Veru Inc.
Nasdaq:VERU

Biopharmaceutical Company Focused on COVID-19 and Oncology

Veru Corporate Presentation
August 2022

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: whether and when the Company will submit an 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 and when sabizabulin will become an available treatment option for certain COVID-19 patients in the U.S. or anywhere outside the U.S.; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization or other approval is granted; whether the Company will secure any advance purchase agreement with the U.S. government or any foreign government; whether the Company will be able to obtain a premium price for sabizabulin as a COVID-19 treatment; whether the potential market, patient populations and revenue examples will be realized; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the U.S. or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; and whether and when ENTADFI will be commercialized successfully. 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 does 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, 2021 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.

Oncology biopharmaceutical company
Focus on breast cancer and prostate cancer with a sexual health division (UREV)

Veru
Drug Pipeline

COVID-19
- Sabizabulin 9mg

Breast Cancer
- Enobosarm
- Sabizabulin 32mg

Prostate Cancer
- Sabizabulin 32mg
- VERU-100
- Zuclomiphene

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

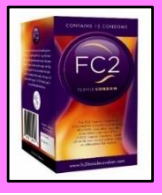
Request for EUA submitted 6/22 for sabizabulin in hospitalized patients with COVID-19 at high risk for ARDS

UREV
Sexual Health Division

ENTADFI® (tadalafil and finasteride) capsules

FDA APPROVED for BPH December 2021

FC2 Female Condom (internal condom)



FC2 FY 2021 Net Revenues:	$ 60.4 mm
FC2 FYTD 2022 Net Revenues:	$ 27.2 mm

Drug candidate pipeline
Oncology biopharmaceutical company focused on breast cancer and prostate cancer

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Breast Cancer						
Enobosarm	Selective androgen receptor targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	Phase 3 ARTEST: 210 Patients *Fast Track Designation* — Ongoing			
Sabizabulin	Oral cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)	Phase 2b: up to200 Patients — Planned			
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)	Phase 3 ENABLAR-2: 186 Patients *Lilly clinical collaboration and supply agreement* — Ongoing			
Sabizabulin + enobosarm	Oral cytoskeleton disruptor + Selective androgen receptor targeting agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	Phase 2b: 111 Patients — Planned			
Prostate Cancer						
Sabizabulin	Oral cytoskeleton 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			
Zuclomiphene citrate	Oral nonsteroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	Phase 2b — Planned			
COVID-19 infection						
Sabizabulin	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS	Phase 3: 210 Patients *Fast Track Designation* — COMPLETED			

Sabizabulin 9 mg

for the treatment of hospitalized **moderate-severe** COVID-19 patients at high risk for acute respiratory distress syndrome

Coronavirus pandemic is in its 3rd year
Society fears death from COVID-19 infection

Collective risk of death from COVID-19 is still too high:
Need new drugs like sabizabulin IN hospital !

OUT of hospital: general population

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

Prevent COVID-19

COVID-19 testing

Vaccines

Treat mild-moderate COVID-19

Antivirals

PAXLOVID and Molnupiravir

Treatment window:
Symptoms less than 5 days

Treat moderate-severe COVID-19

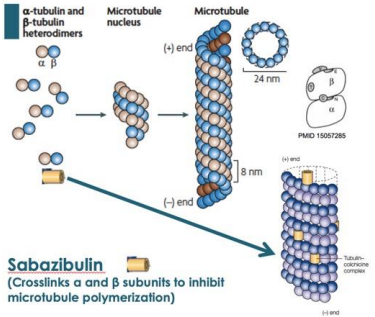
Antiviral
Remdesivir

Dexamethasone

Supportive care

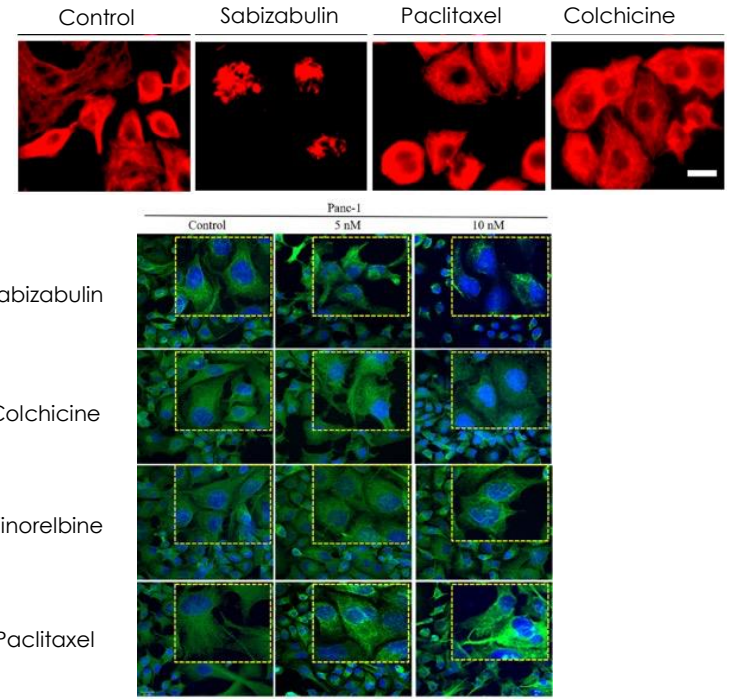
Sabizabulin is an oral agent that targets and disrupts microtubules halting transport of viruses in the cell and cytokine release

Targets cytoskeleton to crosslink and inhibit microtubule assembly[1]



- **Targets the "colchicine binding site" on β-tubulin and unique site on α-tubulin to crosslink α and β subunits to inhibit microtubule polymerization (low nM concentration)**
- **Not a substrate for multidrug resistance proteins (P-gp, MRPs, and BCRP)**
- **Favorable toxicity profile no neurotoxicity and no neutropenia or myelosuppression**
- **Has both antiviral and ant-inflammatory activities**

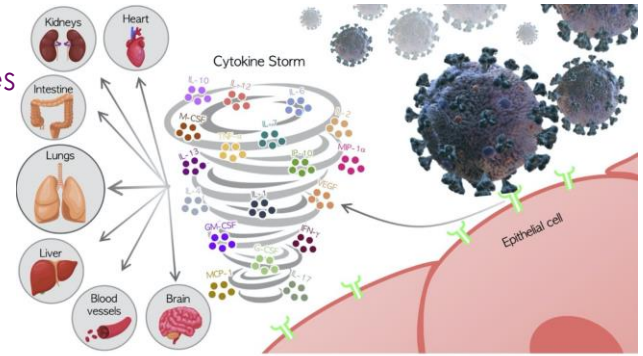
Only sabizabulin, not the other classes of microtubule targeting agents, disrupts and fragments (clumps) microtubules



[1] Chen J et al. J Med Chem 55:7285-7289 2012 | [2] Li CM et al. Pharm Res 29:3053-3063 2012 | [3] Lu Y et al. J Med Chem 57:7355-7366 2014 | [4] 28 day rat and dog toxicity studies on file at Veru, Inc. | [5] Dumontet C et al. Nature Reviews Drug Discovery 9:790, 2010 | [6] Markowski M et al J Clin Onc 37:167, 2019 | [7] Deng S et al Mol Cancer Ther 19:348-63, 2020 | [8] Kashyap VK et al Cancer Lett 470:64-74, 2020 | [9] Foyez M et al Cancer Letters 495:76, 2020 | [10,11] Data on file Veru, Inc. 2020 | [12] Kashyap V et al J Experimental and Clinical Can Res 38:29, 2019 | [13] Chen J et al J Med Chem 55:7285-7289, 2012; Hwang DJ et al ACS Med Chem Lett 6:993-997, 2015 | [14] Data on file Veru, Inc. 2014

Sabizabulin targets and disrupts the intracellular microtubule trafficking network
Novel oral agent has dual antiviral and anti-inflammatory activities

- **Most critical task of virus is to hijack the host's internal transportation system, the microtubules in the cytoskeleton, to replicate and to release new viruses for infection[1-4] Coronavirus's spike(S) protein interacts with microtubules for transport [1-5]**
- **Inflammasomes, the innate immune system, require microtubules to assemble and trigger the inflammatory cascade that leads to the cytokine storm responsible for acute respiratory distress syndrome[6,7]**
- **Sabizabulin**
  - Decreases production of infectious SARS-CoV-2 virus
  - Blocks production and release of inflammatory proteins/cytokines



[1] Ren et al Scientific Reports 5:11451,2015; [2] Rudiger et al Virology 497:185-197, 2016 | [3]V'kovski et al Nature Reviews 19:155-170, 2021 | [4]Wen et al J Mol Cell Bio 12:968-979, 2020 | [5] Preclnical studies data on file Veru, Inc. | [6]Cytokine storm diagram from Costela-Ruiz et al. Cytokine & Growth Factors Reviews 54:62-75, 2020 | [7] Nieto-Torres et al Virology 485:330-339,2015

Sabizabulin: Phase 2 COVID-19 clinical trial design

Double-Blind, Placebo-Controlled, Phase 2 Study of Sabizabulin for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)[1]

Trial design

- 39 subjects were randomized 1:1 (19 Sabizabulin and 20 Placebo)
- Hospitalized subjects with COVID-19 infection symptoms for less than 8 days and who are at high risk for ARDS were enrolled
- Subjects received study drug for up to 21 days
- Key efficacy endpoints of the study were:
  - all-cause mortality (death)
  - days in ICU
  - days on mechanical ventilation

Patient demographics

		Sabizabulin	Placebo
Number of patients		19	20
Mean age (±SD)		59.3 (11.4)	57.8 (13.3)
Gender	Males (%)	10 (53%)	17 (85%)
	Females (%)	9 (47%)	3 (15%)
Mean WHO Score at baseline (±SD)		4.47 (0.61)	4.7 (0.57)
Standard of care treatment use on study	Remdesivir (%)	9 (47%)	15 (75%)
	Dexamethasone (%)	13 (68%)	15 (75%)
	No dexamethasone or remdesivir (%)	4 (21%)	2 (10%)

[1] Veru Inc, *Clinical Trial Protocol*, VERU-111 SARS-CoV-2 (May 2020)

Phase 2 clinical trial of Sabizabulin – hospitalized COVID-19 patients

Key efficacy endpoints

Efficacy Endpoints	Placebo	Sabizabulin	Relative Reduction	p-value
Deaths (ITT)	6/20 (30%)	1/19 (5.3%)	82%	p=0.0442
Mean days in ICU +/- SD (EE)	9.6±12.4	2.6±5.8	73%	p=0.0261
Mean days on Mechanical Ventilation +/- SD (EE)	5.1±11.2	1.2±6.1	78%	P=0.1437

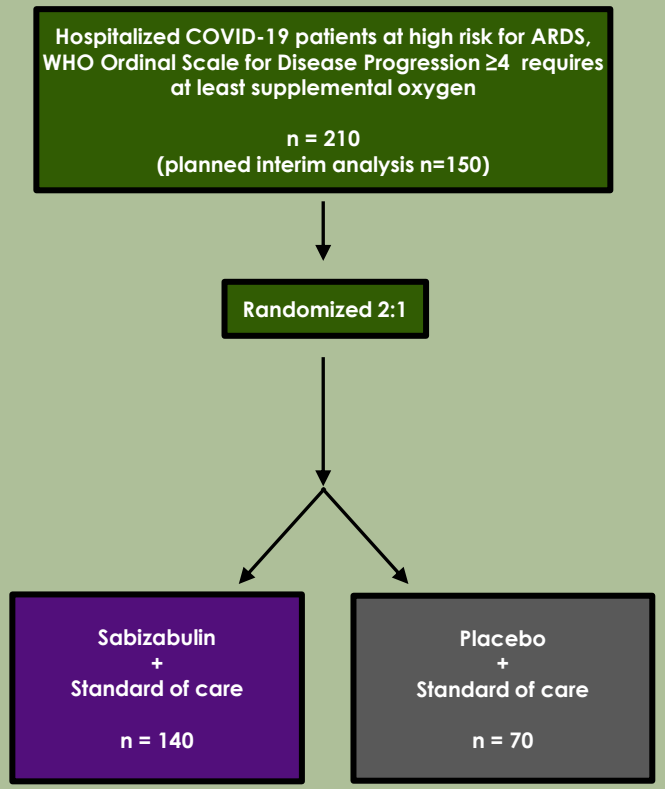
Safety

Preferred Term	Sabizabulin (n=19) N (%)/ events	Placebo (n=20) N (%)/events
Any	10 (52.6)/27	11 (55.0)/41
Constipation	2 (10.5)/2	2 (10.0)/2
Septic shock	1 (5.3)/1	2 (10.0)/2
Alanine aminotransferase increased	1 (5.3)/1	2 (10.0)/2
Aspartate aminotransferase increased	2 (10.5)/2	1 (5.0)/1
Acute kidney injury	0	2 (10.0)/2
Pneumomediastinum	0	2 (10.0)/2
Pneumothorax	1 (5.3)/1	3 (15.0)/3
Respiratory failure	0	4 (20.0)/4

Any adverse event that occurred in ≥ 2 patients on study

Double-Blind, Placebo-Controlled, Phase 3 Study of sabizabulin for the Treatment of in Hospitalized Moderate-Severe COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome – COMPLETED

- **Patients are hospitalized with moderate to severe COVID-19**
  - Key inclusion criteria: high risk for ARDS, hospitalized, WHO Ordinal Scale for Disease Progression ≥4 (requires supplemental oxygen), and oxygen saturation <94% on room air
  - Trial Size:
    - n=210 (2:1 randomization)
    - a=0.05 (two-sided)
    - Power = 92.8%
  - Planned Interim Analysis
    - n=150
    - **a=0.0160** (two-sided) – based on FDA accepted alpha spend
- **Treatment arms: Product sabizabulin 9 mg Capsule vs. Placebo**
  - All patients will be allowed standard of care on the study (Remdesivir/dexamethasone/IL6 receptor antibody/JAK inhibitors)
- **Dosing: daily dosing up to 21-days or until discharge from hospital**
- **Primary endpoint: proportion of patients who die prior to Day 60 (mortality)**
- **Key efficacy endpoints: mortality at Day 29, days in ICU, days on mechanical ventilation, days in the hospital, and viral load**



Phase 3 COVID-19 study interim analysis published in NEJM Evidence 7-6-2022

NEJM Evidence

Published July 6, 2022

DOI: 10.1056/EVIDoa2200145

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*

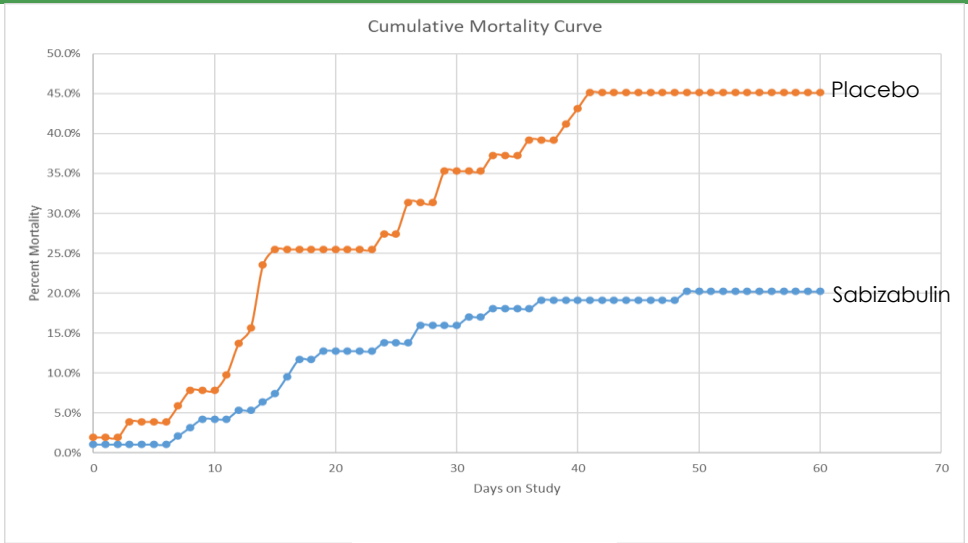
Sabizabulin: Phase 3 clinical trial – Demographics (interim analysis population)

		Sabizabulin	Placebo
Number of patients		N=98	N=52
Mean age (±SD)		59.4 (14.6)	60.3 (15.0)
Gender	Males (%)	70.4	63.5
	Females (%)	29.6	36.5
Mean WHO Score at baseline (±SD)		4.7 (0.55)	4.8 (0.65)
Vaccination Status	Not vaccinated (%)	54.1	57.7
	Vaccinated (%)	45.9	42.3
Standard of care treatment use on study	Dexamethasone	82.9%	80.4%
	Remdesivir	34.0%	29.4%
	Tocilizumab	7.1%	11.8%
	Baricitinib	3.9%	10.3%
	Tofacitinib	2.4%	1.5%

[1] Veru Inc, *Clinical Trial Protocol*, VERU-111 SARS-CoV-2 (April 2022)

Phase 3 COVID-19 clinical trial
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 evidence of clear benefit

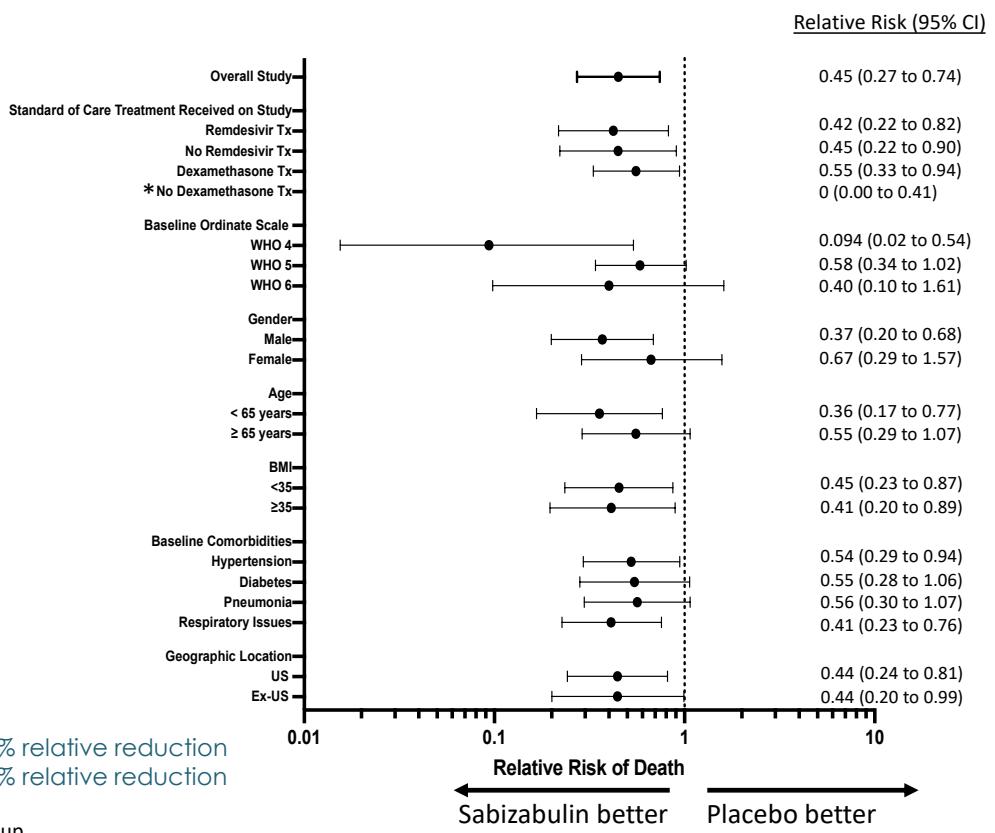


	Sabizabulin 9mg	Placebo	Relative Change	p-value (Fishers Exact)
Mortality Day 15	7/94 (7.4%)	13/51 (25.5%)	-71.0%	0.0046
Mortality Day 29	15/94 (16.0%)	18/51 (35.2%)	-54.5%	0.0122
Mortality Day 60	19/94 (20.2%)	23/51 (45.1%)	-55.2%	0.0022

	Odds Ratio	95% CI	p-value
Sabizabulin vs. Placebo Day 60	3.21	(1.45, 7.12)	0.0041*

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

Subgroup analyses of primary efficacy endpoint
Relative risk of death point estimate (95%CI)



Vaccinated YES: 34.8% relative reduction
Vaccinated NO: 61.8% relative reduction

*No deaths in the treated group

Phase 3 COVID-19 clinical trial
Key secondary endpoints

Days in the ICU

Treatment	Mean (days)	SD	Median (days)	Min,Max
Sabizabulin 9 mg (n=98)	17.4	23.93	4.0	0,60
Placebo (n=52)	30.8	27.83	17.0	0,60
Treatment Comparison	LS mean	SE	95% CI	p-value
Sabizabulin 9mg vs. Placebo	-13.4	4.09	(-21.5, - 5.3)	0.0013

Days on mechanical ventilation

Treatment	Mean (days)	SD	Median (days)	Min,Max
Sabizabulin 9 mg (n=98)	14.4	24.01	0	0,60
Placebo (n=52)	28.5	29.31	11.0	0,60
Treatment Comparison	LS mean	SE	95% CI	p-value
Sabizabulin 9mg vs. Placebo	-14.1	4.28	(-22.5, -5.6)	0.0013

Days in the hospital

Treatment	Mean (days)	SD	Median (days)	Min,Max
Sabizabulin 9 mg (n=98)	25.6	22.87	14.0	0,60
Placebo (n=52)	34.6	24.63	30.5	0,60
Treatment Comparison	LS mean	SE	95% CI	p-value
Sabizabulin 9mg vs. Placebo	-8.4	3.76	(-15.8, -0.9)	0.0277

Safety outcomes Phase 3 clinical trial for ITT population
Adverse Events

Safety - AEs

- There is no imbalance against sabizabulin in adverse events observed in the study
- The proportion of patients that experience any AE was 22% higher in the placebo group compared to the sabizabulin treated group.

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

	Sabizabulin (N=130) N (%) / Events	Placebo (N=69) N (%) / Events
Any	80 (61.5) / 341	54 (78.3) / 285
Atrial fibrillation	6 (4.6) / 6	4 (5.8) / 4
Bradycardia	5 (3.8) / 6	5 (7.2) / 5
Constipation	8 (6.2) / 8	6 (8.7) / 10
Pneumonia	7 (5.4) / 11	8 (11.6) / 11
Pneumonia bacterial	1 (0.8) / 1	5 (7.2) / 5
Septic shock	2 (1.5) / 2	4 (5.8) / 4
Urinary tract infection	8 (6.2) / 8	1 (1.4) / 1
Hyperkalemia	5 (3.8) / 5	6 (8.7) / 7
Hypernatremia	6 (4.6) / 6	4 (5.8) / 4
Hypokalemia	5 (3.8) / 6	4 (5.8) / 4
Hypophosphatemia	2 (1.5) / 3	4 (5.8) / 5
Anxiety	3 (2.3) / 4	4 (5.8) / 4
Delirium	4 (3.1) / 4	4 (5.8) / 4
Acute kidney injury	11 (8.5) / 11	8 (11.6) / 8
Acute respiratory failure	8 (6.2) / 8	4 (5.8) / 4
Bronchitis chronic	2 (1.5) / 2	4 (5.8) / 4
Hypoxia	3 (2.3) / 4	4 (5.8) / 4
Pneumothorax	1 (0.8) / 1	7 (10.1) / 7
Respiratory failure	12 (9.2) / 13	12 (17.4) / 12
Hypotension	3 (2.3) / 3	8 (11.6) / 8

Safety outcomes Phase 3 clinical trial for ITT population
Serious Adverse Events

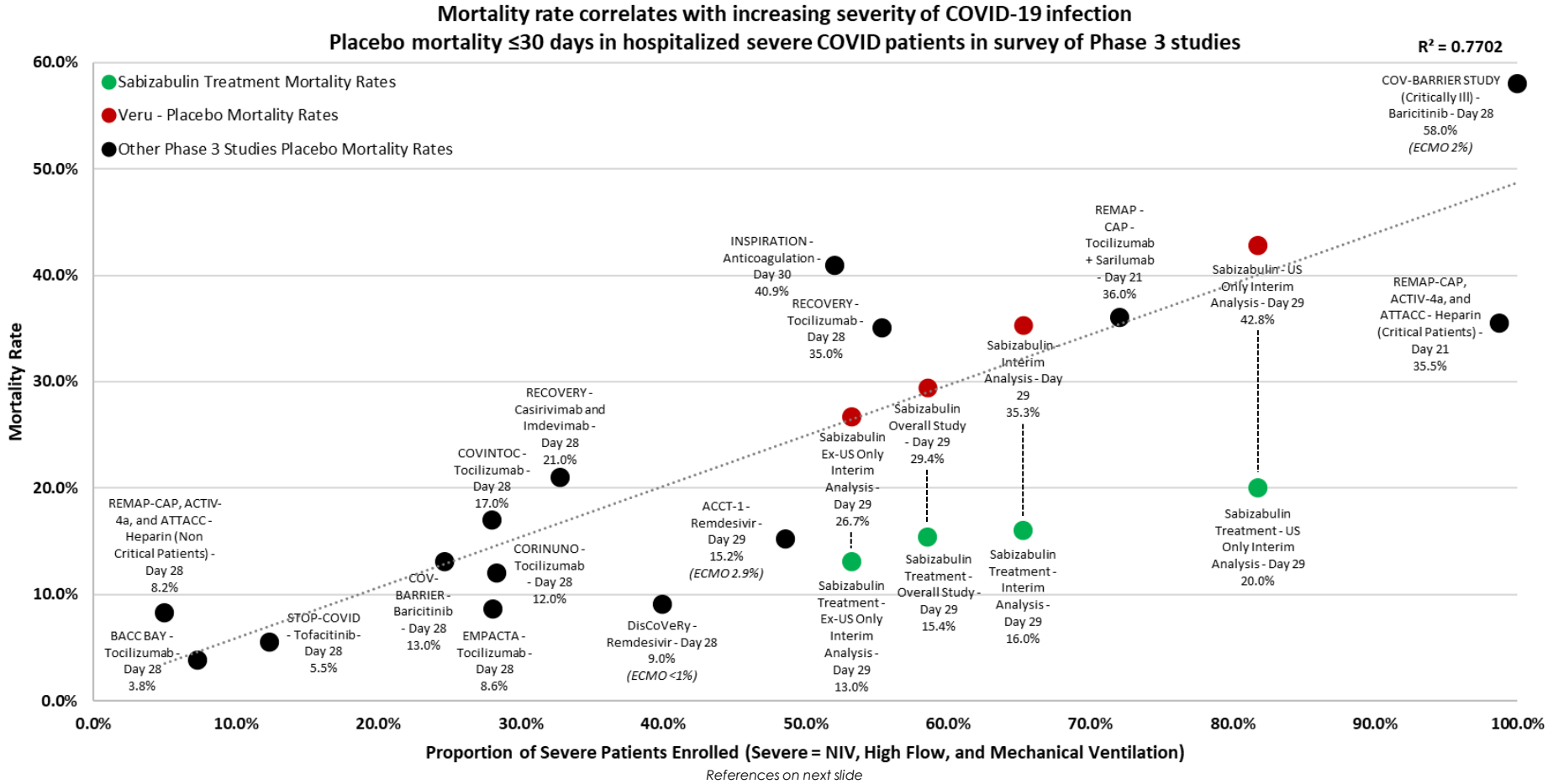
Safety - SAEs

- There is no imbalance against sabizabulin in serious adverse events observed in the study
- The proportion of patients that experienced any SAE was 37% higher in the placebo group compared to sabizabulin treated group

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) / 82	32 (46.4) / 84
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	3 (2.3) / 5	4 (5.8) / 5
Pneumonia bacterial	0	2 (2.9) / 2
Sepsis	3 (2.3) / 4	2 (2.9) / 2
Septic shock	2 (1.5) / 2	4 (5.8) / 4
Acute kidney injury	5 (3.8) / 5	6 (8.7) / 6
Acute respiratory failure	6 (4.6) / 6	4 (5.8) / 5
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	12 (9.2) /13	12 (17.4) /12

Placebo Mortality Rates by Proportion of Severe Patients Enrolled (Severe = NIV, High Flow, and Mechanical Ventilation) up to Day 30



References on next slide

References that detail patient composition to determine placebo mortality rates by proportion of severe patients enrolled

NIH Guidelines included trials	Citation
Veru - Overall Study Sabizabulin	Data on File at Veru
Veru - Full Interim Analysis Sabizabulin	Barnette, et al., Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis, The New England Journal of Medicine Evidence, July 2022, https://doi.org/10.1056/EVIDoa2200145
REMAP – CAP Tocilizumab + Sarilumab	The REMAP-CAP Investigators, Interleukin-6 Receptor Antagonists in Critically Ill Patients with Covid-19, The New England Journal of Medicine, April 2021, N Engl J Med 2021; 384:1491-1502, DOI: 10.1056/NEJMoa2100433
RECOVERY Tocilizumab	RECOVERY Collaborative Group, Tocilizumab in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial, The Lancet, May 2021, VOLUME 397, ISSUE 10285, P1637-1645, https://doi.org/10.1016/S0140-6736(21)00676-0
EMPACTA Tocilizumab	Salama, et al., Tocilizumab in Patients Hospitalized with Covid-19 Pneumonia, The New England Journal of Medicine, January 2021, N Engl J Med 2021; 384:20-30 DOI: 10.1056/NEJMoa2030340
COVINTOC Tocilizumab	Soin, et al., Tocilizumab plus standard care versus standard care in patients in India with moderate to severe COVID-19-associated cytokine release syndrome (COVINTOC): an open-label, multicentre, randomised, controlled, phase 3 trial, The Lancet, March 2021, VOLUME 9, ISSUE 5, P511-521, https://doi.org/10.1016/S2213-2600(21)00081-3
CORINUNO Tocilizumab	Hermine, et al., Effect of Tocilizumab vs Usual Care in Adults Hospitalized With COVID-19 and Moderate or Severe Pneumonia A Randomized Clinical Trial, JAMA Network, October 2020, JAMA Intern Med. 2021;181(1):32-40. doi:10.1001/jamainternmed.2020.6820
BACC BAY Tocilizumab	Stone, et al., Efficacy of Tocilizumab in Patients Hospitalized with Covid-19, The New England Journal of Medicine, December 2020, N Engl J Med 2020; 383:2333-2344 DOI: 10.1056/NEJMoa2028836
COV-BARRIER Baricitinib	Marconi, et al., Efficacy and safety of baricitinib for the treatment of hospitalised adults with COVID-19 (COV-BARRIER): a randomised, double-blind, parallel-group, placebo-controlled phase 3 trial, The Lancet, December 2021, VOLUME 9, ISSUE 12, P1407-1418, https://doi.org/10.1016/S2213-2600(21)00331-3
STOP-COVID Tofacitinib	Guimarães, et al., Tofacitinib in Patients Hospitalized with Covid-19 Pneumonia, The New England Journal of Medicine, July 2021, N Engl J Med 2021; 385:406-415 DOI: 10.1056/NEJMoa2101643
RECOVERY Casirivimab and Imdevimab	RECOVERY Collaborative Group, Casirivimab and imdevimab in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial, The Lancet, February 2022, VOLUME 399, ISSUE 10325, P665-676, DOI:https://doi.org/10.1016/S0140-6736(22)00163-5
ACCT-1 Remdesivir	Beigel, et al., Remdesivir for the Treatment of Covid-19 — Final Report, The New England Journal of Medicine, November 2020, N Engl J Med 2020; 383:1813-1826 DOI: 10.1056/NEJMoa2007764
REMAP-CAP, ACTIV-4a, and ATTACC Heparin	The REMAP-CAP, ACTIV-4a, and ATTACC Investigators, Therapeutic Anticoagulation with Heparin in Critically Ill Patients with Covid-19, The New England Journal of Medicine, August 2021, N Engl J Med 2021; 385:777-789 DOI: 10.1056/NEJMoa2103417
REMAP-CAP, ACTIV-4a, and ATTACC Heparin	The ATTACC, ACTIV-4a, and REMAP-CAP Investigators, Therapeutic Anticoagulation with Heparin in Noncritically Ill Patients with Covid-19, The New England Journal of Medicine, August 2021, N Engl J Med 2021; 385:790-802 DOI: 10.1056/NEJMoa2105911
DisCoVeRy Remdesivir	Ader, et al., Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomised, controlled, open-label trial, The Lancet, September 2021, VOLUME 22, ISSUE 2, P209-221, DOI:https://doi.org/10.1016/S1473-3099(21)00485-0
INSPIRATION Anticoagulation	INSPIRATION Investigators, Effect of Intermediate-Dose vs Standard-Dose Prophylactic Anticoagulation on Thrombotic Events, Extracorporeal Membrane Oxygenation Treatment, or Mortality Among Patients With COVID-19 Admitted to the Intensive Care Unit The INSPIRATION Randomized Clinical Trial, JAMA Network, March 2021, JAMA. 2021;325(16):1620-1630. doi:10.1001/jama.2021.4152
COV-BARRIER (Critically Ill) Baricitinib	Ely, et al., Efficacy and safety of baricitinib plus standard of care for the treatment of critically ill hospitalised adults with COVID-19 on invasive mechanical ventilation or extracorporeal membrane oxygenation: an exploratory, randomised, placebo-controlled trial, The Lancet, February 2022, VOLUME 10, ISSUE 4, P327-336, DOI:https://doi.org/10.1016/S2213-2600(22)00006-6

Regulatory status
Indication: Hospitalized moderate to severe COVID-19 patients at risk for ARDS

- **5/10/22 - Had pre-EUA meeting with US FDA based on current Phase 2 and Phase 3 clinical trials. Positive meeting and FDA agreed on the following:**
  - Efficacy
    - No additional efficacy studies are required to support Request for EUA or for full NDA
  - Safety
    - Current safety data available for sabizabulin is sufficient to support a Request for EUA submission.
    - Additional safety data collected during use of sabizabulin under EUA will be sufficient to support NDA.
    - No additional clinical safety studies are required

- **Emergency Use Authorization requested US FDA June 2022**
- **Triggered Article 18 of Emergency Task Force of EMA July 2022**
- **COVID-19 Task Force to support expedited review by MHRH July 2022**

Commercial activities for sabizabulin

- United States
  - Infectious Disease Franchise formed under Joel Batten's leadership
  - Having discussions with various agencies including CMS and BARDA to secure reimbursement if FDA grants EUA
- Ex- US
  - Veru has initiated regulatory discussions in Europe, Great Britain, and other countries
  - Veru is established a Veru European Infectious Disease Franchise
  - Veru has initiated discussion with potential distribution partners for outside the US
- Expect adequate commercial drug to supply the US and then rest of world when Regulatory authorization and approvals are gained

AT RISK POPULATION - Hospitalized COVID-19 patients on oxygen at high risk for ARDS/death

Assumptions:

- Hospitalized patients with COVID-19 on at least supplemental oxygen
- United States only
- No new surges
- May treat up to 21 days
- Hospitalization rate is 5948 new admissions/day[1]
- WHO 4 (on oxygen) or greater is 52% of hospitalizations[2]
- Target population 5948 X 0.52 X 7days= 21,650 patients/week

• Hospitalization-based model: Hospitalizations at risk population:

- 48,556 patients/month
- 631,248 patients/year

[1] https:www.cdc.gov/covid-data-tracker ; [2] https://www.theatlantic.com/health/archive/2021/09/covid-hospitalization-numbers-can-be-misleading/620062.

Sabizabulin manufacturing capacity

- **Manufacturing of sabizabulin and finished product to supply the US and then rest of world when Regulatory authorization and approvals are gained**
  - Drug available to treat patients
    - July 2022 ≈ 57,000 patients
    - August 2022 ≈ 100,000 patients
    - September and then every 30 days ≈ 250,000 patients/month
- **If no surge, would expect to treat 48,556 patients/month in US**

Coronavirus wave this fall could infect 100 million, administration warns

The projections for fall and winter are part of a pitch for additional funding for vaccines, treatments and tests

By Yasmeen Abutaleb and Joel Achenbach

May 6, 2022 at 6:51 p.m. EDT

100,000,000 new cases fall and winter = 1,200,000 deaths[1]

Sabizabulin treatment would prevent 660,000 deaths

[1]COVID-19 Tracker (covid.cdc.gov) historical death rate/cases =1.2%

Coronavirus pandemic is in its 3rd year: society fears death from COVID-19
Sabizabulin treats patients who have the highest risk of dying from COVID-19

OUT of hospital: general population

IN hospital:
Reduce the death rate for COVID-19 patients at the last opportunity to do so!

Prevent COVID-19

COVID-19 testing

Vaccines

Treat mild-moderate COVID-19

Antivirals

PAXLOVID and Molnupiravir

Treatment window:
Symptoms less than 5 days

Treat moderate-severe COVID-19

Dual antiviral & anti-inflammatory agent

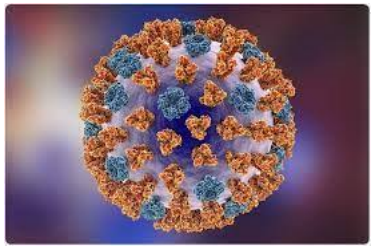
Sabizabulin

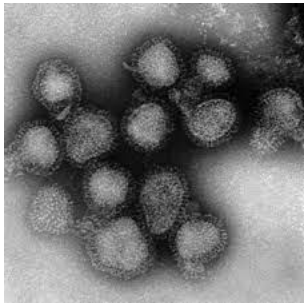
Dexamethasone

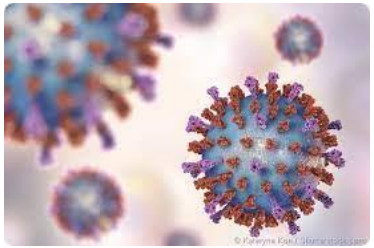
Antiviral
Remdesivir

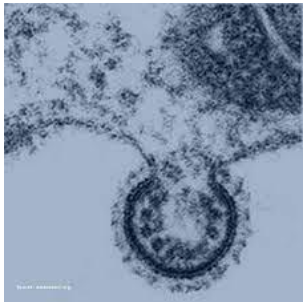
Supportive care

Possible additional indications for sabizabulin (broad spectrum anti-viral and anti-inflammatory agent) for ARDS









Each year in the United States, Influenza leads to:

CDC 2022

Each year in the United States, RSV leads, on average:

- 2.1 million outpatient visits among children younger than 5 years old
- 58,000 hospitalizations among children younger than 5 years old
- 177,000 hospitalizations among adults 65 years and older
- 14,000 deaths among adults 65 years and older

Clinical development plan for sabizabulin against ARDS

- **V3011903 - Phase 3, Randomized, Placebo-Controlled, Efficacy and Safety Study of Sabizabulin for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Hospitalized Patients who are WHO 3 Regardless of Presence of a Comorbidity or WHO 4 (supplemental oxygen) Without a Comorbidity**

- **V3011904 - Phase 3, Randomized, Placebo-Controlled, Efficacy and Safety Study of Sabizabulin for the Treatment of Hospitalized Patients with Acute Respiratory Distress Syndrome**

- **V2011905 – Safety and Pharmacokinetic Assessment of Sabizabulin in Hospitalized Pediatric Patients with COVID-19 at High Risk for Acute Respiratory Distress Syndrome**

CDC 2022

Breast Cancer – Novel Medicines

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Breast Cancer						
Enobosarm	Selective androgen receptor targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	Phase 3 ARTEST: 210 Patients *Fast Track Designation* — Ongoing			
Sabizabulin	Oral targeted cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)	Phase 2b: up to 200 Patients — Planned			
Enobosarm + abemaciclib combination (Lilly)	Selective androgen receptor agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	Phase 3 ENABLAR-2: 186 Patients *Lilly clinical collaboration and supply agreement* — Ongoing			
Sabizabulin + enobosarm	Oral targeted cytoskeleton disruptor + Selective androgen receptor targeting agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	Phase 2b: 111 Patients — Planned			

Phase 3 registration, open label, randomized ARTEST clinical trial (V3002401)(NCT#04869943) 3rd line metastatic setting – AR staining ≥ 40%- enrolling

ARTEST Clinical Trial Design

Designated Fast Track program by FDA

Phase 3 open label, multicenter, multinational, randomized, active control pivotal study evaluating the efficacy and safety of enobosarm 9mg oral daily dose versus active control (exemestane ± everolimus or a SERM) in metastatic AR+ ER+ HER2- breast cancer in subjects who have progressed on nonsteroidal aromatase inhibitor, fulvestrant, and CDK4/6 inhibitor therapy (3rd line metastatic setting)

ARTEST Patient Population

- AR+ ER+ HER2-metastatic breast cancer, not amenable to curative treatment by surgery or radiotherapy, with objective evidence of disease progression
- Must have had received a nonsteroidal AI inhibitor, fulvestrant, and CDK 4/6 inhibitor for metastatic disease
  - Previously responded to hormone Tx for metastatic disease ≥ 6 months
  - Only one prior chemotherapy for the treatment of metastatic breast cancer is permitted
  - Centrally confirmed ≥ 40% AR nuclei staining from breast cancer sample

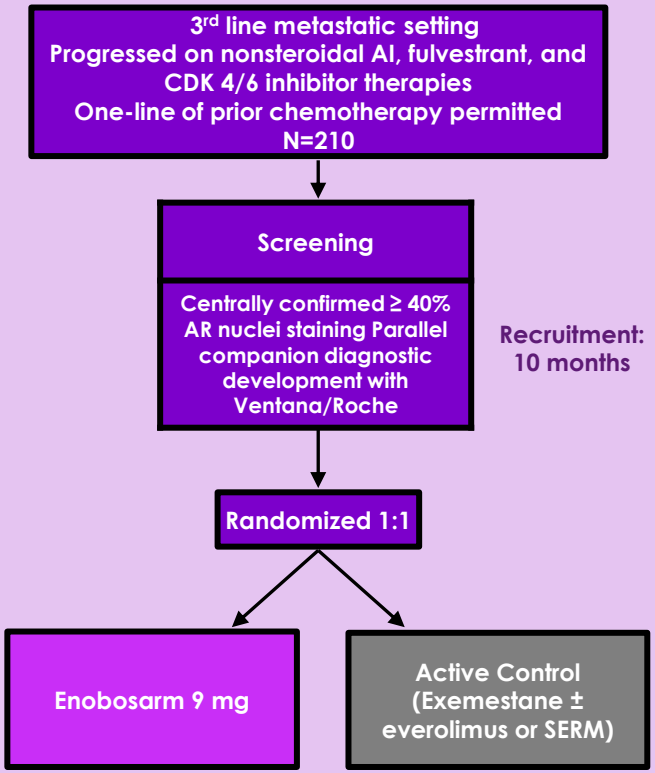
ARTEST Efficacy Endpoints

- Primary endpoint:
  - Median radiographic progression free survival (rPFS)
- Secondary endpoints:
  - Overall response rate (CR+PR)
  - Duration of response
  - Overall survival
  - Change in Short Physical Performance Battery (SPPB)
  - Change in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ)

ARTEST Sample Size Assumptions

- Total sample size: 210
- α = 0.05
- 99% power
- 20% drop out rate
- 123 events
- Active control group (exemestane± everolimus or a SERM): estimated median rPFS = 3 months[1-3]
- Enobosarm arm: estimated median rPFS=6 months

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



[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

Phase 3 (V2000701) ENABLAR-2 study- 2nd line metastatic setting- AR staining ≥ 40%

Open label, dose finding, efficacy and safety of CDK4/6 inhibitor (abemaciclib) + enobosarm 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, CDK 4/6 inhibitor + Enobosarm

Control Group

Alternative estrogen blocking agent*

Entered into clinical collaboration and supply agreement with Lilly February 2022

- **Primary endpoint**
  - Median radiographic progression free survival (rPFS) in subjects with ≥ 40% AR staining
- **Key Secondary endpoints:**
  - Overall response rate (CR+PR)
  - Change in Short Physical Performance Battery (SPPB)
  - DEXA- body composition muscle and bone

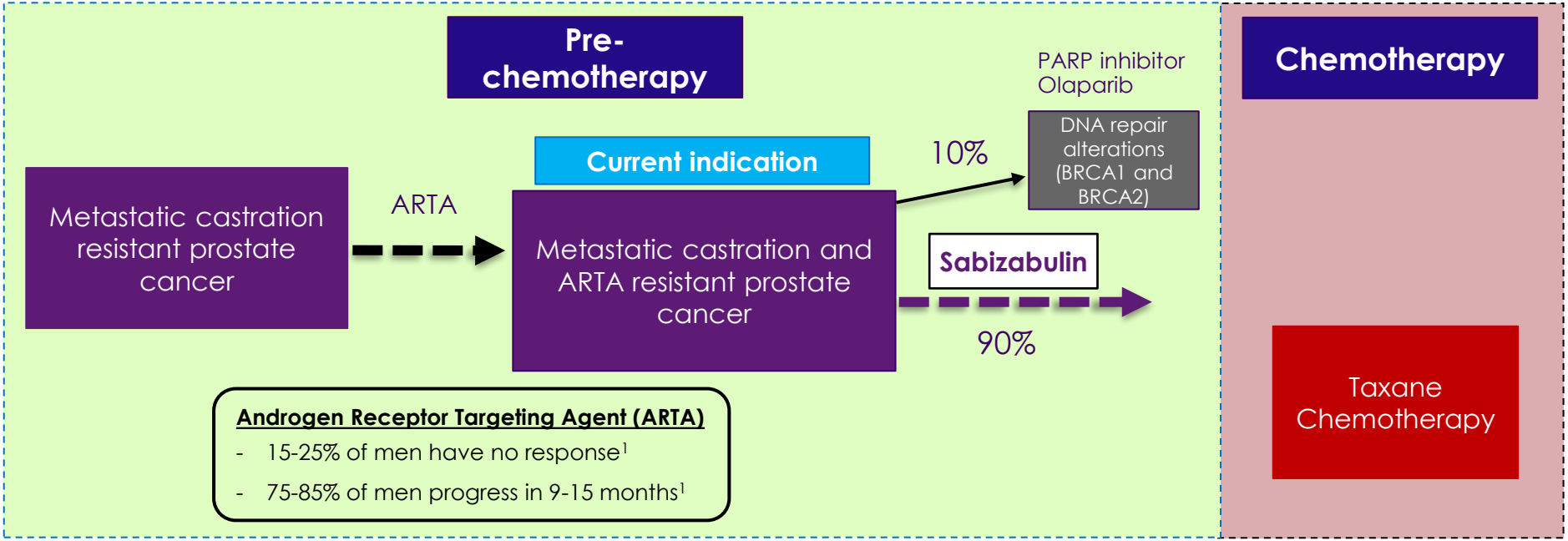
- **Statistical assumptions**
  - Total sample size: 180
  - $\alpha = 0.05$
  - 90% power
  - 37% drop out rate
  - 121 events
  - Control group estimated median rPFS=5 months[1]
  - Combo group: estimated median rPFS=9 months

[1] Ibrance FDA Package Insert (2019)

Prostate Cancer – Novel Medicines

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prostate Cancer						
Sabizabulin	Oral cytoskeleton disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV-chemotherapy	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			
Zuclomiphene citrate	Oral, non-steroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	Phase 2b → Planned			

Sabizabulin prostate cancer treatment paradigm:
Focus is on the prechemotherapy space which is a growing unmet need



Need for new safe and effective treatment alternatives with a distinct mechanism of action (non-AR dependent) and easy mode of administration remains an unmet need

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

Sabizabulin clinical development
Phase 1b (expansion cohort) and Phase 2 clinical study design-

Phase 1b- Dose escalation to evaluate safety of sabizabulin in men with metastatic castration resistant prostate cancer who progressed on AR targeting agent therapy and up to one taxane

- 7 US sites – Johns Hopkins Kimmel Comprehensive Cancer Center (lead center)
- 39 patients enrolled
- Trial design -2 part dosing schedule using standard 3+3 dose escalation strategy
    - Part 1- 7-day dose schedule to determine MTD – At each dose level, orally administered daily on Day 1-7 every 21 days (i.e. 7 days on, 14 days off)
    - Part 2- Expanded dose schedule – If 7-day dosing tolerated/safe, patients were eventually dosed daily until disease progression/toxicity

Phase 2- Evaluate safety and efficacy of sabizabulin RP2D 63mg daily in metastatic castration resistant prostate cancer who progressed on AR targeting agent therapy, but prior to IV chemotherapy

- 13 U.S. clinical centers
- 41 men enrolled
- Completed enrollment in September 2020
- Trial design
    - Open label
    - Recommended Phase 2 dose is 63mg/day
    - PK study to evaluate Phase 2 dosage versus Phase 3 dosage formulations

Phase 1b and 2 clinical studies
Baseline demographics

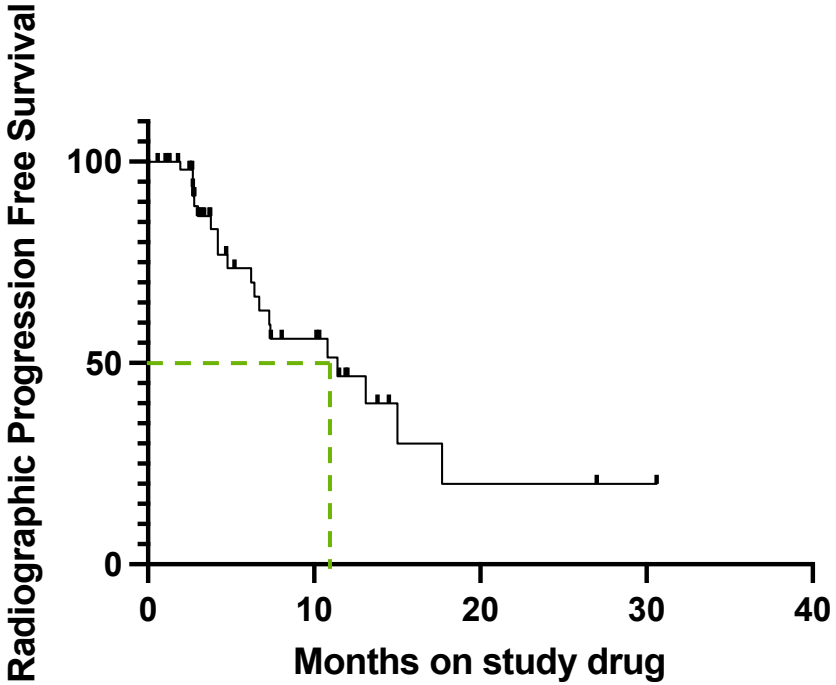
Characteristic	Phase 1b N=39	Phase 2 N=41
Age, years		
Median (range)	74 (61-92)	73 (57-86)
Race/Ethnicity, n (%)		
Caucasian	28 (72%)	31 (76%)
African American	8 (21%)	4 (10%)
Hispanic	3 (8%)	5 (12%)
Other	0	1 (2%)
ECOG performance status, n (%)		
0	21 (54%)	30 (73%)
1	16 (41%)	10 (24%)
2	2 (5%)	1 (2%)
Metastatic disease location		
Bone only	21 (55%)	24 (59%)
Lymph node only	6 (16%)	8 (20%)
Bone and lymph node	8 (21%)	7 (17%)
Visceral only	1 (3%)	0
Bone and visceral	1 (3%)	1 (2%)
Lymph node and visceral	0	1 (2%)
Prior therapies		
Abiraterone	14 (36%)	7 (17%)
Enzalutamide	8 (20%)	13 (32%)
Abiraterone and enzalutamide or apalutamide or proxalutamide	17 (44%)	14 (34%)
Apalutamide or proxalutamide	0	5 (12%)
Abiraterone and enzalutamide and apalutamide or proxalutamide	0	2 (5%)
Taxane	9 (23%)	3 (7%)

Sabizabulin clinical development
Efficacy- Phase 1b (expansion cohort) and Phase 2 study

Sabizabulin had evidence of significant and durable objective tumor responses- cytotoxic activity?	
In ITT population, all patients with measurable disease at baseline (n=29)	ORR (5PR +1CR observed): 20.7%[1]
All evaluable patients that would qualify for Phase 3 (n=26)	ORR: 23.1%[1]
In all patients[1] that received ≥ 63 mg (n=55)	Median rPFS is 11.4 months

[1]Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose as of February 2021 and had measurable disease

Radiographic progression free survival of combined Phase 1b/2 study at 63mg dose- cytostatic activity?



Median = 11.4 months
(95% C.I. 29.63-65.79)
n=55

All patients that received 63mg dose
Kaplan-Meier analysis of combined Phase 1b/2 study (63 mg/daily) (n-=55)
(20 events/35 censored, including 5 on study)

Sabizabulin clinical development
Safety- Phase 1b (expansion cohort) and Phase 2 clinical study

Most prevalent adverse events regardless of grade (>10% frequency) in patients that received 63 mg dose
N=54

Adverse Event	All Grades regardless of relationship to study drug	Grade ≥3 regardless of relationship to study drug
Diarrhea	32 (59.3%)	4 (7.4%)
Fatigue	18 (33.3%)	3 (5.6%)
Nausea	17 (31.5%)	1 (1.9%)
Decreased appetite	17 (31.5%)	0
Constipation	9 (16.7%)	0
ALT increased	10 (18.5%)	3 (5.6%)
AST increased	9 (16.7%)	2 (3.7%)
Back pain	8 (14.8%)	1 (1.9%)
Vomiting	7 (13.0%)	1 (1.9%)
Abdominal pain	6 (11.1%)	0
Dysgeusia	6 (11.1%)	0

Diarrhea was mostly (88%) grade 1 and 2 and medically manageable as only 1 patient discontinued clinical study because of this adverse event; expect this adverse event to be less in Phase 3 because of better oral bioavailability of Phase 3 dosage form and reduced exposure of GI tract to non-absorbed sabizabulin

At the recommended Phase 2 dose (RP2D) of 63 mg oral daily dose of sabizabulin

- Sabizabulin was well tolerated with no reports of clinically relevant neutropenia or neurotoxicity
- Adverse events were mostly grade 1 and 2[1]
- Safety profile appears similar as what is reported for an androgen receptor targeting agent
- Daily chronic drug administration is feasible and safe

[1] Combined Phase 1b/2 efficacy data in men who received sabizabulin 63mg dose

A Phase Ib/II Study of Sabizabulin, a Novel Oral Cytoskeleton Disruptor, in Men with Metastatic Castration-resistant Prostate Cancer with Progression on an Androgen Receptor–targeting Agent

Mark C. Markowski[1], Ronald Tutrone[2], Christopher Pieczonka[3], K. Gary Barnette[4], Robert H. Getzenberg[4], Domingo Rodriguez[4], Mitchell S. Steiner[4], Daniel R. Saltzstein[5], Mario A. Eisenberger[1], and Emmanuel S. Antonarakis[1]

ABSTRACT

Purpose: Sabizabulin, an oral cytoskeleton disruptor was tested in a phase Ib/II clinical study in men with metastatic castration-resistant prostate cancer (mCRPC).

Patients and Methods: The phase Ib portion utilized a 3+3 design with escalating daily oral doses of 4.5–81 mg and increasing schedule in 39 patients with mCRPC treated with one or more androgen receptor–targeting agents. Prior taxane chemotherapy was allowed. The phase II portion tested a daily dose of 63 mg in 41 patients with no prior chemotherapy. Efficacy was assessed using PCWG3 and RECIST 1.1 criteria.

Results: The MTD was not defined in the phase Ib and the recommended phase II dose was set at 63 mg/day. The most common adverse events (>10% frequency) at the 63 mg oral daily dosing (combined phase Ib/II data) were predominantly grade 1–2 events. Grade ≥3 events included diarrhea (7.4%), fatigue (5.6%), and alanine aminotransferase/aspartate aminotransferase elevations (5.6% and 3.7%, respectively). Neurotoxicity and neutropenia were not observed. Preliminary efficacy data in patients treated with ≥1 continuous cycle of 63 mg or higher included objective response rate in 6 of 29 (20.7%) patients with measurable disease (1 complete, 5 partial) and 14 of 48 (29.2%) patients had PSA declines. The Kaplan–Meier median radiographic progression-free survival was estimated to be 11.4 months ($n = 55$). Durable responses lasting >2.75 years were observed.

Conclusions: This clinical trial demonstrated that chronic oral daily dosing of sabizabulin has a favorable safety profile with preliminary antitumor activity. These data support the ongoing phase III VERACITY trial of sabizabulin in men with mCRPC.

Clin Cancer Res. 2022 Apr 13:clincanres.0162.2022. doi: 10.1158/1078-0432.CCR-22-0162. Online ahead of print.PMID: 35416959

Sabizabulin 1b/2 clinical development:
Conclusions

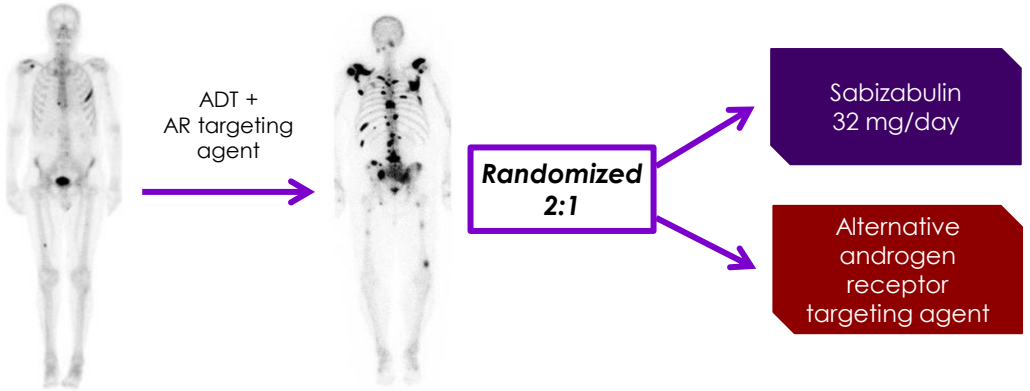
Sabizabulin was well tolerated with evidence of significant and durable objective tumor responses

- At the recommended Phase 2 dose (RP2D) of 63 mg oral daily dose of sabizabulin
  - Well tolerated with no reports of significant neutropenia or neurotoxicity
  - Daily chronic drug administration is feasible and safe
  - Safety profile appears similar to that reported in package inserts for an androgen receptor targeting agent
- Evidence of cytotoxic and cytostatic antitumor activity was observed including PSA reductions and objective and durable tumor responses (CR+PR)
- Based on this target product profile: may be potentially prescribed by both Urologists and Medical Oncologists

Phase 3 VERACITY clinical trial (V3011102) (NCT#-04844749)
Enrolling in approximately 45 clinical sites

VERACITY - Randomized, Active-Controlled, Open label Phase 3 Study of Sabizabulin 32 mg for the Treatment of Metastatic Castration-Resistant Prostate Cancer in Patients Whose Prior Treatment Progressed on at Least One Androgen Receptor Targeting Agent – Lead PI – Robert Dreicer, MD, University of Virginia

- **Efficacy endpoints**
  - Primary endpoints
    - Radiographic progression free survival (rPFS)
  - Secondary endpoints
    - Objective response rate
    - Duration of objective response
    - OS (interim analysis)
    - Time to IV chemo
    - Pain progression
- **Assumptions**
  - Median rPFS- 7.4 months for sabizabulin vs 3.7 months for alternative AR targeting agent*
  - Sample size - 245 men
    - 2:1 randomization
    - 155 events expected
    - a = 0.05
    - 98% power
    - Drop out= 30%
    - 10 months recruitment time, 12 month follow up after last patient first dose



*Based on Olaparib study[1] and CARD study[2] an alternative androgen receptor targeting agent is expected to have a median rPFS of 3.6-3.7 months in this similar population

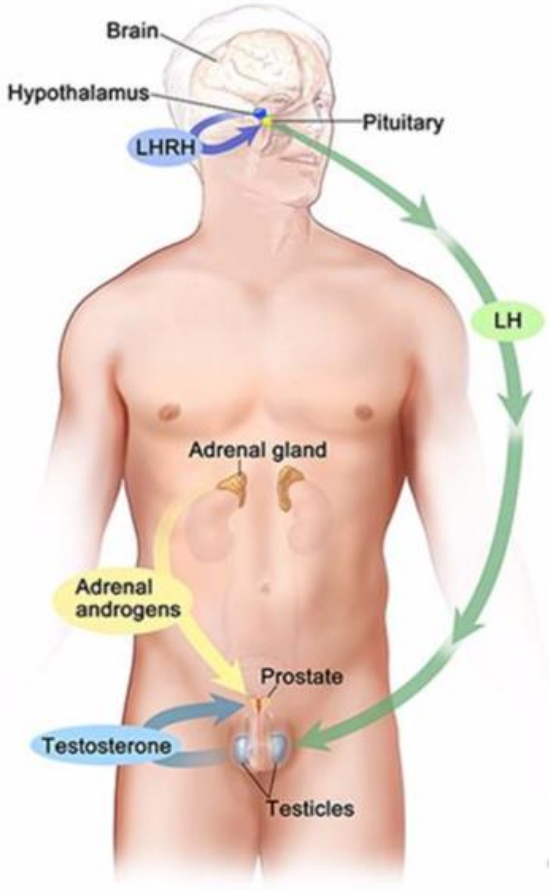
[1] de Bono J et al. NEJM April 28,2020 | [2] de Wit R et al. NEJM 381:2506-18 2019

Quest for a better androgen deprivation therapy: VERU-100
Current commercial limitations

LHRH agonist

Long-acting products: LUPRON® Depot (IM) and ELIGARD® (SC) are leuprolide products

- Concerns over initial surge in T levels- "T surge"
- Escapes from castration T levels – periodic increases in T levels[1]
- Up to 17% of men do not achieve castration[1]
- Does not suppress FSH
- Black box warning for cardiovascular safety concerns



GnRH antagonist

FIRMAGON® (degarelix) (SC)

- Painful subcutaneous injections: large loading and maintenance doses
  - Loading 6mL (2 X 3 mL)
  - Maintenance 4 mL
- No long acting depot available
- Must be given every month

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

New potential product to addresses limitations of current ADT
Long-acting 3 month depot GnRH antagonist may provide better alternative

VERU-100 target product profile[1]

- Novel proprietary GnRH antagonist decapeptide delivery formulation
- 3-month slow release subQ depot with no loading dose
  - Better compliance
  - Injectable delivery formulation is consistent with current medical practice patient visit schedule and billing/reimbursement procedures (Medicare Part B)
- Better castration
  - Immediate testosterone suppression no initial testosterone surge
  - Suppression of testosterone to less than 20ng/dL
  - Fewer testosterone escapes (micro-increases in testosterone)
- No black box warning for cardiovascular adverse effects for this class of drugs

Phase 2

Open label, dose finding VERU-100 GnRH antagonist long acting 3-month depot clinical trial

2 Optimized formulations will be released in June 2022 and patients will be dosed early July 2022

Planned Phase 3 (1H 2022)

Open label, VERU-100 GnRH antagonist long acting 3-month depot clinical trial

N=100 subjects for 1 year

[1]Developed in collaboration with Drug Delivery Experts, LLC (San Diego, California)

veru

ENTADFI®
(tadalafil and finasteride)
capsules

UREV
Sexual Health Division

ENTADFI™ capsule (finasteride and tadalafil), a new treatment for BPH with low potential for adverse sexual side effects, approved in 12/2021[1-3]

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

US and global markets expected to be >$200 million

Company has partnered with GoodRx and plans to launch product in August 2022 through telemedicine and 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.

FC2® Female Condom (internal condom) business

UREV
Sexual Health

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

Rapidly growing US prescription business for high margin revenues

Prescription business is growing:

- Existing and anticipated new contracts with additional telemedicine and internet pharmacy partners
- **Established a direct to patient telemedicine and pharmacy services portal**

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 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 2022 Results of operations	
FYTD 2022 Net Revenues	$ 27.2 mm
FYTD 2022 Gross Profit	$ 23.0 mm
FYTD 2022 Operating Loss	$ (16.7) mm

Veru – Q2 FY 2022 Results of operations	
Q2 FY 2022 Net Revenues	$ 13.0 mm
Q2 FY 2022 Gross Profit	$ 11.2 mm
Q2 FY 2022 Operating Loss	$ (11.8) mm

Veru – Balance Sheet as of March 31, 2022	
Cash	$ 112.0 mm
Receivables	$ 8.1 mm
PREBOOST Payment Due	$ 2.5 mm[2]
US/UK NOL carryforward	$ 38.6/$63.5 mm
Common Shares Outstanding[1]	~ 80.1 mm

Record revenue
FY 2021
$61.3 million

Veru closes public offering of $115 million in February 2021[3,4]

PREBOOST sale for $20 million[2]

[1] An aggregate of 13.0 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 80.1 million common shares above
[2] PREBOOST sale was $15 million in cash and $2.5 million in receivables at 12 months and $2.5 million in receivables at 18 months
[3] Cash received from the public offering, net of underwriting discounts and commissions, was $108.1 million
[4] Veru issued 7,419,354 shares of common stock in the public offering

Milestones

Program	Mechanism	Indication	2021	2022	2023	2024
Breast Cancer						
Enobosarm	Selective androgen receptor targeting agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	Phase 3 FPI		Phase 3 data	NDA
			Phase 3 ARTEST study – Fast Track			
Sabizabulin 32 mg	Oral cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)	Planned			
Enobosarm + abemaciclib combination	Selective androgen receptor targeting agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	Lilly clinical collaboration and supply agreement			
				Phase 3 Initiation		Phase 3 data
			Phase 3 ENABLAR-2 study			
Sabizabulin + enobosarm	Oral cytoskeleton disruptor + Selective androgen receptor targeting agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	Planned			
Prostate Cancer						
Sabizabulin 32 mg	Oral targeted cytoskeleton disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV-chemo	Phase 3 FPI		Phase 3 data	NDA
			Phase 3 VERACITY study			
VERU-100	Long-acting GnRH antagonist peptide subcutaneous 3-month depot injection	Advanced hormone sensitive prostate cancer	Phase 2 FPI	Phase 2 data		
					Phase 3 Initiation	Phase 3 data
Zuclomiphene citrate	Oral, non-steroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	Planned			
Virology						
Sabizabulin 9 mg	Oral cytoskeleton disruptor	Hospitalized COVID-19 patients at high risk for ARDS	Phase 3 FPI	Phase 3 data	EUA/NDA	EUA submitted
			Phase 3 COVID study- Fast Track			