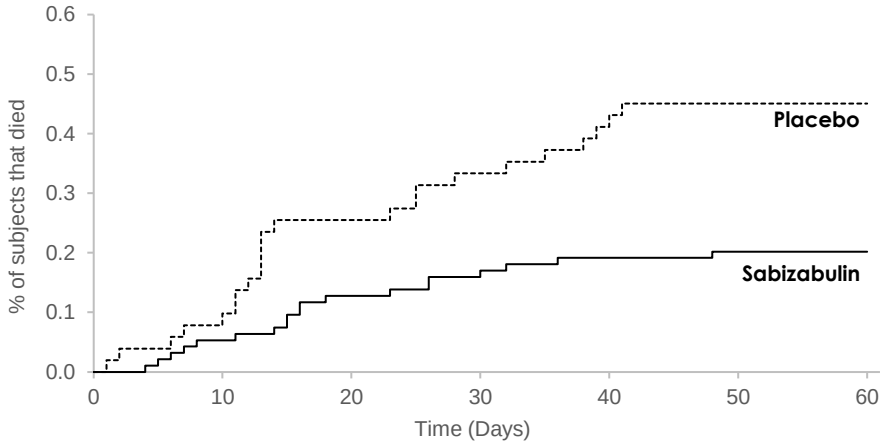
Dexamethasone

Supportive Care

Phase 3 study: results (interim analysis)

Primary endpoint, mortality rate by Day 60, was met

After planned interim analysis of first 150 patients, Independent Data Monitoring Committee unanimously recommended early stopping of Phase 3 study for clear evidence of benefit



	Sabizabulin 9 mg	Placebo	Relative risk reduction	P-value (Fishers Exact)
Mortality Day 15	7/94 (7.4%)	13/51 (25.5%)	-71.0%	0.003
Mortality Day 29	15/94 (16.0%)	18/51 (35.2%)	-54.5%	0.008
Mortality Day 60	19/94 (20.2%)	23/51 (45.1%)	-55.2%	0.004*

Treatment comparison	Odds ratio	95% CI	p-value (logistic regression)
Sabizabulin 9mg vs. Placebo	3.21	(1.45, 7.12)	0.0042*

*Statistical analysis per SAP was logistic regression model with multiple imputation

Safety conclusions

Sabizabulin was well-tolerated in COVID-19 studies

- Most common TEAE were respiratory failure, acute kidney injury, pneumonia
  - All 3 were experienced in a higher proportion of subjects in the placebo group
- Most common serious TEAE were respiratory failure, acute kidney injury, and acute respiratory failure
  - All 3 were experienced in a higher proportion of subjects in the placebo group

Safety observations confirm the efficacy findings of sabizabulin in treating COVID-19

Safety findings from the prostate cancer program at a dose of 3.5-fold higher show sabizabulin is well tolerated

FDA outcome for request for EUA on COVID-19 clinical program[1,2]

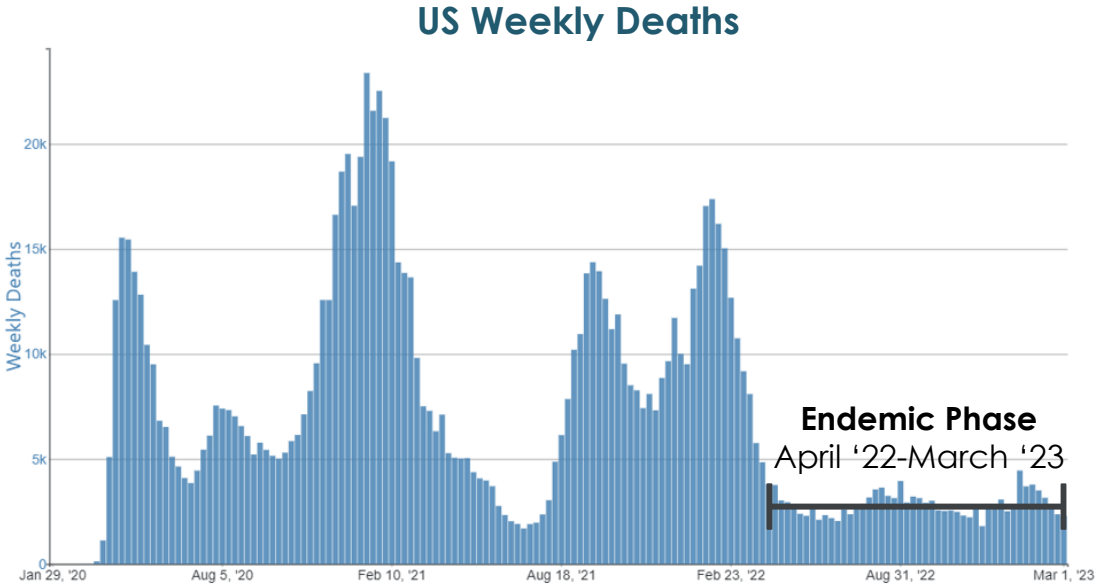
- **FDA's statistical efficacy summary of Phase 3 clinical study[1]**
  - Study met statistical criterion for stopping at the interim analysis
  - Data in all 204 subjects completing study indicate treatment benefit for all cause mortality at Day 60
  - Results robust to missing data assumptions
  - Exploratory analyses indicate minimal impact of baseline imbalances in timing of enrollment and duration of SoC
  - Positive numerical trend consistent across subgroups defined by age, baseline WHO category, region, SoC use at baseline
- **March 2, 2023, FDA declined to grant EUA at this time because of the possibility of unknown influences or uncertainties in a smaller study including the influences of clinical data that are not routinely collected in clinical trials**
  - FDA requested a confirmatory Phase 3 study in same population and "strong consideration should be given to appropriate time frames for interim analyses so that – should a strong efficacy signal **again** be observed – the trial could be stopped in an efficient time frame."[2]
  - At that time, FDA states that Veru may submit a new request for EUA; please note, if we follow FDA advice, the study will contribute safety information from an additional 104 patients to the 149 patients currently in the COVID-19 safety database.
  - Veru expects to meet with FDA soon, and we will communicate the details of the final design and timing of this potential Phase 3 confirmatory study after the meeting.
- **We are also simultaneously exploring our options under the FDA's formal dispute resolution process because we believe we have met the EUA standard and their reasons for declination seem arbitrary and capricious. We will keep you informed as we pursue this pathway too.**

[1] FDA Pulmonary-Allergy Drugs Advisory Committee Meeting slides 11-9-22, slide 88 | [2] FDA Disclosure letter published 3-10-23 in FDR

Global regulatory update

- **European Submission**:
  - Submitted under Article 18; EMA procedure on hold pending additional clinical information
- **ACCESS Consortium Submission**:
  - EOI Submitted to Australia (TGA), UK (MHRA), and Switzerland (Swissmedic) - 23 Sept 2022
  - Target ACCESS dossier rolling submission - Oct/Nov 2022
- **Other Active Regulatory Interactions**:
  - Canada, Israel, South Africa, South Korea, New Zealand, and Egypt

Endemic Phase of COVID-19 has an unacceptable mortality rate
Major opportunity for sabizabulin therapy for this unmet medical need

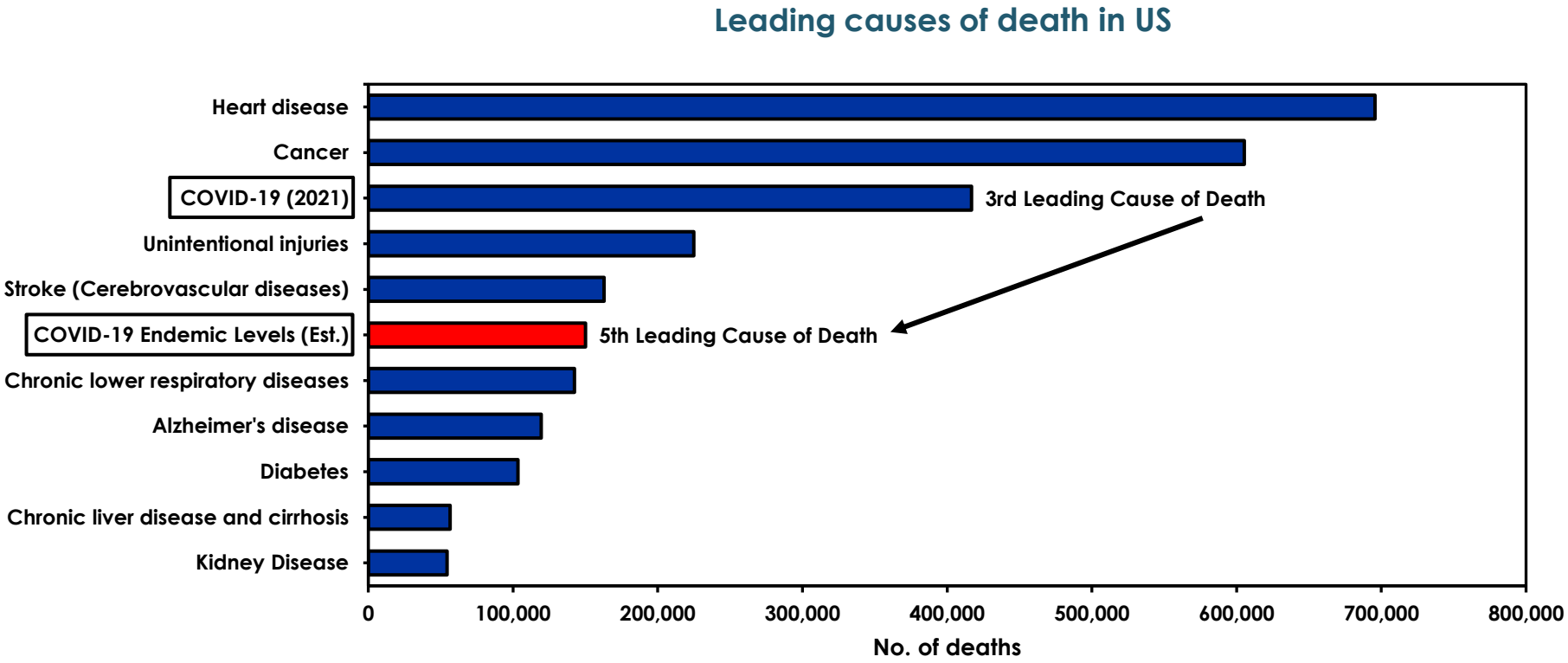


Endemic Phase in US

- **Estimated Deaths**
  - Daily deaths average: 410
  - Annual deaths: 150,000
- **Estimated Hospitalizations**
  - Daily new hospitalizations average: 4,192
  - Annual new hospitalizations: 1.5mm patients with 750,000 receiving oxygen

CDC.gov, Weekly Trends in Number of COVID-19 Deaths in The United States Reported to CDC, https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

Endemic COVID-19 is estimated to be the 5th leading cause of death in the United States with no significant treatment options with mortality benefit

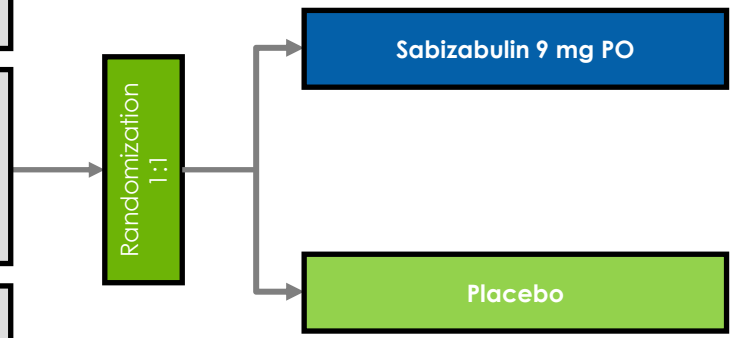


Draft Phase 3 confirmatory COVID-19 study design: Double blind, placebo-controlled study in hospitalized moderate to severe COVID-19 patients at risk for ARDS

N≈408
Sample size calculation
- Placebo 25%
- Sabizabulin 12.5%
- a=0.05 (two-sided)
- Power 90%
- N=408 patients (204/arm)
- Planned interim analysis when 50% of the patients complete the study (102 patients/arm)*

Key Inclusion criteria:
- Age ≥18 years
- SARS-CoV-2 infection confirmed by PCR
- WHO 4, WHO 5 or WHO 6 regardless of comorbidities
- Peripheral SpO_2 ≤94% on room air

Key exclusion criteria:
- Pregnant or breastfeeding
- Moderate to severe renal impairment
- Hepatic impairment
- Required ventilation plus additional organ support



Treatment Period
Days 1-21 or until discharge

Follow-up Period
Days 22-60

FDA has reviewed and commented on this potential Phase 3 COVID-19 confirmatory clinical study design:

FDA stated that "strong consideration should be given to appropriate time frames for interim analyses so that – should a strong efficacy signal again be observed – the trial could be stopped in an efficient time frame."

*Recommended by FDA in their review comments on this protocol | WHO 4: Hospitalized, oxygen by mask or nasal prongs; WHO 5: Hospitalized, non-invasive ventilation (NIV) or high-flow oxygen; WHO 6: Hospitalized, intubation and mechanical ventilation.

Justification for pursuing Phase 3 confirmatory trial in hospitalized moderate to severe COVID-19 patients at high risk for ARDS

COVID-19 is here to stay – large market size, lack of effective treatment options, and high mortality rates in patients with ARDS

Sabizabulin has demonstrated efficacy in Phase 2 and Phase 3 clinical studies

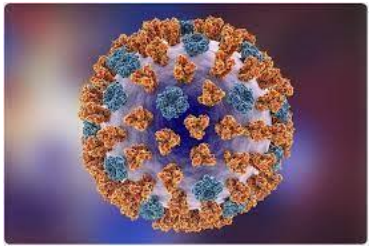
- Unique mechanism of action Indirect antiviral and broad anti-inflammatory agent –viral mutant strain agnostic
- Regulatory clarity – Phase 3 COVID-19 confirmatory study and may conduct interim analyses to assess efficacy of sabizabulin earlier
- May request a new EUA and/or NDA with additional data from the Phase 3 COVID-19 confirmatory study
- Under section 564 of the Federal Food, Drug, and Cosmetic Act, FDA may continue to issue EUA and EUA drugs may be available after the lifting of the national public health emergency on May 11th 2023

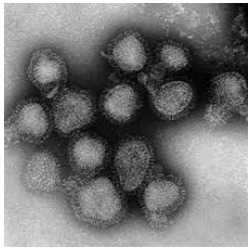
Lack of therapeutic competition- clinical evaluation of other drug candidates by competitors had marginal or no activity; less competition for patients to enroll into clinical trials

Having positive Phase 3 (902) COVID-19 study with sabizabulin treatment mortality benefit clinical data published in *NEJM Evidence* should help with patient recruitment into clinical trials

Sabizabulin as a broad indirect antiviral and anti-inflammatory agent has the potential to treat other viral ARDS, such as influenza

Influenza ARDS





Each year in the United States, Influenza leads to:

CDC 2022

- **Preclinical data evaluated sabizabulin in murine H1N1 influenza pulmonary inflammation model[1]**
  - Sabizabulin treatment reduced the cytokines in bronchoalveolar lavage:
    - KC, IL-6,TNF-alpha, INF-gamma, and CXCL-10
  - Sabizabulin treatment resulted in a reduction in the severity of lung inflammation caused by H1N1 viral challenge (histopathology)
- **Pathogenesis and mortality rates for patients with hospitalized influenza ARDS are similar to COVID-19 ARDS**
- **Planned Phase 3 Study V3011904 – hospitalized adult patients with influenza at high risk for ARDS**

[1] Nonclinical data performed by Labcorp Drug Development 2022 (data on file).

Plan of action- enobosarm for oncology/metastatic breast cancer

- **Fold Phase 3 ARTEST indication into the Phase 3 ENABLAR-2 study (combination enobosarm + abemaciclib)- clinical data targeted 2024**
  - Studies have overlapping target patient population based on current and evolving standards of care
  - Focus on earlier 2nd line metastatic setting in AR+ER+HER2- breast cancer patients
  - 2nd line is a larger patient population than 3rd line alone
  - Combination therapies are preferred over monotherapies by investigators
  - Remove AR threshold inclusion criteria as coadministration of CDK4/6 inhibitor increases expression of AR
  - New clinical data show that an estrogen blocking agent, as an active treatment control, in 2nd line metastatic setting following a CDK4/6 inhibitor and estrogen blocking agent[1] had an estimated median PFS=1.9-2.8 months
- **Plan Phase 3 study in bone-only nonmeasurable metastatic breast cancer**
  - Underserved patient population, which is 1/3 of the metastatic breast cancer patients
  - Enobosarm builds both cortical and trabecular bone and muscle/physical function in clinical and/or nonclinical models which may reduce skeletal related events and positively impact QOL

[1] Bidard F-C J Clin Onc 40:3246, 2022.

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

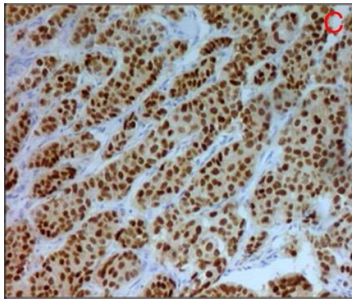
What is the androgen receptor's function in breast tissue?

Does activation of the androgen receptor stimulate or suppress breast cancer growth?

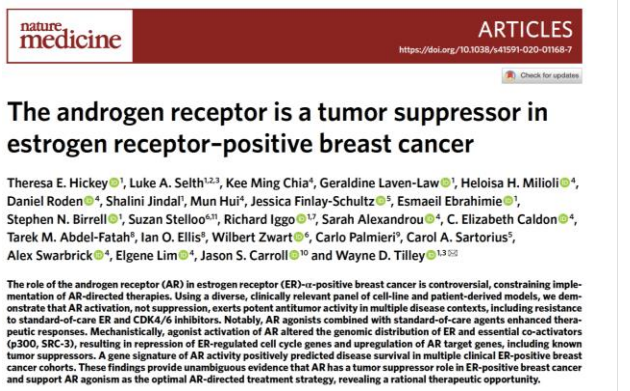
- In normal and cancerous breast tissue, androgens inhibit cellular proliferation [1-3]
- AR positivity is an independent predictor of beneficial breast cancer outcome[2,3,5,6]

Historically, androgens have been used in breast cancer treatment with good efficacy, but their masculinizing effects, increase in hematocrit, and liver toxicity have prohibited their use as a viable treatment

The development of novel strategies *to target and to activate* AR, tumor suppressor, as a treatment for AR+ER+ breast cancer that have become resistant to drugs that target the ER is warranted[3]



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



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

Check for updates

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

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

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

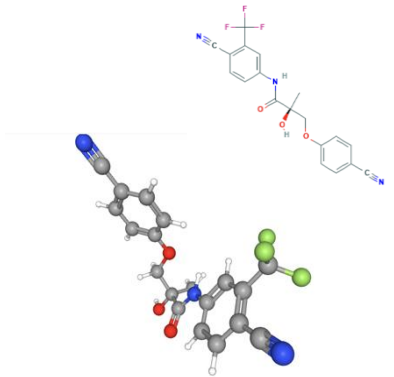
[1]Birrell et al, J Steroid Biochem Mol Biol 52:459-67, 1995 | [2]Peters et al, Cancer Res 69: 6131-40, 2009 | [3]Hickey et al, Nature Medicine 2021 | [4]Moinfar et al, Cancer 98:703–11, 2003 | [5]Hu et al, Clin Cancer Res 17:1867–74, 2011 | [6]Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | [7]Bronte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

Enobosarm, first-in-class, novel oral selective AR targeting agonist for the treatment for AR+ER+ HER2- metastatic breast cancer

Enobosarm is a non-steroidal, selective androgen receptor agonist[1, 2]

- Once-a-day oral daily dosing
- Selectivity to activate the androgen receptor with no cross-reactivity to other steroidal hormone receptors
- Selective tissue activities translate to a favorable side-effect profile
  - Non-masculinizing (no unwanted hair growth or acne)
  - No liver toxicity
  - No changes in hematocrit
- Not a substrate for aromatase, thus cannot be aromatized to estrogen
- Builds and heals bone- potential to treat antiestrogen-induced osteoporosis and prevents skeletal related events[3,4,5]
- Anabolic on muscle to improve muscle mass and physical function[2,6]

Breast cancer is only cancer type that enobosarm has been evaluated in



Chemical structure of Enobosarm

Enobosarm suppresses AR+ER+ breast cancer in cell and patient-derived xenograft models of endocrine sensitive and resistant disease[7]

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

Enobosarm has an extensive clinical experience - safety has been derisked

Evaluated in 25 clinical trials comprising 1485 subjects dosed (235 subjects dosed at ≥ 9mg)

4 Phase 2 studies in breast cancer

- G200801 – Proof of concept 9 mg enobosarm in AR+ ER+ metastatic breast cancer- completed/positive
- G200802 - Efficacy and safety of 9 mg and 18 mg (randomized) enobosarm in AR+ ER+ metastatic breast cancer- completed/positive
- G200901 – Efficacy of 18 mg enobosarm in heavily pretreated metastatic AR+ TNBC- discontinued
- [1]City of Hope Investigator Initiated/ Merck – Efficacy of 18 mg enobosarm in combination with pembrolizumab in AR+ TNBC- completed/positive

12 Phase 1 studies for NDA and label that have been 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

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)

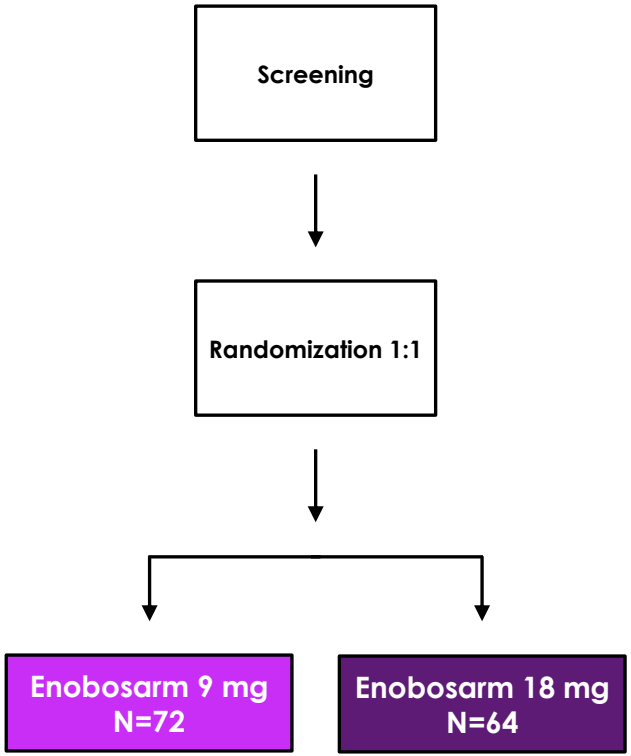
Carlo Palmieri[1], Hannah Linden[2], Stephen Birrell[3], Elgene Lim[4], Lee S Schwartzberg[5], Hope S Rugo[6], Patrick Cobb[7], Kirti Jain[8], Charles Vogel[9], Joyce A O'Shaughnessy[10], Stephen Johnston[11] , Robert H Getzenberg[12], Mitchell Steiner[12], Adam Brufsky[13] and Beth Overmoyer[14]

[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+ HER2- metastatic breast cancer in a heavily pretreated population[1]

Trial design

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



Patient population - 136 women enrolled

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

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

Phase 2 clinical trial (G200802)
Patient baseline demographics

Demographics	9 mg cohort	18 mg cohort
Age (median), years (range)	60.5 (35-83)	62.5 (42-81)
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)
Bone only non-measurable (%)	38.0	32.7
Prior chemotherapy (%)	90.0	92.3
Median prior lines of endocrine therapy (range)	3.2 (1-7)	3.2 (1-7)

Phase 2 clinical trial (G200802)
Overall safety and efficacy summary

Efficacy
Evaluable population (AR+)

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

Safety

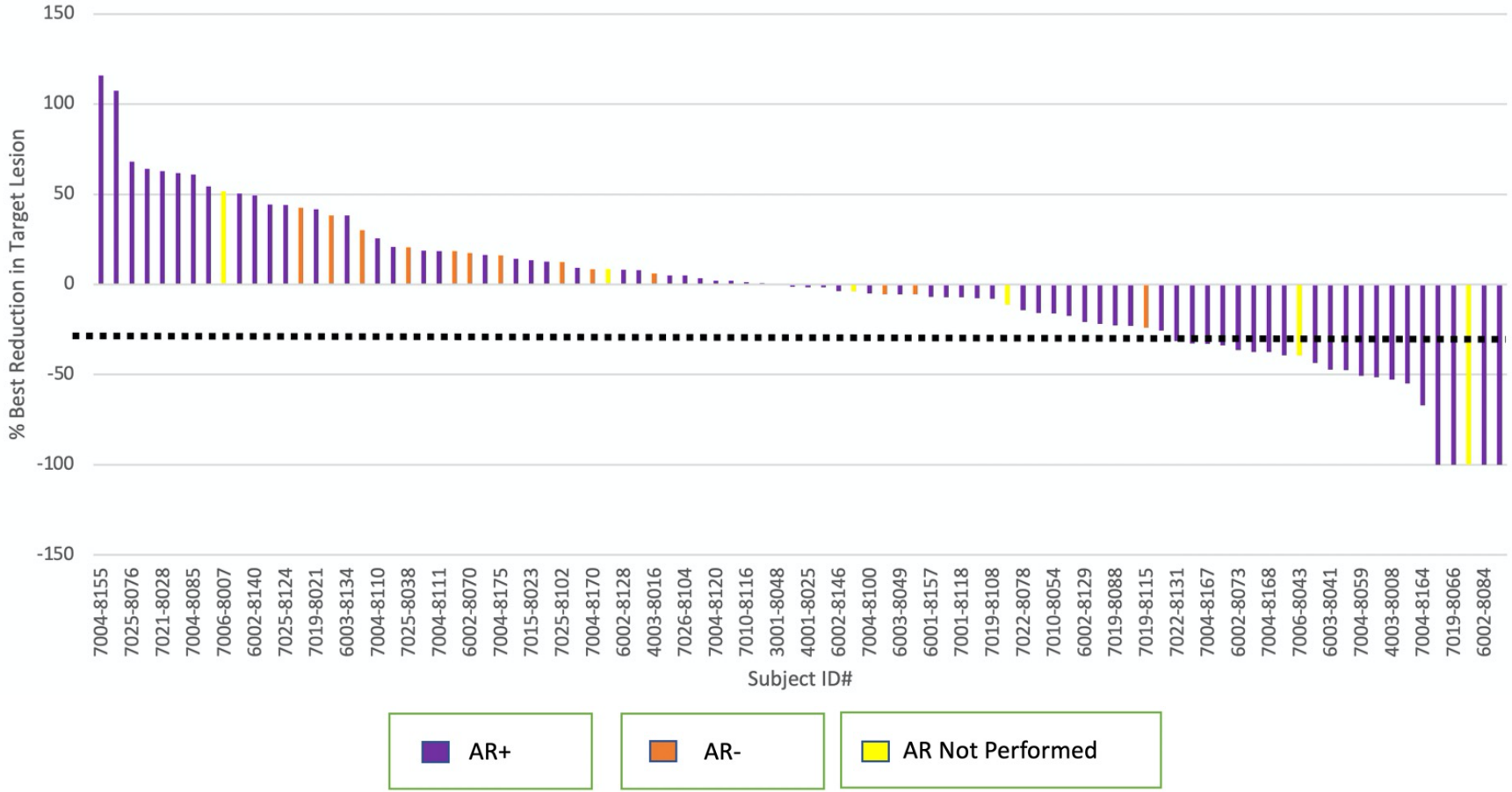
- Enobosarm was well tolerated
- Majority of events were Grade 1 and 2

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

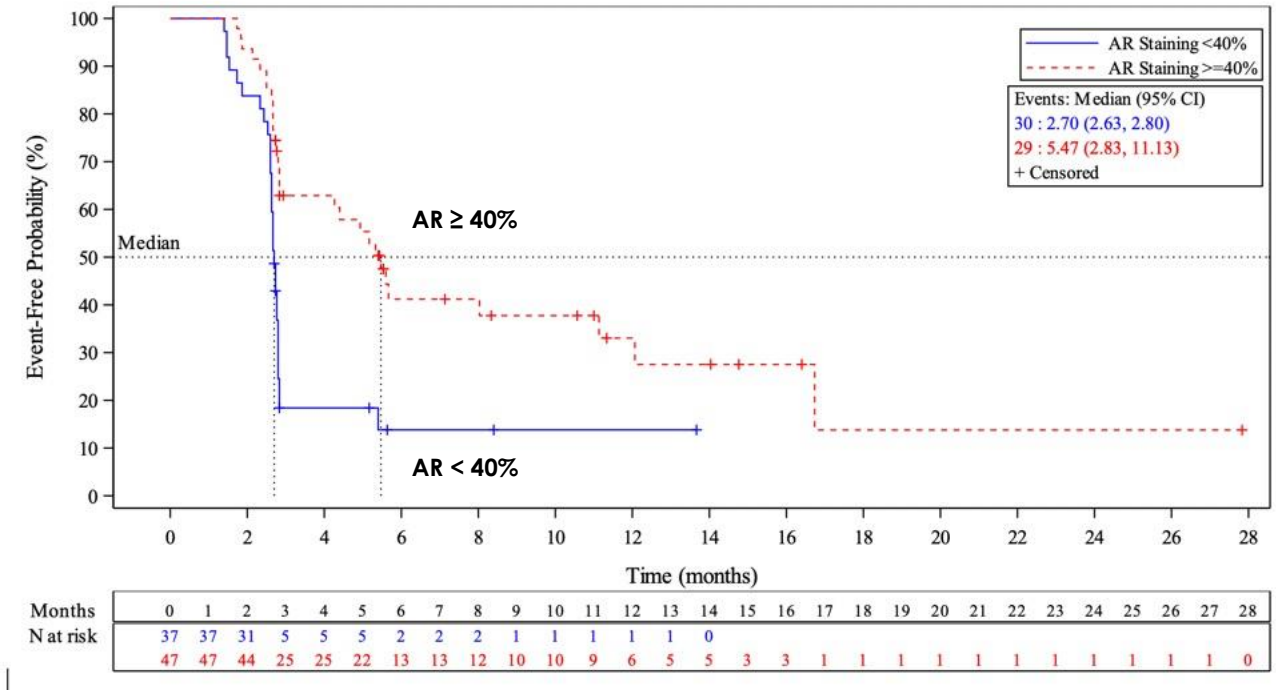
Grade 3 and 4 Drug Related Adverse Events	9 mg N=75	18 mg N=61
Increased alanine aminotransferase	1 (1.3%)	2 (3.3%)
Increased aspartate aminotransferase	2 (2.7 %)	
Hypercalcemia	2 (2.6%)	2 (3.3%)
Headache	1 (1.3%)	1 (1.6%))
Anemia	1 (1.3%)	
Dry mouth		1 (1.6%)
Decreased white blood cell count		1 (1.6%)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

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

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



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



AR ≥ 40%
Median PFS = 5.47; p<0.001

Phase 2 clinical trial (G200802)- Conclusions

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

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

Scientific rationale for combining CDK 4/6 inhibitor + enobosarm after metastatic breast cancer progression following first line CDK 4/6 inhibitor + estrogen blocking agent

San Antonio Breast Cancer Symposium - December 6-10, 2022
P4-08-16

Garvan Institute of Medical Research

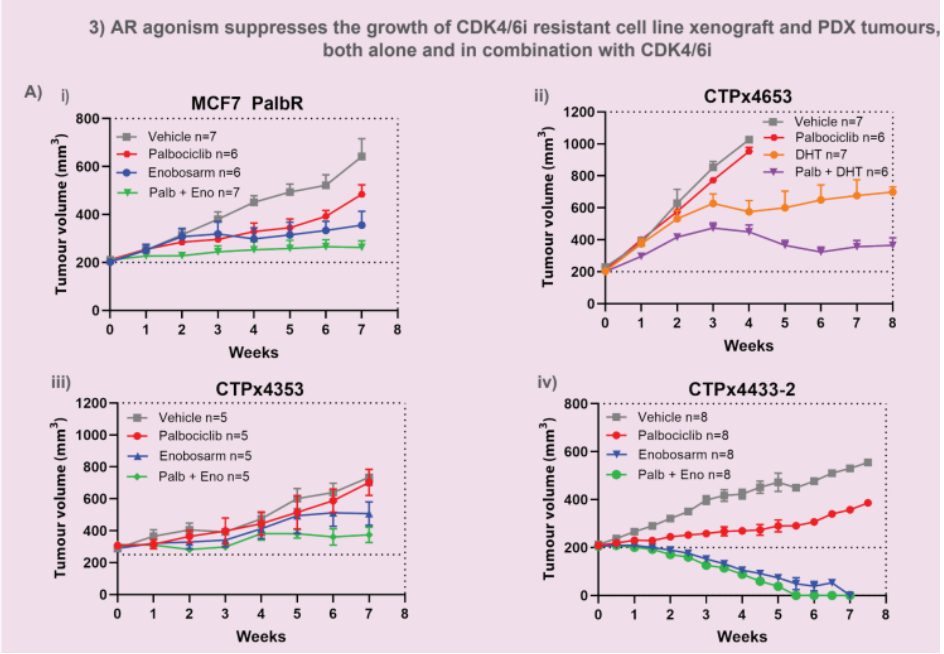
Selective Androgen Receptor Modulators in Combination with CDK4/6 Inhibitors Demonstrate Anti-cancer Activity in Preclinical Treatment Resistant ER+/AR+ Breast Cancer Models

Allegra Freelander[1,2], Leila Eshraghi[1,2], Geraldine Laven-Law[3], Kee Ming Chia[1,2], Marie Pickering[3], Sarah Alexandrou[1,2], C. Elizabeth Caldon[1,2], Theresa E. Hickey[3], Wayne D. Tilley[3], Elgene Lim[1,2]

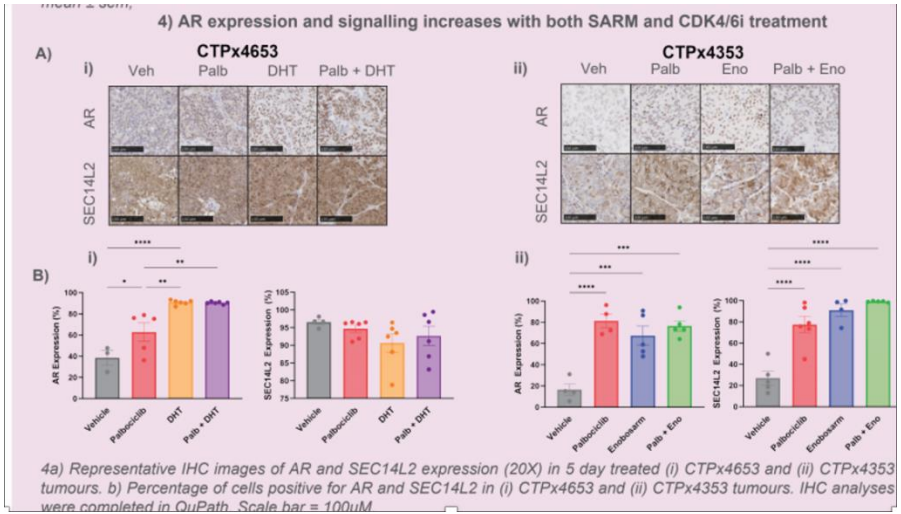
1. The Garvan Institute of Medical Research, Sydney, NSW 2010, Australia, 2. St. Vincent's Clinical School, Faculty of Medicine, UNSW Sydney, Sydney, NSW 2010, Australia, 3. Dame Roma Mitchell Cancer Research Laboratories, Adelaide Medical School, University of Adelaide, Adelaide, SA 5001, Australia.

UNSW SYDNEY

CDK 4/6 inhibitor and enobosarm suppresses growth of CDK4/6 inhibitor resistant tumors



CDK 4/6 inhibitor and enobosarm increases AR expression of CDK4/6 inhibitor resistant tumors



4a) Representative IHC images of AR and SEC14L2 expression (20X) in 5 day treated (i) CTPx4653 and (ii) CTPx4353 tumours. b) Percentage of cells positive for AR and SEC14L2 in (i) CTPx4653 and (ii) CTPx4353 tumours. IHC analyses were completed in QuPath. Scale bar = 100uM

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

Enrolling

Palbociclib resistance after first line metastatic Tx

Progressed on Nonsteroidal AI + Palbo or Fulvestrant + Palbo

Stage 1
n=up to 6

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

Stage 2
1:1 rando
n =180

Combination group

Abemaciclib + Enobosarm

Control Group

Alternative estrogen blocking agent

Entered into clinical collaboration and supply agreement with Lilly February 2022

- First patient enrolled 2022
- 37 clinical sites in US
- Plan to complete enrollment 2023
- Clinical trial results 2H 2024

Primary endpoint

- Median progression free survival (PFS)

Key Secondary endpoints:

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

Statistical assumptions

- Total sample size: 180
- $\alpha = 0.05$
- 90% power
- 37% drop out rate
- 121 events
- Control group estimated median PFS=5 months and combination group median PFS= 9 months

[1] Bidard F-C J Clin Onc 40:3246, 2022- estrogen blocking agent had an estimated median PFS=1.9-2.8 months in 2nd line metastatic setting following a CDK4/6 inhibitor and estrogen blocking agent

Phase 3 (V2000701) ENABLAR-2 study- 2nd line metastatic setting
Stage 1 of study portion

Stage 1 results

- Pharmacokinetics: No drug-drug interactions between enobosarm and abemaciclib
- Well tolerated
- No new safety findings

Central read CT scan results at 8 week scan: target lesions

Pt.#	Central Reader	Target Lesion	Baseline Long diameter	Day 56 Long diameter	% Change from Baseline
701-002	R1	Adrenal, left	42	22	-48%
	R2	Adrenal, left	37	18	-51%
701-003	R1	Liver	56	44	-21%
	R2	Liver, T1	28	25	-11%
		Liver, T2	14	11	-21%
701-004	R1	Fallopian Tube, T1	30	32	7%
		Fallopian Tube, T2	37	35	-5%
	R2	Liver	24	7	-71%

veru

ENTADFI®
(tadalafil and finasteride)
capsules

UREV
Sexual Health Division

FC2 Female Condom® (internal condom) business

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

Focus on growing US prescription business for high margin revenues

- Existing and anticipated new contracts with additional telemedicine and internet pharmacy partners
- **Established a direct to patient telemedicine portal that can plug into multiple existing pharmacy fulfilment services platforms**

www.fc2condoms.com

Sold in U.S. and 149 other countries

Manufacturing plant with annual capacity of 100 million units

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

FC2 business profitable from FY 2006-present[1]

Medical Device

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

UREV
Sexual Health

ENTADFI® capsule (finasteride and tadalafil), a new treatment for benign prostatic hyperplasia (BPH) without adverse sexual side effects, launched 8/2022[1-3]

ENTADFI®
(tadalafil and finasteride)
capsules

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

Company has partnered with GoodRx and launched product in August 2022 through traditional sales channel as well as seek additional partners in US and ROW

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

Financial highlights

Veru Net Revenues	
FY 2022 Net Revenues	$ 39.4 mm
FY 2021 Net Revenues	$ 61.3 mm
FY 2020 Net Revenues	$ 42.6 mm
FY 2019 Net Revenues	$ 31.8 mm
FY 2018 Net Revenues	$ 15.9 mm

Veru – FY 2022 Results of operations	
FY 2022 Net Revenues	$ 39.4 mm
FY 2022 Gross Profit	$ 30.6 mm
FY 2022 Operating Loss	$ (83.2) mm

Veru – Q1 FY 2023 Results of operations	
Q1 FY 2023 Net Revenues	$ 2.5 mm
Q1 FY 2023 Gross Profit	$ 0.7 mm
Q1 FY 2023 Operating Loss	$ (35.6) mm

Veru – Balance Sheet as of December 31, 2022	
Cash	$ 46.9 mm
Receivables	$ 3.9 mm
US/UK NOL carryforward	$112.5/$63.1 mm
Common Shares Outstanding[1]	~ 80.6 mm

Total cumulative net revenues from FY 2017-2022 $204.5 million

[1] An aggregate of 16.9 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 80.6 million common shares above

Restructuring and prioritization plans: focus drug development, conserve resources, and deliver near term Phase 3 clinical data in infectious disease and oncology

- **Reduced number of employees/contractors**
  - Infectious disease commercial headcount reduced by 98% (60/61)
  - Pharma program by 32% (8/25)

- **Clinical development**
  - Streamline Phase 3 opportunities with near term potential for clinical data in 2024
    - Phase 3 COVID-19 confirmatory study (n=408) with planned interim analysis at n=204 patients as recommended by FDA
    - Phase 3 ENABLAR-2 study for 2nd line metastatic AR+ER+HER2- Breast cancer (n=186)

  - Projected costs for clinical trials
    - Phase 3 COVID-19 confirmatory study – will cost $16 million for next 14 months to complete 204 patients for interim analysis in 2024
    - Phase 3 ENABLAR-2 – will cost $13 million for next 18 months to complete study and get clinical data in 2024

- **UREV sexual health business- seeing an increase in revenues this quarter from our UREV program as our customers are turning around, and we expect to see more revenues from our own telemedicine (digital medicine) website portal**

- **Seeking partnerships for drug candidates in clinical development and Phase 2 assets that have been paused**

New Drug candidate pipeline timeline

Biopharmaceutical company focused on infectious disease and oncology

Program	Mechanism	Indication	2022	2023	2024	2025
Infectious Disease- ARDS						
Sabizabulin	Oral microtubule disruptor	Phase 3 (902) study- Hospitalized COVID-19 patients at high risk for ARDS	Fast Track Designation ● Positive Phase 3 study			COMPLETED
		Phase 3 (903) Confirmatory study- Hospitalized COVID-19 patients at high risk for ARDS		● Phase 3 FPI	● Phase 3 IA	Planned mid 2023
		Phase 3 study- Hospitalized Influenza patients at high risk for ARDS	Phase 3 study			Planned
Breast Cancer						
Enobosarm + abemaciclib combination	Selective androgen receptor targeting agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Fast Track Designation ● Phase 3 FPI Phase 3 ENABLAR-2 study Lilly clinical collaboration and supply agreement		● Phase 3 data	Ongoing Lilly
Enobosarm	Selective androgen receptor targeting agonist	Bone-only nonmeasurable metastatic HR+HER2- breast cancer	Phase 3 study			Planned