Veru Inc.
Nasdaq:VERU

Biopharmaceutical Company Focused on Oncology and Viral ARDS Infectious Diseases

Veru Corporate Presentation
H.C. Wainwright 25th Annual Global Investment Conference
September 11-13, 2023

Forward looking statements

The statements in this release 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: the planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company's current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 3 study of enobosarm in bone-only non-measurable hormone receptor and HER2- metastatic breast cancer, the Phase 3 study of sabizabulin in hospitalized influenza patients at high risk of ARDS, and studies of sabizabulin in smallpox virus and Ebola virus, and whether any of such studies will meet any of its primary or secondary endpoint; whether the ENABLAR-2 study will show results consistent with or greater than the ARTEST results reported above; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients will occur and what the results of any such interim analyses will be; whether the results of such interim analyses or the completed confirmatory Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether and when the Company will receive the future installment payments of the ENTADFI purchase price or sales milestone payments; and the outlook for growth in the Company's FC2 business through telehealth customers, our direct to patient telehealth portal and the global public health sector. 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 as well as other operations of the Company; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines, anti-virals and other treatments become widely distributed the need for new COVID-19 or other ARDS 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 or other ARDS treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 or other ARDS treatments; the Company's existing products, including FC2 and, if authorized, sabizabulin, and any future products, if approved, possibly not being commercially successful; 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; 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, development costs, and market awareness and acceptance of any telehealth platform we develop; risks relating to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of a large telehealth customer; 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, product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims and securities litigation; 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
Oncology and viral ARDS infectious diseases with a sexual health division

Enobosarm - Oncology

- 2nd line metastatic HR+ breast cancer

Late-stage clinical pipeline focused on oncology and viral acute respiratory distress syndrome infectious diseases

Sabizabulin – Infectious Disease

- COVID-19 ARDS
- Influenza ARDS
- Smallpox ARDS
- Ebola ARDS

Sexual Health Division UREV

FC2 Female Condom (Internal Condom)

FY 2021 Net Revenues: $ 60.4 mm
FY 2022 Net Revenues: $ 39.4 mm

Pipeline - Oncology and infectious disease

Program	Mechanism	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	
Breast Cancer – Phase 3 Studies							
Enobosarm + abemaciclib combination	Selective androgen receptor agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Phase 3 ENABLAR-2 -enrolling				*Clinical collaboration and supply agreement* Lilly *Fast Track Designation*
Infectious Disease- Viral Acute Respiratory Distress Syndrome							
Sabizabulin	Oral microtubule Disruptor: Antiviral and anti-inflammatory agent	Phase 3 (902) study- Hospitalized COVID-19 patients at high risk for ARDS	Completed Positive Phase 3				*Completed* *Fast Track Designation*
		Phase 3 (903) Confirmatory study- Hospitalized patients with viral pneumonia at high risk for ARDS	Confirmatory Phase 3				*Planned 2H 2023* *Interim Analysis Expected 2H 2024*
		Smallpox virus	Animal Rule regulatory path				*Planned*
		Ebola virus	Animal Rule regulatory path				*Planned*

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

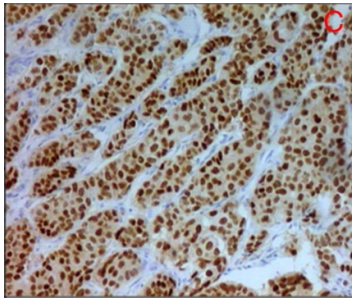
What is the androgen receptor's function in breast tissue?

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

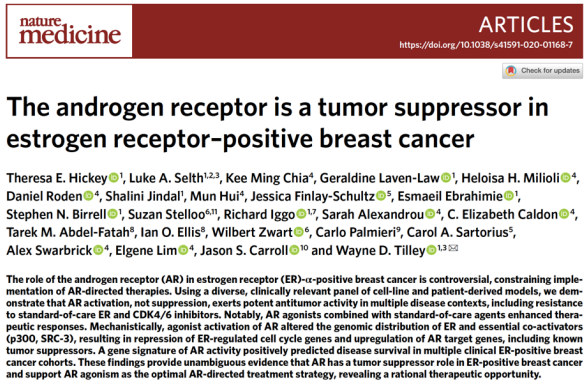
- In normal and cancerous breast tissue, androgens inhibit cellular proliferation [1-3]
- AR positivity is an independent predictor of beneficial breast cancer outcome[2,3,5,6]

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.

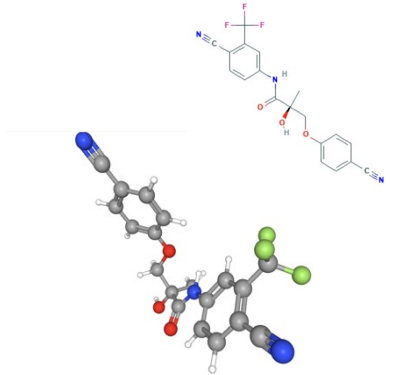
[1]Birrell et al, J Steroid Biochem Mol Biol 52:459-67, 1995 | [2]Peters et al, Cancer Res 69: 6131-40, 2009 | [3]Hickey et al, Nature Medicine 2021 | [4]Moinfar et al, Cancer 98:703–11, 2003 | [5]Hu et al, Clin Cancer Res 17:1867–74, 2011 | [6]Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | [7]Bronte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

In oncology, enobosarm has only been evaluated in breast cancer



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

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

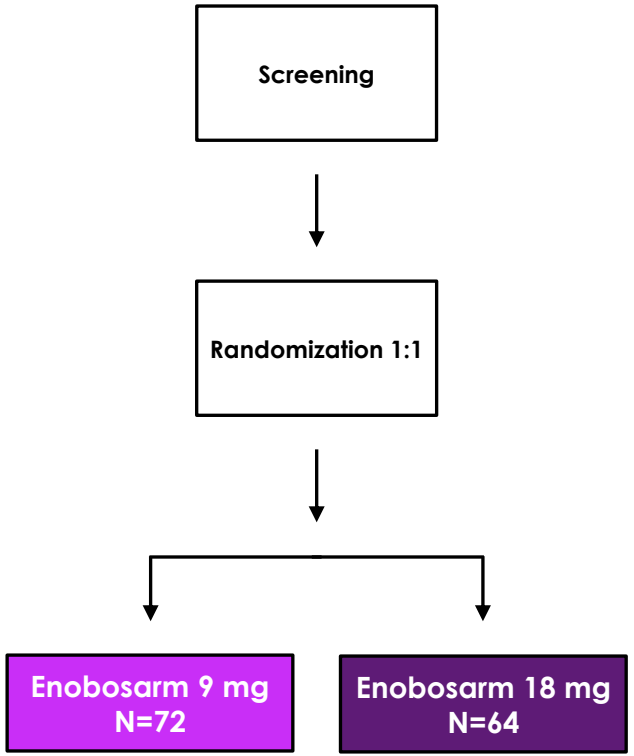
Clinical trial design – heavily pretreated population
Phase 2 (G200802)

Trial design

- To assess the efficacy and safety of enobosarm 9 mg or 18 mg oral daily dose in postmenopausal subjects with AR+ER+ MBC
- Open label, multicenter, multinational, randomized parallel design
- Primary endpoint: Clinical benefit rate (CR + PR + SD) at 6 months in subjects with AR+ breast cancer treated (by RECIST 1.1)

Patient population - 136 heavily pretreated women enrolled

- ER+ metastatic or locally recurrent breast cancer not amenable to surgery
  - AR status was assessed centrally (>10%)
  - 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 therapies for ≥3 years, or most recent endocrine therapies for metastatic disease ≥ 6 months



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

Patient baseline demographics
Phase 2 (G200802)

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)**

Overall safety and efficacy summary
Phase 2 (G200802)

Efficacy
- Evaluable population (AR+)

Efficacy	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 Grade 2

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

Grade 3 and 4 Drug Related Adverse Events (AEs)	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)- overall Post-Hoc population analysis
Best objective tumor responses of target lesion central read by % AR nuclei staining

Table 2: G200802 Study – by AR nuclei staining both doses combined

% AR nuclei Staining	n	Average rPFS (months)	Objective Responses (CR+PR)	Objective Response Rate	Clinical Benefit Responses (CR+PR+SD)	Clinical Benefit Response Rate
<20	21	3.15	1	4.8%	3	14.3%
20-40	16	3.21	0	0%	5	31.3%
40-60	14	4.31	3	21.4%	9	64.3%
60-80	16	6.91	8	50.0%	10	62.5%
>80	17	6.92	5	29.4%	10	58.8%
<40	**37**	**3.18**	**1**	**2.7%**	**8**	**21.6%**
>40	**47**	**6.14**	**16**	**34.0%**	**29**	**61.7%**

CR=complete response, PR=partial response, SD=stable disease, AR=androgen receptor, rPFS=radiographic progression free survival. This analysis is a post-hoc analysis conducted by Veru.

Conclusions
Phase 2 (G200802)

Androgen receptor targeted therapy exhibits efficacy and safety in AR+ER+HER2- MBC patients

- Clinical benefit was demonstrated with objective tumor responses in women with heavily pretreated estrogen blocking agent resistant AR+ ER+ HER2- MBC
- Patients with androgen receptor expression of ≥ 40% are more likely to benefit from enobosarm
- 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 different and new class of endocrine therapy 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

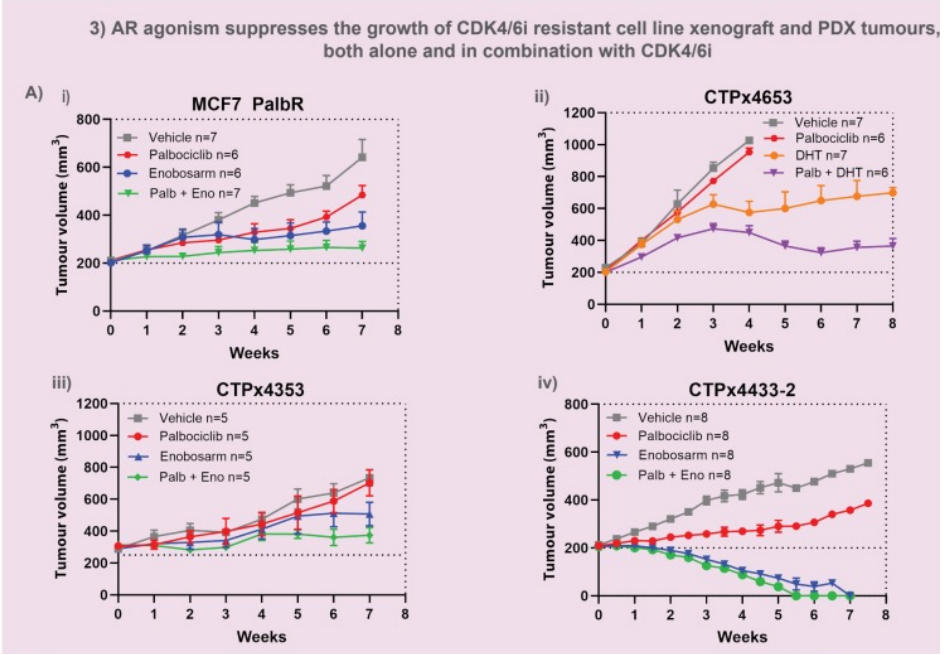
Selective Androgen Receptor Modulators in Combination with CDK4/6 Inhibitors Demonstrate Anti-cancer Activity in Preclinical Treatment Resistant ER+/AR+ Breast Cancer Models

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]

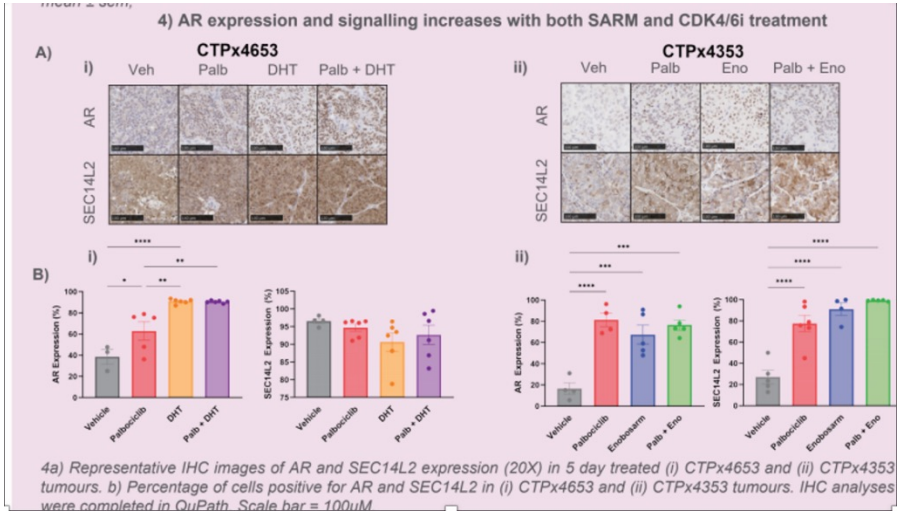
1. The Garvan Institute of Medical Research, Sydney, NSW 2010, Australia, 2. St. Vincent's Clinical School, Faculty of Medicine, UNSW Sydney, Sydney, NSW 2010, Australia, 3. Dame Roma Mitchell Cancer Research Laboratories, Adelaide Medical School, University of Adelaide, Adelaide, SA 5001, Australia.

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 2 (G200802) study
Evaluable patients with palbociclib resistance in the metastatic setting (Ad Hoc)

Objective tumor responses
- 30% overall

CBR at 24 weeks
- 50% overall

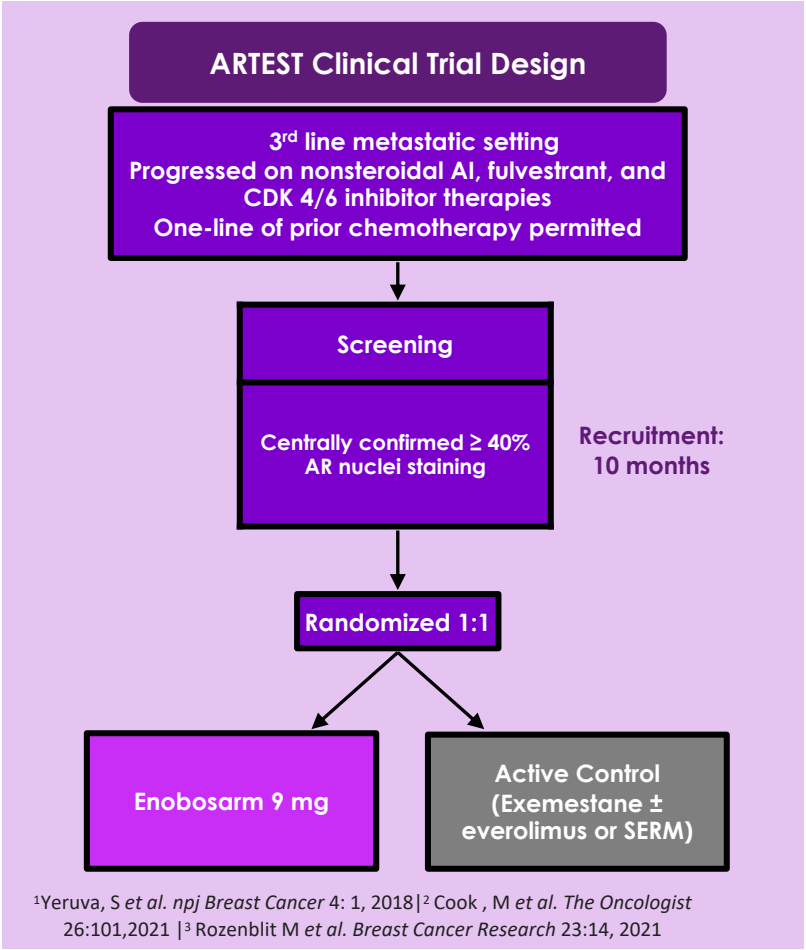
Mean duration on study (either PFS or censored)
- 7.3 months (9 mg and 18 mg groups)
- 10.0 months (9 mg dose group)

Palbociclib resistant subjects with measurable disease

9 mg patient ID	Outcome
7004-8120	
7019-8066	Complete Response
7026-8083	
7019-8087	Complete Response
7019-8106	Stable Disease

18 mg patient ID	Outcome
6003-8133	
7001-8001	Partial Response
7001-8118	Stable Disease
7004-8100	
7022-8078	

Phase 3 open label, randomized ARTEST clinical trial (V3002401) 3rd line or greater metastatic setting – AR staining ≥ 40%- discontinued



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

Clinical results from discontinued ARTEST study

- **34 patients randomized**
  - Enobosarm monotherapy (n=16)
  - Standard of care therapy (n=18)
- **Prior lines of therapy**
  - Enobosarm monotherapy= 2.9 (range 1-5)
  - Standard of care active control= 2.6(range 1-4)
  - On average, ARTEST patients receive 4th line therapy
- **Safety: enobosarm well tolerated without masculinizing adverse events and no hematocrit changes**

Efficacy (ORR)	Enobosarm monotherapy	Estrogen blocking agent active control
Evaluable patients	2 PR /16 (12.5%)	0 PR/18 (0%)
Evaluable patients - including an unconfirmed response	3 PR /16 (18.8%)	0 PR/18 (0%)
Patients with ≤3 lines of prior endocrine therapy	2 PR /10 (20%)	0 PR/15 (0%)
Patients with ≤3 lines of prior endocrine therapy with ≤1 prior treatment with CDK 4/6 inhibitor	2 PR /6 (33.3%)	0 PR/10 (0%)

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

CDK4/6 inhibitor resistance after first line metastatic Tx

Progressed on Nonsteroidal AI + CDK 4/6i or SERD + CDK 4/i

Stage 1
1:1:1:1 rando
n=160

Primary endpoint= ORR

Open label safety study to optimize enobosarm dose +/- abemaciclib 150mg BID

- Estrogen blocking agent n=32
- Abemaciclib + Enobosarm 1mg n=32
- Abemaciclib + Enobosarm 3mg n=32
- Abemaciclib + Enobosarm 9mg n=32
- Enobosarm 9mg n=32

Treatment group

Enobosarm +/- Abemaciclib

Control Group

Alternative estrogen blocking agent

Stage 2
1:1 rando
n =208

Entered into clinical collaboration and supply agreement with Lilly February 2022

Primary endpoint= PFS

Primary endpoint

- Median progression free survival (PFS)

Key Secondary endpoints:

- Overall response rate (CR+PR)
- Physical function tests
- DEXA- body composition (muscle and bone)

Statistical assumptions

- Total sample size: 180
- a = 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 ORR of 4.5 % and 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

Patient 1 - On Study 9+ Months

	Baseline 9/21/22	D56 11/29/22	D112 1/23/23	D168 3/22/23	D224 5/15/23	D280 7/6/23
TL1 – Adrenal gland	3.3	1.3	0.8	0.7	0.6	0.6
TL2 – Adrenal Gland	2	1.3	0.4	0.5	0.5	0.5
Total	5.3	2.6	1.2	1.2	1.1	1.1
Percent Change		-51%	-77%	-77%	-79%	-79% (PR)

Patient 2 – Progressed: On Study 10+ Months

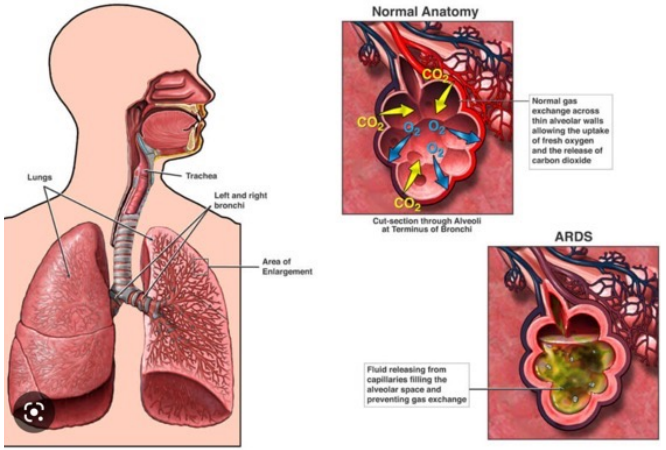
	Baseline 9/12/22	D56 11/16/22	D 112 1/13/23	D168 3/1/23	D224 5/3/23	D280 6/26/23
T1 - Liver	6.4	4	2.8	2.8	2.8	Not assessed, obscured by background liver changes
T2 - Liver	1	0.6	0	0	0	0
T3 - Liver	1.9	1.9	1.4	1.3	1.3	1.3
Total	9.3	6.5	4.2	4.1	4.1	New Liver Lesion
Percent Change		-30%	-55%	-56%	-56% (PR)	NE

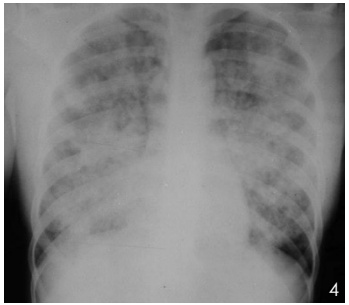
Patient 3 - On Study 9+ Months

	Baseline 09/27/22	D56 12/9/22	D 112 2/1/23	D168 3/29/23	D224 5/22/23	D280 7/17/23
T1 - Liver	1.7	1.6	1.6	1.6	1.6	1.7
Total	1.7	1.6	1.6	1.6	1.6	1.6
Percent Change		-5%	-5%	-5%	-5%	0% (SD)

Viral induced acute respiratory distress syndrome (ARDS)

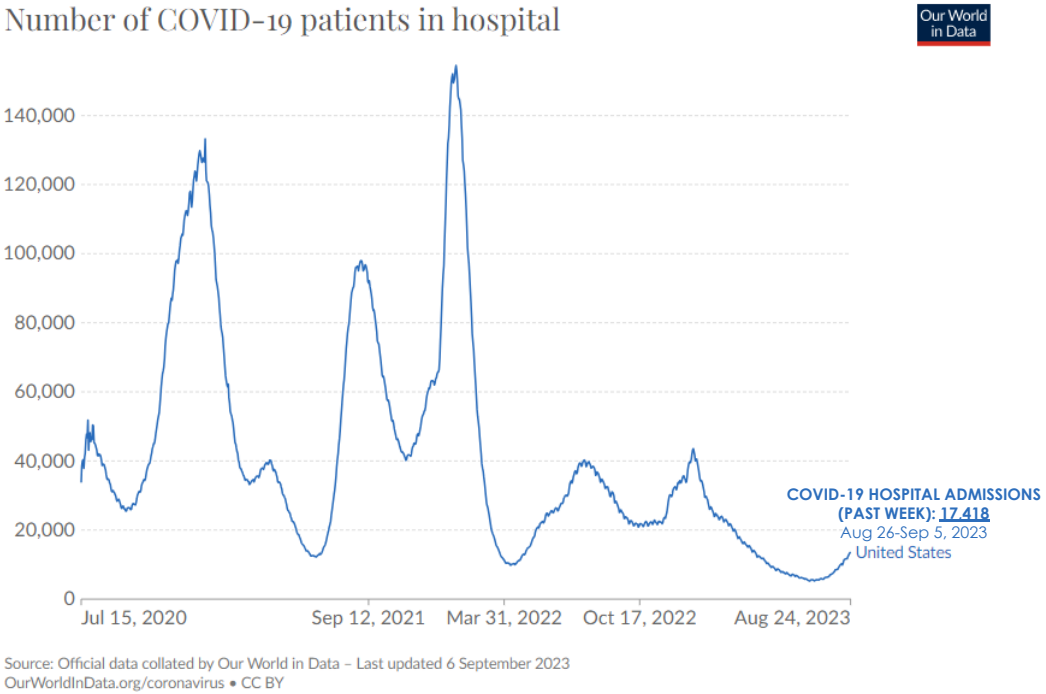
- **ARDS- a form of noncardiogenic, pulmonary edema and diffuse alveolar damage associated with systemic inflammatory conditions**
- **Viruses cause up to 1/3 of community acquired pneumonia**
  - Common viruses that cause ARDS are SARS-CoV-2, Influenza A/B, and RSV
- ***Viral induced ARDS results from the over-exaggerated immune inflammatory response by patient to the virus infection, rather than by viral mediated direct injury, thus an antiviral agent alone may not be effective***





1 Swenson KE et al. Crit Care Clin 37:749-776, 2021 | 2 Ruuskanen O et al. Lancet 377:1264-75, 2011 | 3 Shah RD et al. Clin Chest Med 38:113-125, 2017 | NIH, NHLBI
4: http://learningradiology.com/notes/chestnotes/ards.htm

COVID-19 is back and on the rise!
Summer cycle



Hospitalizations

Hospital Admissions

17,418

(August 20 to August 26, 2023)

Trend in Hospital Admissions

+15.7% in most recent week

Jul 28, 2023 Aug 26, 2023

Deaths

% Due to COVID-19

2.0%

(August 20 to August 26, 2023)

Trend in % COVID-19 Deaths

+17.6% in most recent week

Jul 8, 2023 Aug 26, 2023

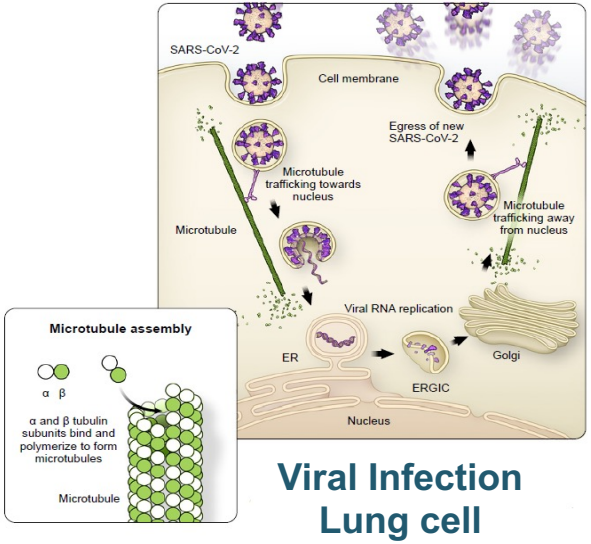
https://covid.cdc.gov/covid-data-tracker/#datatracker-home

Sabizabulin has dual antiviral and anti-inflammatory activities
Host targeted (indirect) antiviral agent

Sabizabulin Mechanism of action

- Targets and disrupts rapidly forming microtubules:
  - Arrests **dividing cancer cells**
  - Halts **virus transport**
  - Suppresses **cytokine production and release**

- By targeting microtubules, sabizabulin has broad indirect, host targeted, antiviral activity against:
  - SARS CoV-2 and other SARS-CoV-2 mutants (delta and omicron)
    - A549 lung cell culture IC50 and IC90 for sabizabulin as an indirect antiviral agent was similar to reported values for remdesivir and Paxlovid
  - Other viruses
    - Vaccinia pox virus



Viral Infection Lung cell

References: 1. Baggin J, et al. *Nat Microbiol*. 2021;6:1219-1232| 2. V'kovski P, et al. *Nat Rev Microbiol*. 2021;19(3):155-170| 3. Bohn MK, et al. *Physiol* (Bethesda). 2020;35(5):288-301| 4. Zhang Q, et al. *Signal Transduct Target Ther*. 2021;6(1):233 | 5. Boechat JL, et al. *Pulmonol*. 2021;27:423-437| 6. Hu B, et al. *J Med Virol*. 2021;93:250-256| 7. Montazersaheb S, et al. *Virol J*. 2022;19:92| 8. Wu D, et al. *Front Immunol*. 2022;13:826106| 9. Aminpour M, et al. *Life* (Basel). 2022;12(6):814| Ward, B. University of Rochester 2022 (data on file); 10 confirmed by Serra-Moreno et al University of Rochester

Phase 3 COVID-19 study interim analysis published in NEJM Evidence

NEJM Evidence

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ORIGINAL ARTICLE

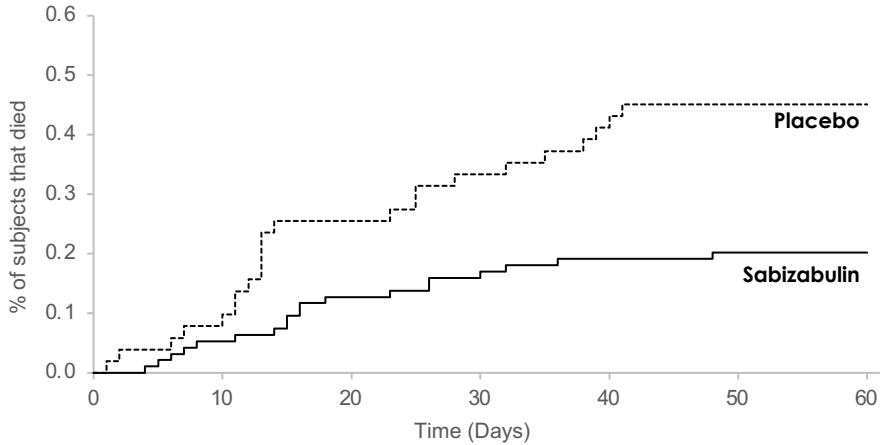
Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis

K. Gary Barnette, Ph.D.,[1] Michael S. Gordon, M.D.,[2] Domingo Rodriguez, M.D.,[1] T. Gary Bird, Ph.D.,[1] Alan Skolnick, M.D.,[3] Michael Schnaus, M.D.,[4] Paula K. Skarda, M.D.,[5] Suzana Lobo, M.D.,[6] Eduardo Sprinz, M.D.,[7] Georgi Arabadzhiev, M.D.,[8] Petar Kalaydzhiev, M.D.,[9] and Mitchell Steiner, M.D.[1] for the Phase 3 COVID-19 Investigators*

Interim analysis results
Completed Phase 3

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

Risk of mortality by Day 60 for subgroups based on SARS-CoV-2 variant

Subgroup	Sabizabulin 9mg	Placebo	Absolute difference	Relative difference
Delta variant (randomized prior to 12/15/2021)	13/48 (27.1%)	12/26 (46.2%)	-19.1%	-41.3%
Omicron variant (randomized on or after 12/15/2021)	12/82 (14.6%)	15/42 (35.7%)	-21.1%	-59.1%
Omicron variant (randomized on or after 1/15/2022)	7/61 (11.5%)	9/32 (28.1%)	-16.6%	-59.1%

Sabizabulin trial secondary endpoints: reduction in ICU days and days on ventilator vs placebo SOC (Phase 3 Final Data Analysis)

Key Secondary Endpoints

Sabizabulin treatment resulted in:

- 39% relative reduction in ICU days vs. placebo + SOC (p=0.0045)
- 44% relative reduction in mechanical ventilation days vs. placebo + SOC (p=0.0038)
- 23% reduction in hospital length of stay vs. placebo + SOC (p=0.0463)

Secondary Endpoint	Mean (SD)	Median
Days in ICU		
sabizabulin	16.0 (23.50)	2.0
Placebo	26.3 (28.11)	9.0
Days on Mechanical Ventilation		
sabizabulin	13.7 (23.57)	0.0
Placebo	24.6 (29.00)	0.0
Days in Hospital		
sabizabulin	24.0 (21.78)	13.0
Placebo	31.0 (24.61)	16.5

ICU – Intensive care unit; SD – Standard deviation; SOC – Standard of Care

Adverse events
Completed Phase 3 safety set

Any adverse event that occurred in ≥5% of patients in either treatment group

	Sabizabulin (n=130) N (%)/Events	Placebo (n=69) N (%)/Events
Any	82 (**63.1%**)/369	54 (**78.3%**)/294
Pneumonia	8 (6.2%)/12	9 (13.0%)/12
Pneumonia bacterial	2 (1.5%)/2	5 (7.2%)/5
Septic shock	2 (1.5%)/2	5 (7.2%)/5
Acute kidney injury	11 (8.5%)/11	8 (11.6%)/8
Acute respiratory failure	7 (5.4%)/7	3 (4.3%)/3
Hypoxia	3 (2.3%)/4	4 (5.8%)/4
Pneumothorax	1 (0.8%)/1	7 (10.1%)/7
Respiratory failure	13 (10.0%)/14	14 (20.3%)/14
Hypotension	5 (3.8%)/9	8 (11.6%)/8
Anemia	7 (5.4%)/7	3 (4.3%)/3
Atrial fibrillation	6 (4.6%)/6	5 (7.2%)/5
Bradycardia	6 (4.6%)/7	5 (7.2%)/5
Constipation	9 (6.9%)/9	6 (8.7%)/10
Hyperkalemia	6 (4.6%)/6	6 (8.7%)/7
Hypernatremia	6 (4.6%)/6	4 (5.8%)/4
Hypokalemia	6 (4.6%)/7	5 (7.2%)/7
Hypophosphatemia	2 (1.5%)/3	4 (5.8%)/5
Anxiety	4 (3.1%)/5	4 (5.8%)/4
Delirium	5 (3.8%)/5	4 (5.8%)/4
Urinary tract infection	8 (6.2%)/8	1 (1.4%)/1

Safety – AEs

The proportion of patients that experience any AE was **24% higher in the placebo group** compared to the sabizabulin treated group

Serious adverse events
Completed Phase 3 safety set

Any serious adverse event that occurred in ≥2% of patients in either treatment group

	Sabizabulin (n=130) N (%)/Events	**Placebo (n=69)** N (%)/Events
Any	38 (**29.2%**)/84	32 (**46.4%**)/85
Cardiac arrest	0	3 (4.3%)/4
Multiple organ dysfunction syndrome	0	2 (2.9%)/2
COVID-19	4 (3.1%)/4	3 (4.3%)/3
Pneumonia	4 (3.1%)/6	4 (5.8%)/5
Pneumonia bacterial	0	2 (2.9%)/2
Sepsis	4 (3.1%)/5	2 (2.9%)/2
Septic shock	2 (1.5%)/2	5 (7.2%)/5
Acute kidney injury	6 (4.6%)/6	6 (8.7%)/6
Acute respiratory failure	5 (3.8%)/5	3 (4.3%)/3
Hypoxia	2 (1.5%)/3	3 (4.3%)/3
Pneumothorax	1 (0.8%)/1	6 (8.7%)/6
Pulmonary embolism	3 (2.3%)/3	3 (4.3%)/3
Respiratory failure	13 (10.0%)/14	14 (20.3%)/14

Safety – SAEs

The proportion of patients that experienced any SAE was **59% higher in the placebo group** compared to sabizabulin treated group

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 and/or NDA

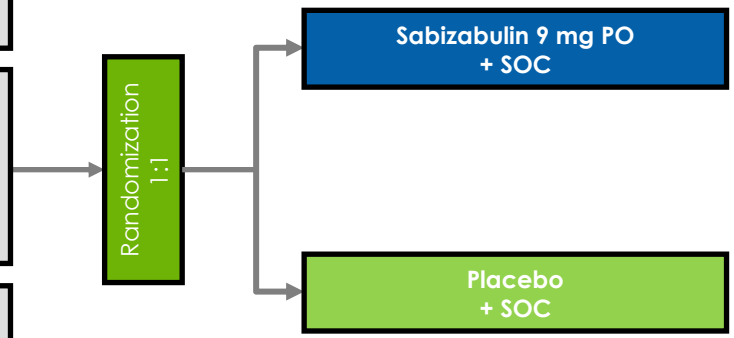
[1] FDA Pulmonary-Allergy Drugs Advisory Committee Meeting slides 11-9-22, slide 88 | [2] FDA Disclosure letter published 3-10-23 in FDR

FDA agreed to 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% (204 patients) and 71% (290 patient) complete the study

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



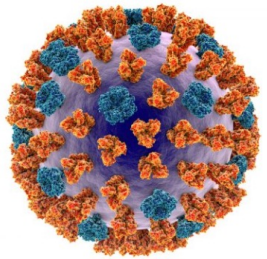
FDA has reviewed and agreed on Phase 3 COVID-19 confirmatory clinical study design:

- Expanded hospitalized population
- 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.

Sabizabulin has the potential to treat other viral ARDS, such as influenza

- **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 [4-5]**
- **Oseltamivir had no significant effect on mortality in patients with influenza [6]**



[1] Nonclinical data performed by Labcorp Drug Development 2022 (data on file) | [2] The NativeAntigen Company | [3] Stat News/ED MURPHY/CDC VIA AP | [4] Kronibus N et al. J Clin Med 11:6237, 2022 | [5] Yildirim M et al. Acute and Critical Care 37: 168-176, 2022 | [6] Kwon SK et al. BMC Infect Dis 17:785, 2017

Sabizabulin as a potential therapeutic for smallpox and Ebola viruses

- **Any smallpox or Ebola virus outbreak would be an immediate global emergency with limited existing options available for treatment**
- **Sabizabulin prevented both the release of vaccinia poxvirus from infected cells and the spread of poxvirus to healthy cells[1]**
- **FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans**
- **The Company had pre-IND meeting with the FDA in August 2023**
  - FDA agreed that the Animal Rule regulatory pathway is appropriate to evaluate the efficacy of sabizabulin for smallpox
  - We are evaluating the nonclinical plan for the conduct of the animal studies that may support the requirements for efficacy

1 Conducted by Dr. Brian Ward et al , University of Rochester School of Medicine

veru

UREV
Sexual Health Division

UREV
Sexual Health

ENTADFI® capsule (finasteride and tadalafil), a new treatment for benign prostatic hyperplasia (BPH) without adverse sexual side effects, sold 4/2023

ENTADFI®
(tadalafil and finasteride)
capsules

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

Company has sold asset for $20 million and up to $80 million in sales milestones April 2023

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

FC2 Female Condom® (internal condom) business

FC2 Female Condom (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

Increase in public sector sales: UNFPA, USAID, Brazil, and South Africa

Increase in US public sector sales

Medical Device

Focus on growing US prescription business for high margin revenues

- Established a direct to patient telemedicine portal that can plug into multiple existing pharmacy fulfilment services platforms
  - Growing number of new and refilled prescriptions
- Increase business with existing and anticipated new contracts with additional telemedicine and internet pharmacy partners

www.fc2condoms.com

[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.

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 – FYTD 2023 Results of operations	
FYTD 2023 Net Revenues	$ 12.4 mm
FYTD 2023 Gross Profit	$ 6.0 mm
FYTD 2023 Operating Loss	$ (70.1) mm

Veru – Q3 FY 2023 Results of operations	
Q3 FY 2023 Net Revenues	$ 3.3 mm
Q3 FY 2023 Gross Profit	$ 1.2 mm
Q3 FY 2023 Operating Income	$ 4.9 mm

Veru – Balance Sheet as of June 30, 2023	
Cash	$ 16.2 mm
Receivables	$ 5.1 mm
US/UK NOL carryforward	$112.7/$63.1 mm
Common Shares Outstanding[1]	~ 89.2 mm

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

[1] An aggregate of 18.0 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 89.2 million common shares above

Near term strategy

- **Clinical development - Streamline Phase 3 opportunities with near term potential for clinical data**
  - Phase 3 stage 1 ENABLAR-2 study for 2nd line metastatic AR+ER+HER2- breast cancer (n=160)
  - Phase 3 COVID-19 confirmatory study (n=408) with two interim analyses: at n=204 patients and n=290 patients
- **UREV sexual health business- we expect to see growing revenues from our own telemedicine (digital medicine) website portal and obtain additional telemedicine partners**
- **Seeking, and in some cases, in discussions for potential partnerships for drug candidates in clinical development**
- **Sold ENTADFI asset for $20m to increase balance sheet**

Drug candidate pipeline
Biopharmaceutical company focused on oncology and infectious disease

Program	Mechanism	Indication	2022	2023	2024	2025
Breast Cancer						
Enobosarm + abemaciclib combination (Lilly)	Selective androgen receptor agonist + CDK 4/6 inhibitor	Phase 3 ENABLAR-2 AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Fast Track Designation; Phase 3 FPI; Lilly clinical collaboration and supply agreement	Ongoing; Phase 3 data-stage 1		
Infectious Disease- Acute Respiratory Distress Syndrome						
Sabizabulin	Oral microtubule Disruptor Broad host targeted antiviral and anti-inflammatory agent	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 or All comers ARDS study		Planned 2H 2023; Phase 3 FPI; Phase 3 Interim Analysis		
		Phase 3 study- Hospitalized Influenza patients at high risk for ARDS		Planned; Phase 3 study		
		Smallpox virus		Planned; Animal Rule regulatory path		
		Ebola virus		Planned; Animal Rule regulatory path		