Veru Inc.
Nasdaq:VERU

Biopharmaceutical Company Focused on Oncology and Viral ARDS Infectious Diseases

Veru Corporate Presentation
Jefferies Healthcare Conference
June 7-9, 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 2b/3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 2b/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 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 any potential EUA or NDA would be grated; whether and when the Company will meet with BARDA regarding any potential partnering opportunities and whether those efforts will be successful; whether and how the Company will fund the planned Phase 3 studies of sabizabulin in influenza, pox virus and COVID-19; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether the current and future clinical development efforts of the Company, including all studies of sabizabulin in infectious disease indications and enobosarm in oncology indications, and any of their results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company's drug candidates; whether the drug candidates will be approved for the targeted line of therapy; whether sabizabulin will become a treatment for broad ARDS; whether the Company's FC2 telemedicine portal sales will grow or replace prior revenue from the U.S. prescription sales of FC2; whether the Company will recover any of the monies owed it by The Pill Club; whether and when the Company will receive the remaining installments from Blue Water in connection with the sale of ENTADFI or will receive any of the potential sales milestones related thereto; whether, when and how many shares may be sold under the Lincoln Park Capital Fund equity line; 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 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 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's existing products, including FC2 and ENTADFI and, if authorized, sabizabulin, 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; 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 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
- Bone only metastatic 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 2b/3 ENABLAR-2 (First Patient In 4Q 2022)				*Clinical collaboration and supply agreement* Lilly *Fast Track Designation*
Enobosarm	Selective androgen receptor agonist	Bone-only nonmeasurable HR+HER2- metastatic breast cancer	Planned Phase 3				*Planned*
Infectious Disease- Acute Respiratory Distress Syndrome							
Sabizabulin	Oral microtubule disruptor	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 COVID-19 patients at high risk for ARDS	Confirmatory Phase 3				*Planned 2H 2023* *Interim Analysis Expected 2H 2024*
		Phase 3 study- Hospitalized Influenza patients at high risk for ARDS	Phase 3				*Planned*
		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]

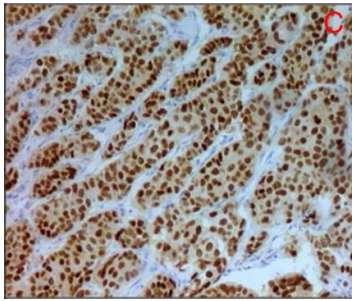
What is the androgen receptor's function in breast tissue?

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

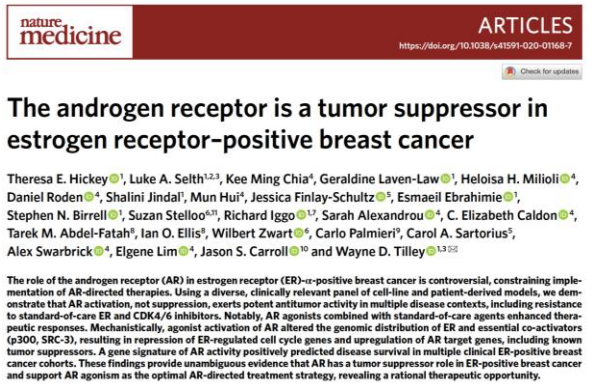
- In normal and cancerous breast tissue, androgens inhibit cellular proliferation [1-3]
- AR positivity is an independent predictor of beneficial breast cancer outcome[2,3,5,6]

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.

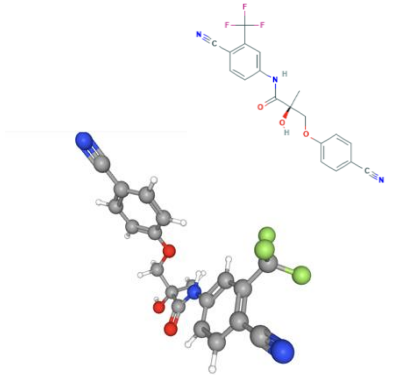
[1]Birrell et al, J Steroid Biochem Mol Biol 52:459-67, 1995 | [2]Peters et al, Cancer Res 69: 6131-40, 2009 | [3]Hickey et al, Nature Medicine 2021 | [4]Moinfar et al, Cancer 98:703–11, 2003 | [5]Hu et al, Clin Cancer Res 17:1867–74, 2011 | [6]Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | [7]Bronte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

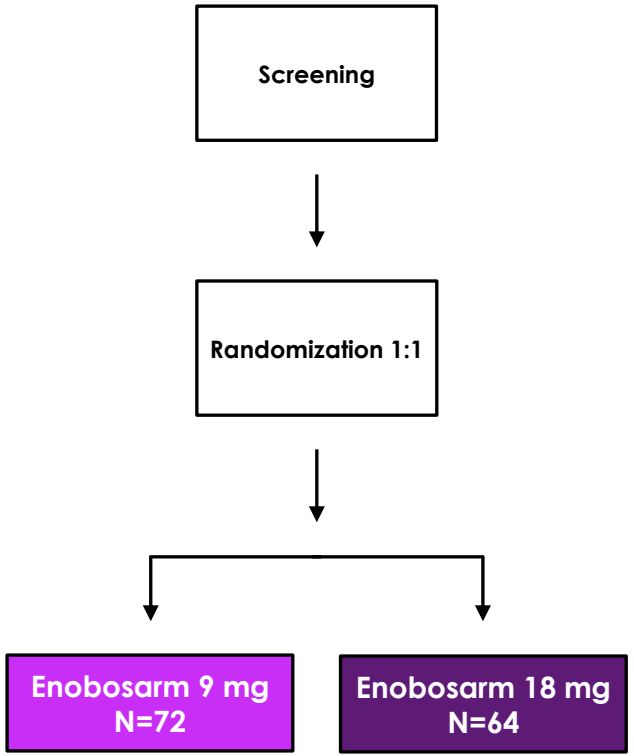
Clinical trial design – heavily pretreated population
Phase 2 (G200802)

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%)

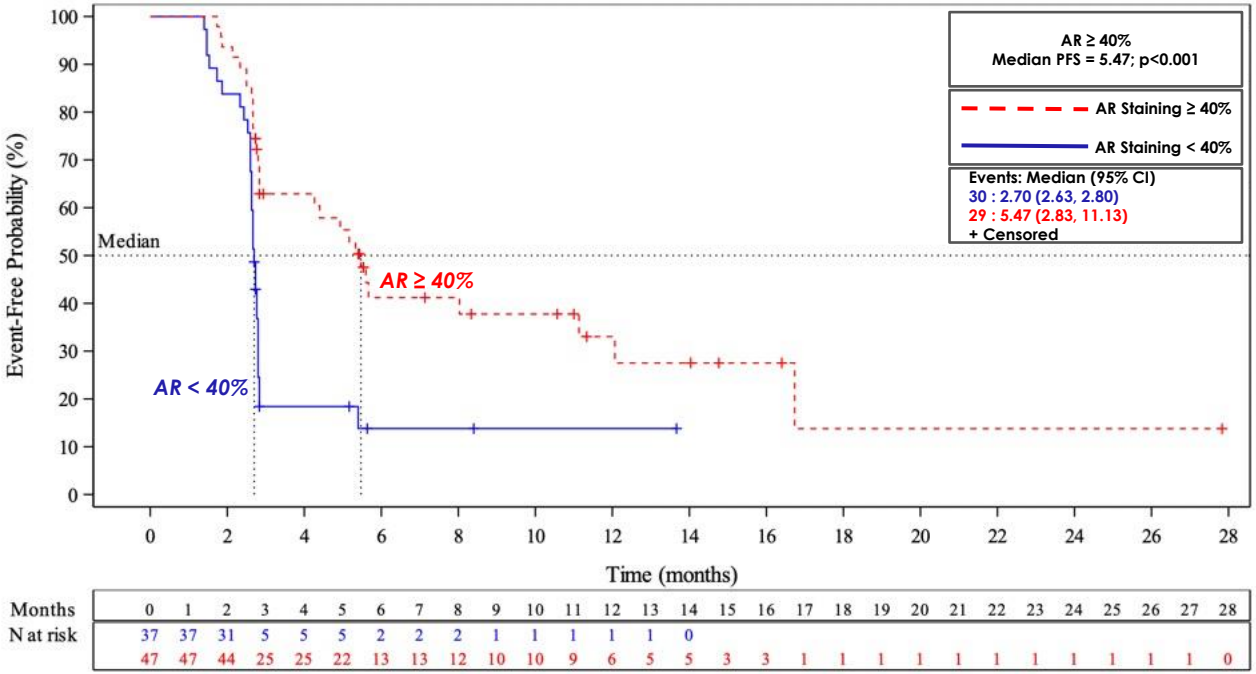
Safety
- Enobosarm was well tolerated
- Majority of events were Grade 1 and Grade 2

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%)

Presence of androgen receptor ≥ 40% results in better progression free survival
Phase 2 (G200802)

Kaplan-Meier Curve: Progression Free Survival (PFS)
Enobosarm 9 and 18 mg cohorts combined



Conclusions
Phase 2 (G200802)

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

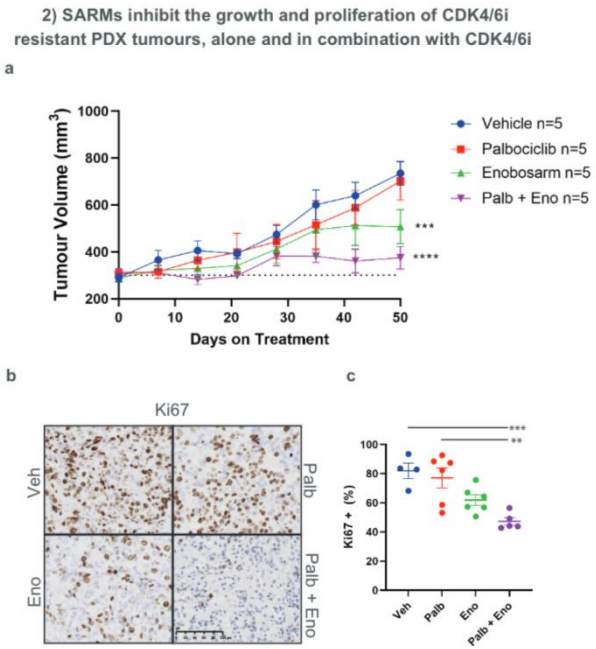
- Clinical benefit was demonstrated with objective tumor responses in women with heavily pretreated estrogen blocking agent resistant AR+ ER+ HER2- MBC
- Patients with androgen receptor expression of ≥ 40% are more likely to benefit from enobosarm
- Quality of life measurements demonstrated overall improvement including mobility, anxiety/depression and pain
- Enobosarm appears safe and well tolerated without masculinizing effects, increase in hematocrit, or liver toxicity

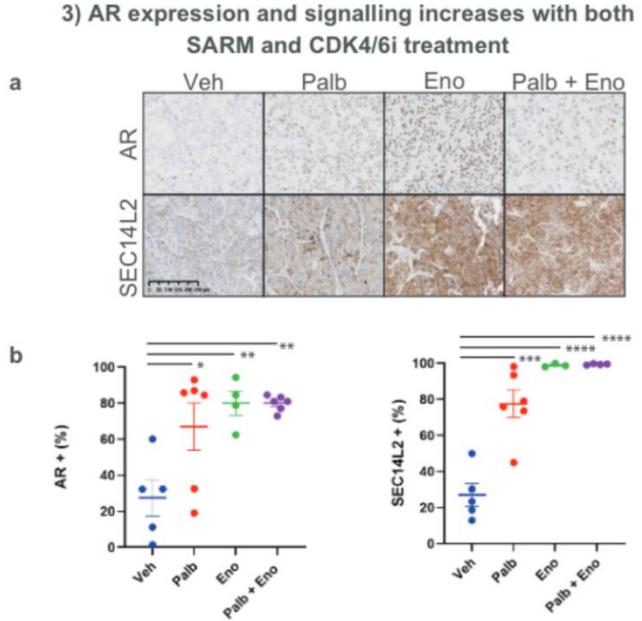
Enobosarm represents a new class of endocrine therapy in AR+ ER+ HER2- metastatic breast cancer

Enobosarm and CDK4/6 inhibitor for AR+ER+HER2- metastatic breast cancer

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

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





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

[1] Freelander A et al. 2021 SABCS presentation

Phase 2b/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

Palbociclib resistance after first line metastatic Tx

Progressed on Nonsteroidal AI + Palbo or Fulvestrant + Palbo

Stage 1
1:1:1 rando
n=120

Primary endpoint= ORR

Open label safety study to optimize enobosarm dose in combination with abemaciclib 150mg BID

- **Estrogen blocking agent n=40**
- **Abemaciclib + Enobosarm 1mg n=40**
- **Abemaciclib + Enobosarm 9mg n=40**

Combination group

Abemaciclib + Enobosarm

Control Group

Alternative estrogen blocking agent

Stage 2
1:1 rando
n =180

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)
- 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 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

Patient 1

	Baseline 9/21/22	D56 11/29/22	D 112 1/23/23	D168 3/22/23	D224 5/15/23
TL1 – Adrenal gland	3.3	1.3	0.8	0.7	0.6
TL2 – Adrenal gland	2.0	1.3	0.4	0.5	0.5
	5.3	2.6	1.2	1.2	1.1
		51% ⁻	77% ⁻	77% ⁻	79% ⁻

On study: 8+ mos

Patient 2

	Baseline 9/12/22	D56 11/16/22	D 112 1/13/23	D168 3/1/23	D224 5/3/23
T1- Liver	6.4	4.0	2.8	2.8	2.8
T2 - Liver	1.0	0.6	0	0	0
T3 - Liver	1.9	1.9	1.4	1.3	1.3
	9.3	6.5	4.2	4.1	4.1
		30%⁻	55%⁻	56%⁻	56% ⁻

On study: 8.5+ mos

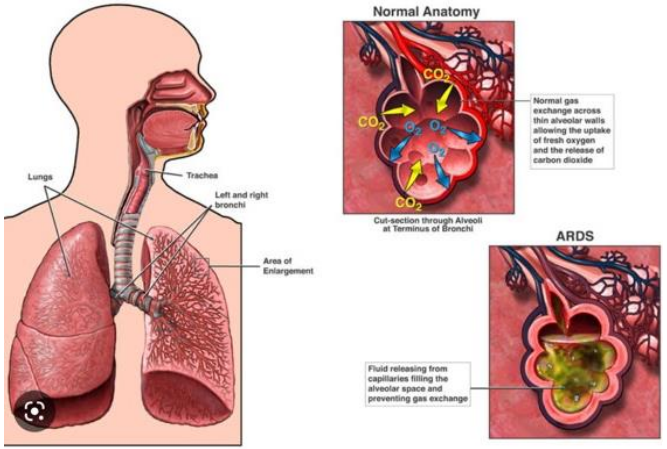
Patient 3

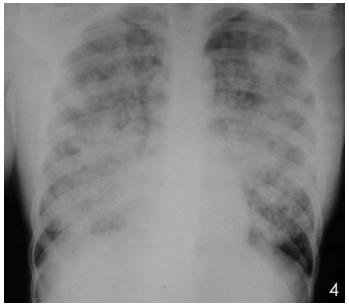
	Baseline 9/27/22	D56 12/9/22	D 112 2/1/23	D168 3/29/23
T1 – Liver	1.7	1.6	*1.6*	1.6
		5% ⁻	5% ⁻	5% ⁻

On study: 8+ mos

Viral acute respiratory distress syndrome (ARDS)
High mortality rate

- **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 influenza, SARS-CoV-2, and RSV
- **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**

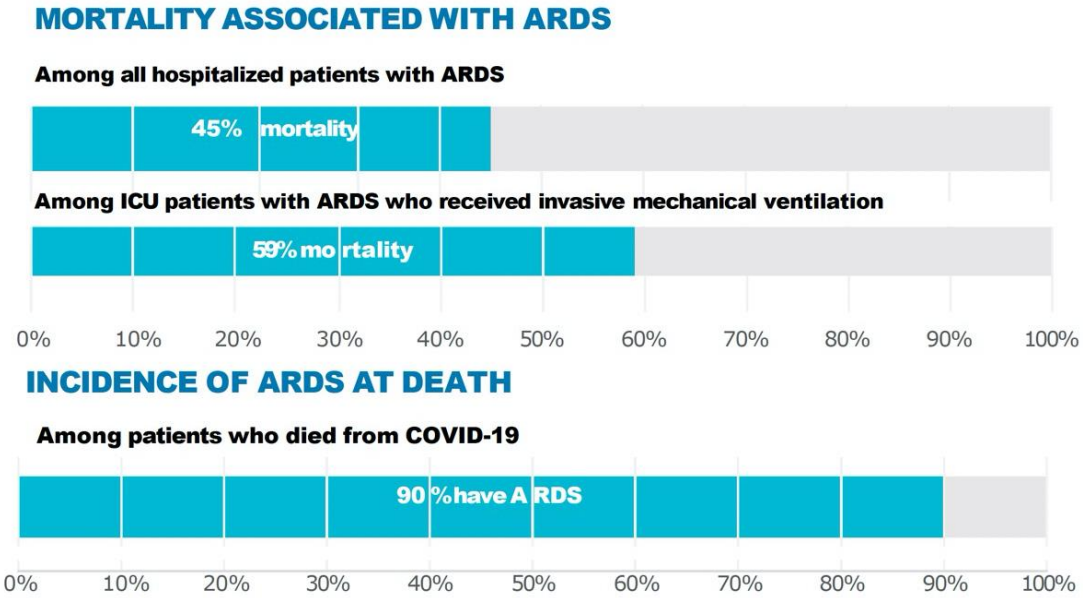




1 Swenson KE et al. Crit Care Clin 37:749-776, 2021 | 2 Ruuskanen O et al. Lancet 377:1264-75, 2011 | 3 Shah RD et al. Clin Chest Med 38:113-125, 2017 | NIH, NHLBI
4: http://learningradiology.com/notes/chestnotes/ards.htm

ARDS increases the risk of death due to severe COVID-19
Successful treatment for COVID-19 ARDS is a path to all viral induced ARDS

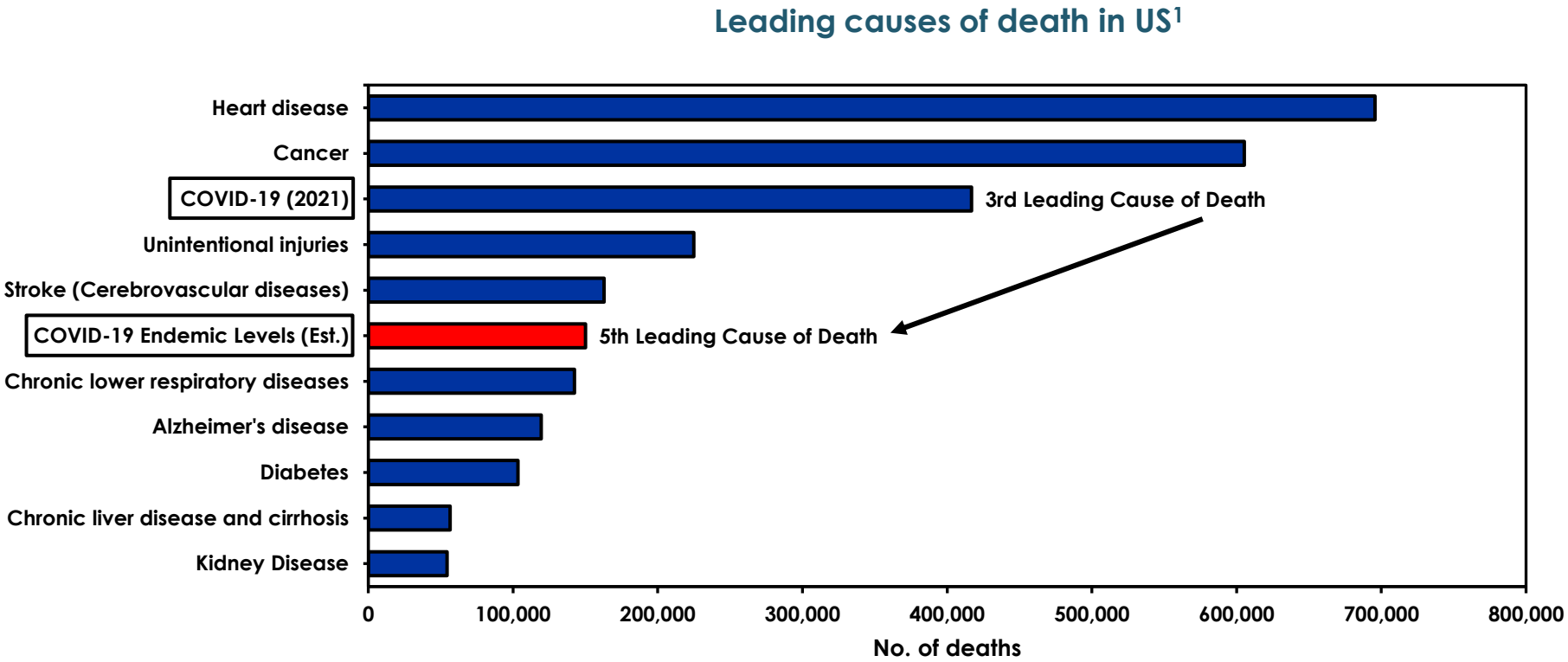
A literature survey of 17 studies from 5 countries that included a total of 2212 patients hospitalized with COVID-19 found a high rate of COVID-19–associated ARDS, mortality, and need for mechanical ventilation.



ARDS, acute respiratory distress syndrome; ICU, intensive care unit.

Reference: Tzotzos SJ et al. *Crit Care*. 2020;24(1):516. doi:10.1186/s13054-020-03240-7

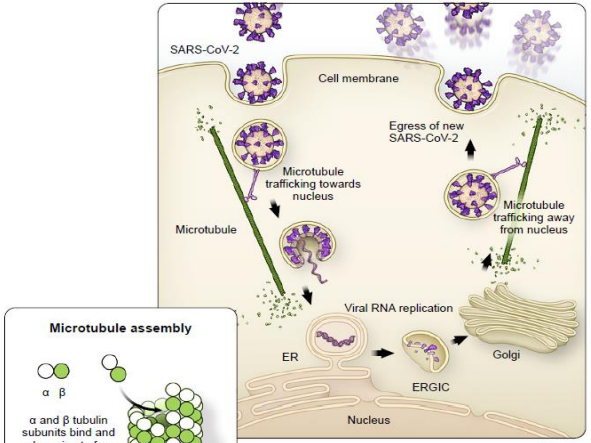
Endemic COVID-19 is estimated to be the 5th leading cause of death in the United States with no significant treatment options with mortality benefit



1: https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm

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

- **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

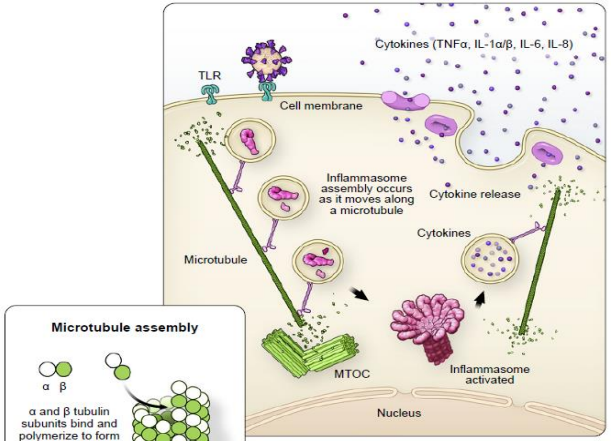


Viral Infection Lung cell

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

Sabizabulin has dual antiviral and anti-inflammatory activities
Broad spectrum anti-inflammatory agent

- **By targeting microtubules, has broad anti-inflammatory activity**
  - Sepsis cytokine storm LPS endotoxin model- University of Tennessee
  - COVID-19 ARDS mouse model – NIH
  - Influenza H1N1 Influenza ARDS mouse model- Labcorp laboratories



Immune Response T-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| 10. Beebe KE Labcorp Early Development Laboratories Ltd 2022 (data on file)|)

Coronavirus pandemic is in its 4th year as we transition to a still deadly endemic

Risk of death from COVID-19 is unacceptably high

OUT of hospital: general population

Prevent COVID-19

Vaccines

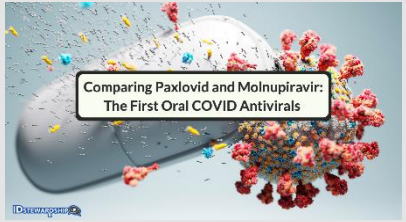
1

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

2

Supportive Care


3

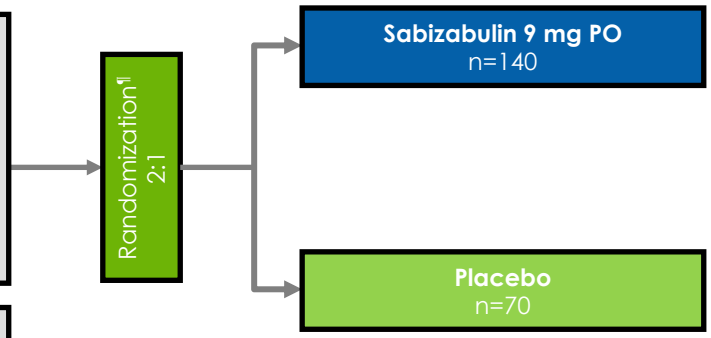
1: Hopkinsmedicine.Org | 2: Shutterstock.com | 3: Science X

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

Sample size calculation (N≈210)
- Placebo 30%
- Sabizabulin 15%
- a=0.05 (two-sided)
- Power >92%

Key Inclusion criteria:
- Age ≥18 years
- SARS-CoV-2 infection confirmed by PCR
- WHO 4 with ≥1 known comorbidity for being at high risk for ARDS; **OR**
  WHO 5 or 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

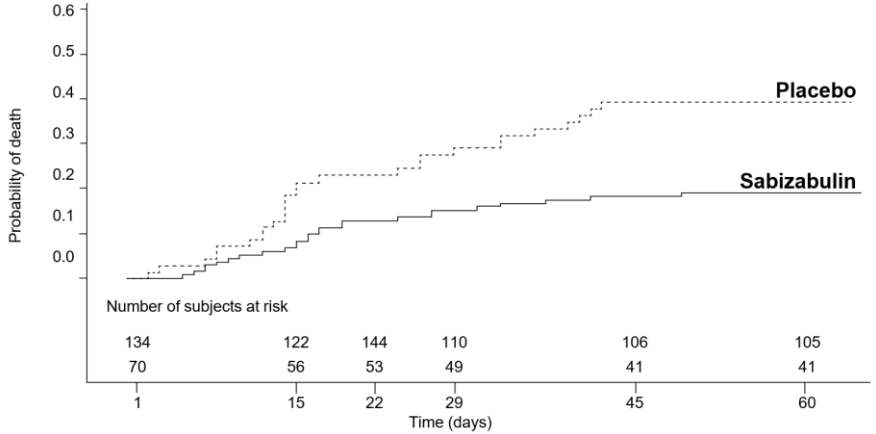
WHO 4: Hospitalized, oxygen by mask or nasal prongs; WHO 5: Hospitalized, non-invasive ventilation (NIV) or high-flow oxygen; WHO 6: Hospitalized, intubation and mechanical ventilation.

Full study results (ITT analysis)
Completed Phase 3

Analysis of ITT set (n=204) is consistent with interim efficacy analysis

Sensitivity Analyses:

- Kaplan-Meier Log-rank p=0.0019
- Kaplan-Meier Wilcoxon p=0.0023
- Cox Proportional hazard model p=0.0029
- Logistic Regression Proportion p=0.0046



	Sabizabulin 9 mg	Placebo	Relative risk reduction	p-value (logistic regression)
Mortality Day 15	11/131 (8.4%)	15/69 (21.7%)	-61.4%	
Mortality Day 22	17/131 (12.9%)	16/69 (23.2%)	-44.0%	
Mortality Day 29	20/130 (15.4%)	20/68 (29.4%)	-47.6%	
Mortality Day 60	25/130 (19.2%)	27/68 (39.7%)	-51.6%	0.0046

Treatment comparison	Odds ratio	95% CI	p-value (logistic regression)
Sabizabulin 9 mg vs. Placebo	2.77	(1.37, 5.60)	0.0046

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

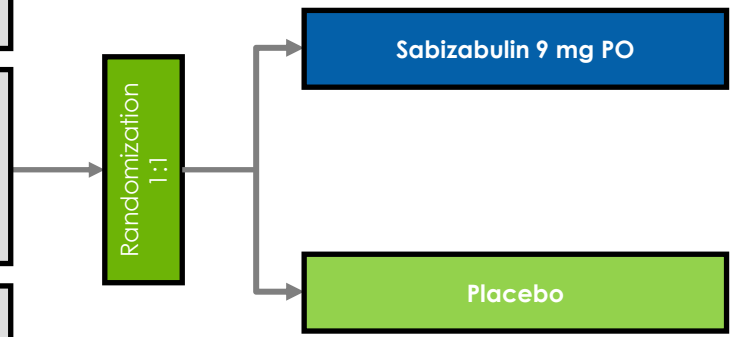
[1] FDA Pulmonary-Allergy Drugs Advisory Committee Meeting slides 11-9-22, slide 88 | [2] FDA Disclosure letter published 3-10-23 in FDR

Final 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



Treatment Period
Days 1-21 or until discharge

Follow-up Period
Days 22-60

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.

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

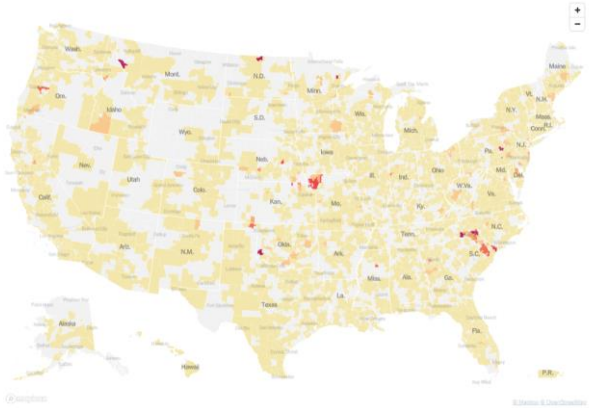
COVID-19 is here to stay – large market size, lack of effective treatment options, and high mortality rates in patients with ARDS

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

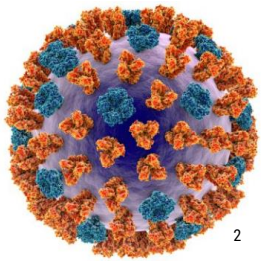


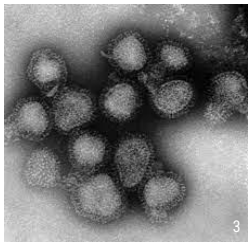
Daily hospitalization May 19, 2023
Source: NY Times

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**
- **Planned Phase 3 Study V3011904 – hospitalized adult patients with influenza at high risk for ARDS**

Influenza ARDS





Each year in the United States, Influenza leads to:

CDC 2022

[1] Nonclinical data performed by Labcorp Drug Development 2022 (data on file) | 2: The NativeAntigen Company | 3: Stat News/ED MURPHY/CDC VIA AP

Sabizabulin as a therapy 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 in a study conducted by a team of researchers led by Brian M. Ward, Ph.D., Associate Professor of Microbiology and Immunology, University of Rochester School of Medicine and Dentistry, Rochester, New York
- The Company plans to have pre-IND meetings with the FDA to discuss Animal Rule regulatory requirements for assessing the efficacy of sabizabulin for smallpox as well as Ebola viruses
- 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.

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

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, 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 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.

UREV Sexual Health

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.

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	$ 9.1 mm
FYTD 2023 Gross Profit	$ 4.8 mm
FYTD 2023 Operating Loss	$ (75.0) mm

Veru – Q2 FY 2023 Results of operations	
Q2 FY 2023 Net Revenues	$ 6.6 mm
Q2 FY 2023 Gross Profit	$ 4.1 mm
Q2 FY 2023 Operating Loss	$ (39.4) mm

Veru – Balance Sheet as of March 31, 2023	
Cash	$ 23.5 mm
Receivables	$ 4.2 mm
US/UK NOL carryforward	$112.5/$63.1 mm
Common Shares Outstanding[1]	~ 82.6 mm

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

[1] An aggregate of 16.1 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 82.6 million common shares above

Near term strategy

- **Clinical development - Streamline Phase 3 opportunities with near term potential for clinical data in 2024**
  - Phase 2b/3 ENABLAR-2 study for 2nd line metastatic AR+ER+HER2- breast cancer
  - 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 more 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 2b/3 ENABLAR-2 AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Fast Track Designation; Ongoing; Phase 2b/3 FPI; Phase 2b/3 data-stage 1; Lilly clinical collaboration and supply agreement			
Enobosarm	Selective androgen receptor agonist	Phase 3- Bone-only nonmeasurable metastatic HR+HER2- breast cancer	Planned; Phase 3 study			
Infectious Disease- Acute Respiratory Distress Syndrome						
Sabizabulin	Oral microtubule disruptor	Phase 3 (902) study- Hospitalized COVID-19 patients at high risk for ARDS	Fast Track Designation; COMPLETED; Positive Phase 3 study			
		Phase 3 (903) confirmatory study- Hospitalized COVID-19 patients at high risk for ARDS		Planned mid 2023; Phase 3 FPI	Phase 3 IA	
		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			