Veru Inc.
Nasdaq:VERU

Biopharmaceutical Company

Focused on Oncology and Viral Acute Respiratory Distress Syndrome

Veru Corporate Presentation
Cantor Fitzgerald Global Healthcare Conference
September 26-28, 2023

Forward looking statements and safe harbor

The statements in this release that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding: the planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company's current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 3 study of sabizabulin in adult hospitalized patients with ARDS, 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 or any other trial will occur and what the results of any such interim analyses will be; whether the results of any such interim analyses or any completed Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA for sabizabulin for any indication; 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, and when the Company might learn the results of any potential partnering efforts with BARDA; whether and how the Company will fund the planned Phase 3 studies of sabizabulin in influenza, pox virus, COVID-19 and ARDS; whether the current and future clinical development efforts of the Company, including all studies of sabizabulin in COVID-19, ARDS, smallpox or any other infectious disease indications or 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.

Pipeline - Oncology and infectious disease

Program	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3	
Breast Cancer – Phase 3 Studies							
Enobosarm +/- abemaciclib combination	Selective androgen receptor agonist + CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Phase 3 ENABLAR-2 - Active				*Clinical collaboration and supply agreement* Lilly *Fast Track Designation*
Infectious Disease- Viral Acute Respiratory Distress Syndrome							
Sabizabulin	Oral microtubule Disruptor: Antiviral and anti-inflammatory agent	Phase 3 (902) study- Hospitalized COVID-19 patients at high risk for ARDS	Completed Positive Phase 3				*Completed* *Fast Track Designation*
		Phase 3 (903) Confirmatory study- Hospitalized patients with viral pneumonia at high risk for ARDS	Confirmatory Phase 3				*Planned*
		Phase 3 (904) study- Hospitalized patients with viral ARDS	Phase 3				*FDA meeting September 2023*
		Smallpox virus	Animal Rule regulatory path				*Planned*

Enobosarm for ER+HER2- metastatic breast cancer

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

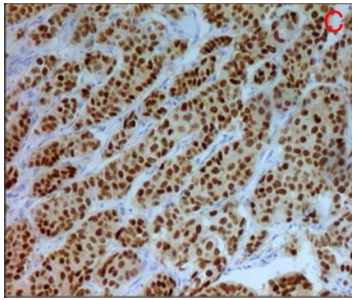
What is the androgen receptor's function in breast tissue?

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, steroidal androgens (fluoxymesterone) 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 [8, 9]

The development of novel strategies *to target, but 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.

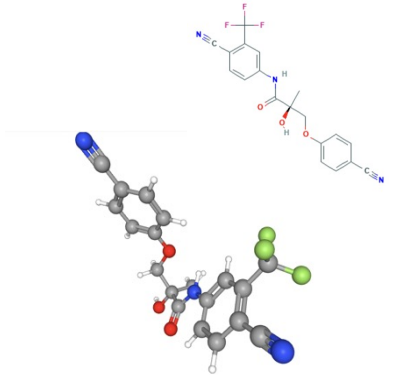
[1] Ponnusamy et al, iScience 21:341-358, 2019 | [2]Peters et al, Cancer Res 69: 6131-40, 2009 | [3]Hickey et al, Nature Medicine 2021 | [4]Moinfar et al, Cancer 98:703–11, 2003 | [5]Hu et al, Clin Cancer Res 17:1867–74, 2011| [6]Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | [7]Bronte et al, Trans Oncol 11: 950–956, 2018 | [8]Kono et al, Breast Cancer Res Treat 160:101-109, 2016 | [9] Tormey DC et al, Ann Intern Med 98:139-144, 1983 |

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[7,8]

[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 | [8]Ponnusamy et al, iScience 21:341-358, 2019

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

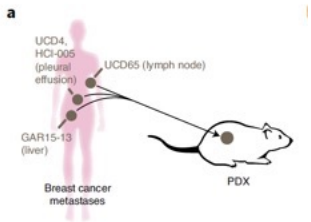
- QT – no QT effects
- Drug interactions- no significant drug-drug interactions
- Food effect- no food effect
- Renal impairment- no significant effects
- Hepatic impairment- no significant effects
- Major metabolites analysis and route of elimination- renal elimination and only metabolite is enobosarm glucuronide
- Cytochrome P450 3A4- enobosarm is not an inhibitor

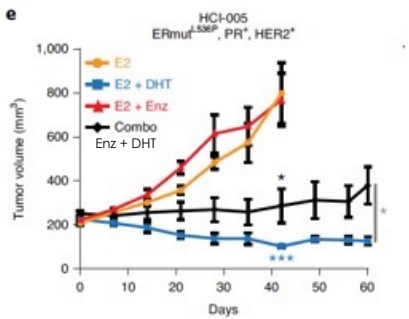
[1]Lee-Bitar JS et al J Clin Onco 37: supplement abstract 1069 2019 NCT02971761

AR antagonists have no efficacy against AR+ER+HER2- advanced breast cancer

No AR antagonist has been advanced to Phase 3 study in clinicaltrials.gov

Preclinical studies: AR antagonist does not suppress AR+ER+HER2- breast cancer PDX





E2= estradiol
Enz = enzalutamide is an AR antagonist
DHT = dihydrotestosterone is an AR agonist
PDX= Patient derived xenograft

AR antagonists studies in AR+ER+HER2- advanced breast cancer clinical trials

Trial	Ph	N	Prior lines	Efficacy	Safety	Reference
Bicalutamide and aromatase inhibitor in AR+ER+ HER2− metastatic breast cancer	2	18	1	ORR= 0 mPFS= 2.7 mon	Well tolerated	Lu et al. Oncologist 2020
Exemestane with or without enzalutamide in HR+ metastatic breast cancer (Randomized)	2	247	1	No statistically significant improvement in mPFS vs control	Grade 3/4- increase with enza	Krop et al. Clin Cancer Res 2020
Fulvestrant plus enzalutamide in ER+HER2− advanced breast cancer	2	32	7	ORR= 0 mPFS= 8 weeks	Grade 3- 9%	Elias et al. NPG Breast Cancer 2023

[1]Hickey et al, Nature Medicine 2021

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

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

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

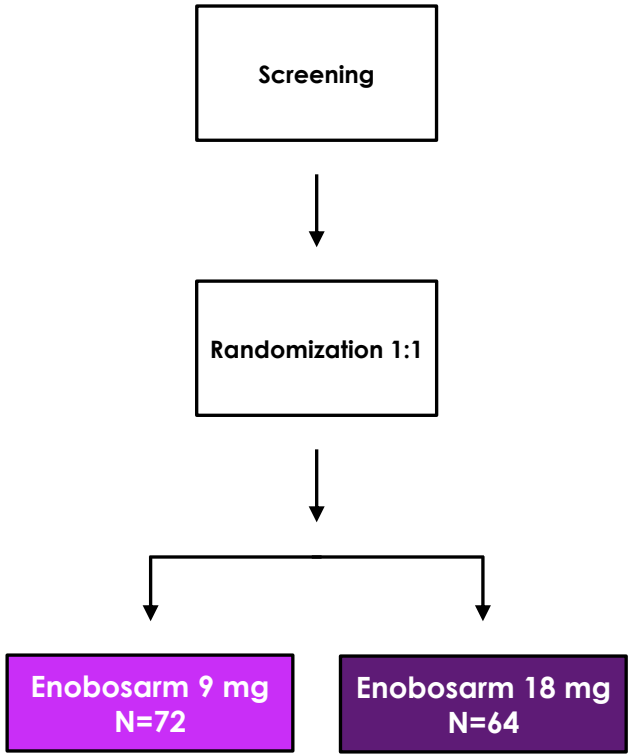
Clinical trial design – heavily pretreated population
Phase 2 (G200802)

Trial design

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

Patient population - 136 heavily pretreated women enrolled

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



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

Patient baseline demographics
Phase 2 (G200802)

Demographics	9 mg cohort	18 mg cohort
Age (median), years (range)	60.5 (35-83)	62.5 (42-81)
Initial presentation of Stage IV metastatic breast cancer	12%	26.9%
Median months since initial diagnosis (range)	110.0 (19-435)	86.0(15-323)
Median months since metastatic diagnosis (range)	34.3 (1-167)	27.4 (1-225)
Source of tissue AR primary/metastatic (%)	52/44	57.7/40.4
Median % of cells staining AR+ (range)	53.4 (11-96)	51.4 (14-98)
Bone only non-measurable (%)	38.0	32.7
Prior chemotherapy (%)	**90.0**	**92.3**
Median prior lines of endocrine therapy (range)	**3.2 (1-7)**	**3.2 (1-7)**

Overall safety and efficacy summary
Phase 2 (G200802)

Efficacy
- Evaluable population (AR+)

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

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

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

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

Phase 2 clinical trial (G200802)- overall Post-Hoc population analysis
Best objective tumor responses of target lesion central read by % AR nuclei staining

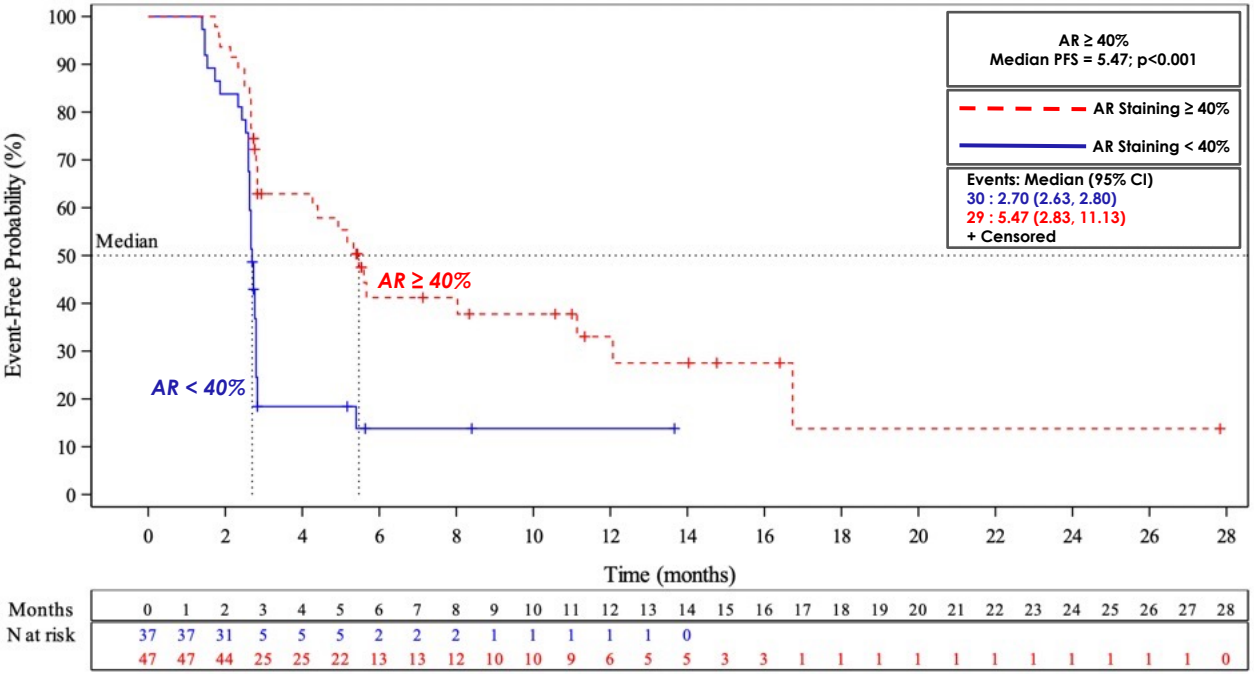
Table 2: G200802 Study – by AR nuclei staining both doses combined

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

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

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

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



Conclusions
Phase 2 (G200802)

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

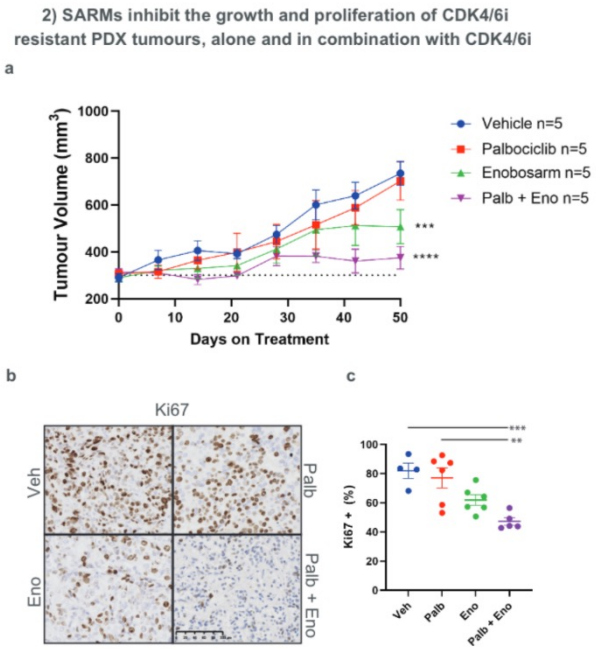
- Clinical benefit was demonstrated with objective tumor responses in women with heavily pretreated estrogen blocking agent resistant AR+ ER+ HER2- MBC
- Patients with androgen receptor expression of ≥ 40% are more likely to benefit from enobosarm
- Quality of life measurements demonstrated overall improvement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

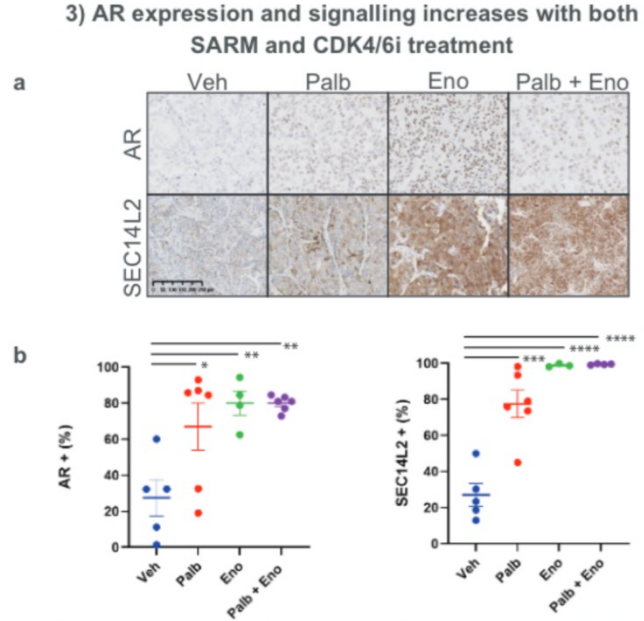
Enobosarm represents a different and new class of endocrine therapy in AR+ ER+ HER2- metastatic breast cancer

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

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

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

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

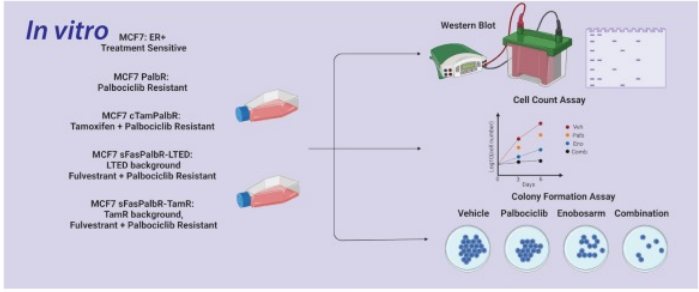
1. The Garvan Institute of Medical Research, Sydney, NSW 2010, Australia, 2. St. Vincent's Clinical School, Faculty of Medicine, UNSW Sydney, Sydney, NSW 2010, Australia, 3. Dame Roma Mitchell Cancer Research Laboratories, Adelaide Medical School, University of Adelaide, Adelaide, SA 5001, Australia.

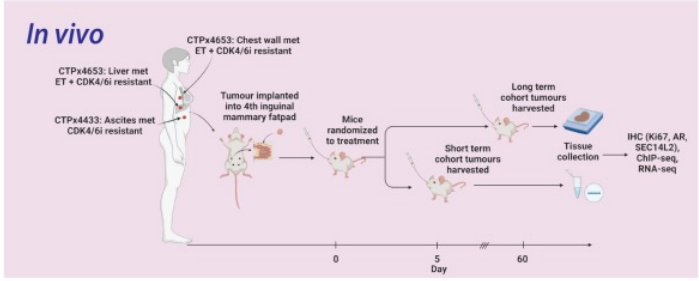
We hypothesised that AR agonism with a SARM or DHT, either alone or in combination with a CDK4/6i, would be an effective treatment for tumours that are resistant to ET and CDK4/6i. This was explored in two aims;

1) To assess the efficacy of combination AR agonist + CDK4/6i on the growth of ER+/AR+ CDK4/6i resistant model.

2) To investigate the effect of AR agonist and CDK4/6i on proliferation and hormone receptor signalling

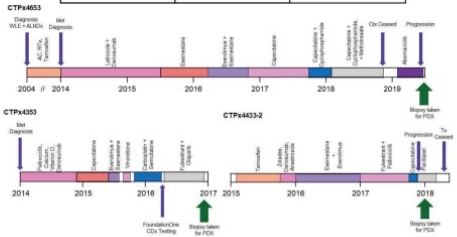
Materials and Methods





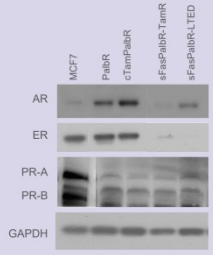
Patient History and Mutational Profile of PDX Models

CTPx4353	CTPx4653	CTPx4433
BRCA2, p.E3223fs *FAT1*, p.F2268fs *ESR1*, p.L539Q *CHECK2*, p.R535H *RUNX1*, p.S424A *CDK12*, p.S717R *APC*, p.L1129S	*RB1*, p.K8N *RUNX1*, p.S424A *PIK3CA*, p.E545K & p.E726K *ESR1*, p.E380Q *JAK2*, p.K167*	*NOTCH2*, p.G1143W *TP53*, p.Y163* *CHEK2*, p.R535H *PIK3CA*, p.H1047R



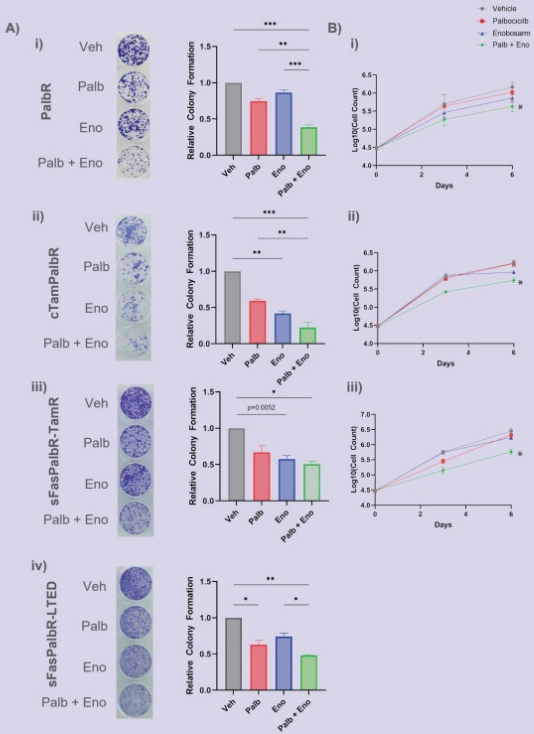
Results

1) CDK4/6i resistant ER+ breast cancer cell lines express key hormone receptors, including the AR



1 a) Western blot for key hormone receptors in MCF7 Parental, MCF7 PalbR, MCF7 cTamPalbR, MCF7 sFasPalbR-TamR and MCF7 sFasPalbR-LTED cells.

2) Combination AR agonist and CDK4/6i therapy suppresses the growth of CDK4/6i resistant cells *in vitro*



2. a) Colony forming assays of i) PalbR, ii) cTamPalbR, (iii) sFasPalbR-LTED, and (iv) sFasPalbR-TamR cells treated with vehicle, palbociclib, enobosarm and combination. Cells were treated for 9 days, then fixed in 0.05% crystal violet. b) Cell count assays of (i) PalbR, (ii) cTamPalbR, (iii) sFasPalbR-TamR cells. Cells were treated for 3 and 6 days, and cell number calculated by trypan blue. Error bars = mean ± sem;

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

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

Garvan Institute of Medical Research

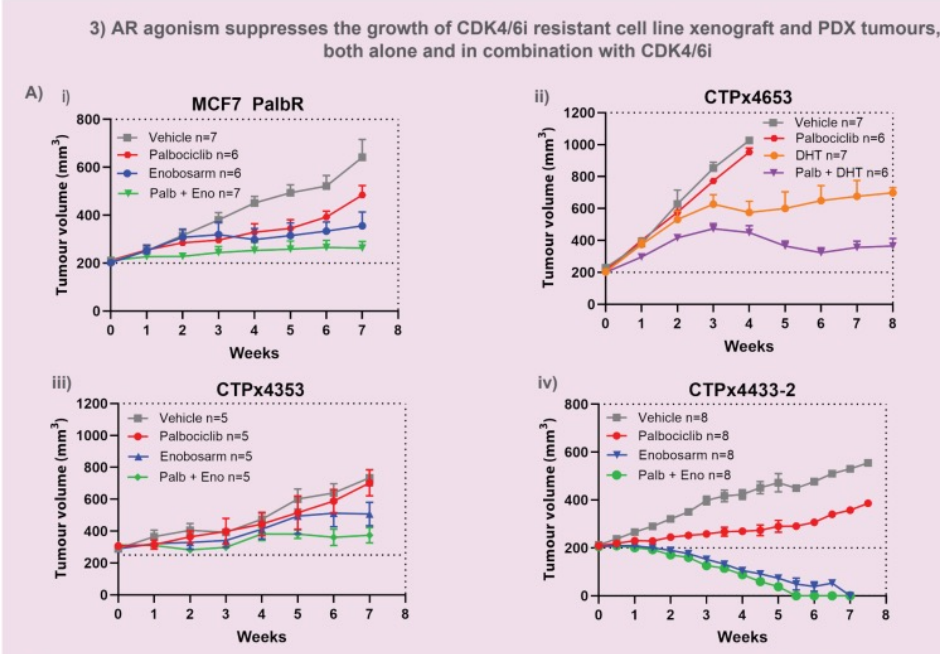
Selective Androgen Receptor Modulators in Combination with CDK4/6 Inhibitors Demonstrate Anti-cancer Activity in Preclinical Treatment Resistant ER+/AR+ Breast Cancer Models

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

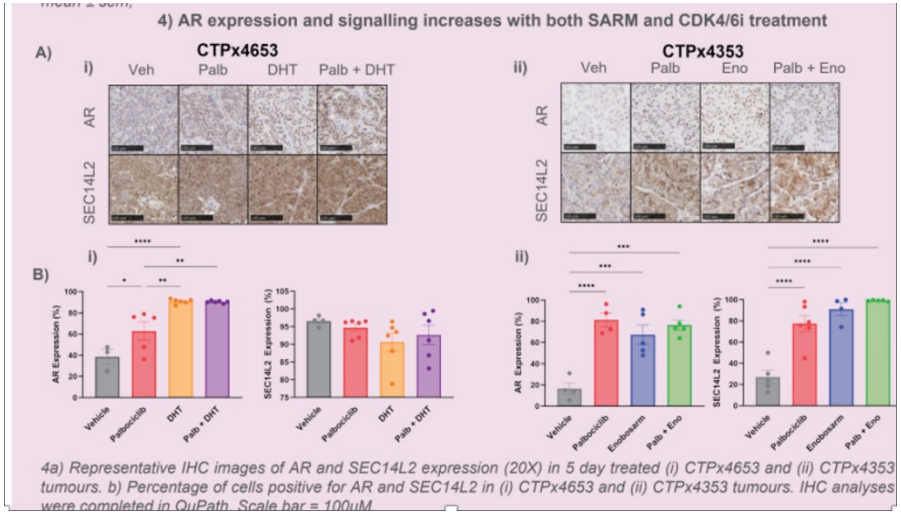
1. The Garvan Institute of Medical Research, Sydney, NSW 2010, Australia, 2. St. Vincent's Clinical School, Faculty of Medicine, UNSW Sydney, Sydney, NSW 2010, Australia, 3. Dame Roma Mitchell Cancer Research Laboratories, Adelaide Medical School, University of Adelaide, Adelaide, SA 5001, Australia.

UNSW SYDNEY

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



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



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

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

Objective tumor responses
- 30% overall

CBR at 24 weeks
- 50% overall

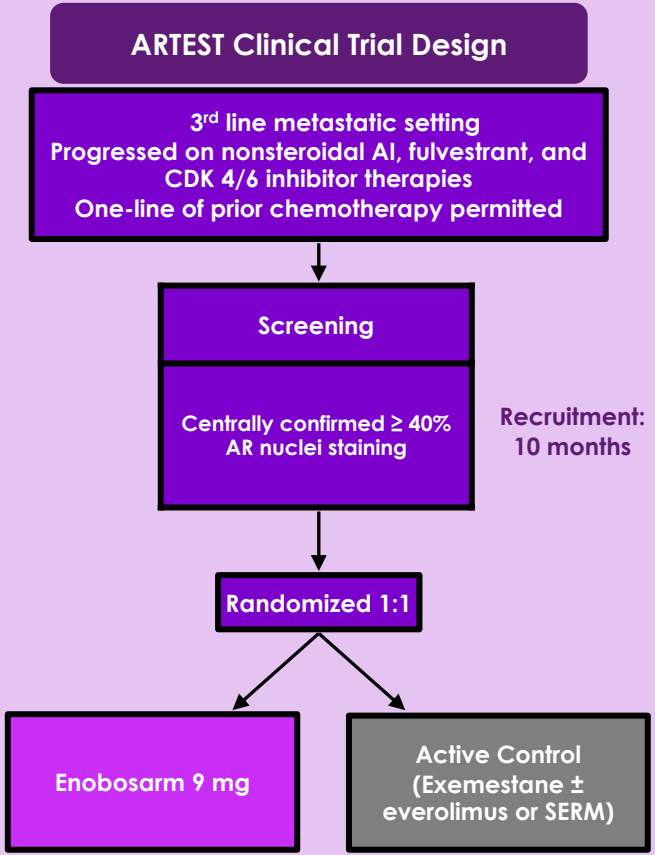
Mean duration on study (either PFS or censored)
- 7.3 months (9 mg and 18 mg groups)
- 10.0 months (9 mg dose group)

Palbociclib resistant subjects with measurable disease

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

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

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



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

Clinical results from discontinued ARTEST study

- **34 patients randomized**
  - Enobosarm monotherapy (n=16)
  - Standard of care therapy (n=18)
- **Prior lines of therapy**
  - Enobosarm monotherapy= 3.1 (range 2-5)
  - Standard of care active control= 2.8 (range 1-5)
  - On average, ARTEST patients receive 4th line therapy
- **Safety: enobosarm well tolerated without masculinizing adverse events and no hematocrit changes**

Efficacy (ORR)	Enobosarm monotherapy	SOC Active control
Evaluable patients	2 PR /16 (12.5%)	0 PR/18 (0%)
Evaluable patients - including an unconfirmed response	3 PR /16 (18.8%)	0 PR/18 (0%)
Patients with ≤3 lines of prior therapy	2 PR /10 (20.0%)	0 PR/15 (0%)
Patients with ≤3 lines of prior therapy with ≤1 prior treatment with CDK 4/6 inhibitor	2 PR /6 (33.3%)	0 PR/10 (0%)

Best ORR from central read or local read of target lesions

Summary of enobosarm clinical studies and tumor responses

Study	Cohort	N=	% ORR[1]	Dose
Phase 2 802 study	Multiple lines estrogen blocking agents and chemo	47	34%	Enobosarm 9mg or 18mg and > 40% AR staining
Phase 2 802 study subgroup	Multiple lines estrogen blocking agents, chemo, and CDK4/6 inhibitor	10	30%	Enobosarm 9mg or 18mg
Phase 3 ARTEST study[2]	≤3 lines of prior therapy + CDK 4/6 inhibitor	10	20%	Enobosarm 9mg
Phase 3 ENABLAR-2	2nd line metastatic after CDK 4/6 inhibitor	3	66%	Enobosarm 9mg + abemaciclib

[1]Best ORR from central read or local read of target lesions | [2]Patients remaining in discontinued study

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

CDK4/6 inhibitor resistance after first line metastatic Tx

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

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

Primary endpoint= ORR

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

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

Treatment group

Enobosarm +/- Abemaciclib

Control Group

Alternative estrogen blocking agent

Stage 2
1:1 rando
n =208

Entered into clinical collaboration and supply agreement with Lilly February 2022

Primary endpoint= PFS

Primary endpoint

- Median progression free survival (PFS)

Key Secondary endpoints:

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

Statistical assumptions

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

[1] Bidard F-C J Clin Onc 40:3246, 2022- estrogen blocking agent had ORR of 4.5 % and estimated median PFS=1.9-2.8 months in 2nd line metastatic setting following a CDK4/6 inhibitor and estrogen blocking agent

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

Stage 1 results

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

Patient 1 - On Study 9+ Months

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

Patient 2 – Progressed: On Study 10+ Months

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

Patient 3 - On Study 9+ Months

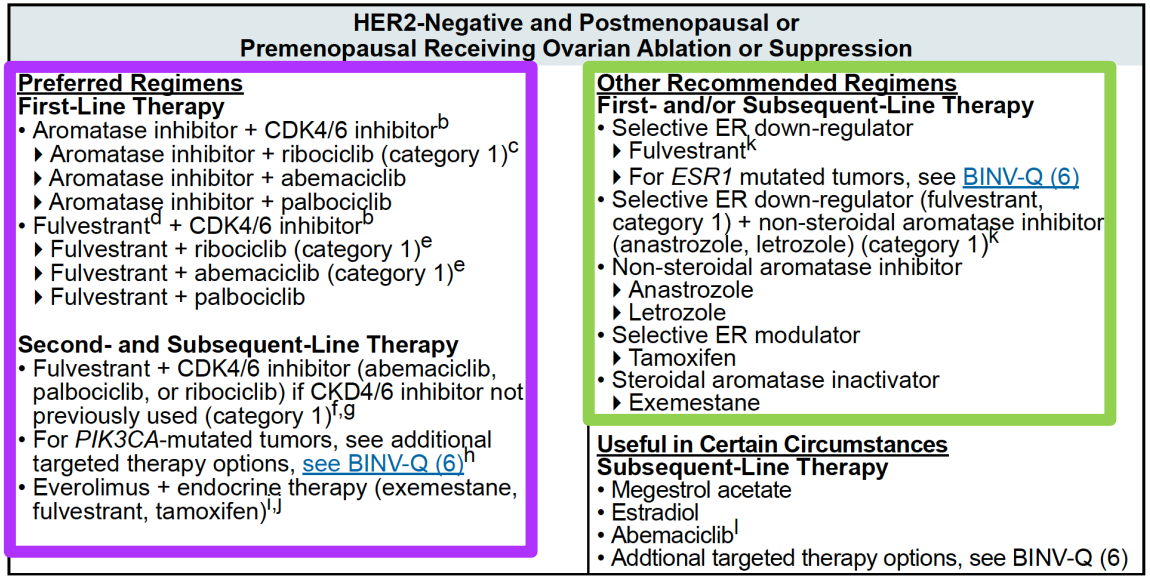
	Baseline 09/27/22	D56 12/9/22	D 112 2/1/23	D168 3/29/23	D224 5/22/23	D280 7/17/23
T1 - Liver	1.7	1.6	1.6	1.6	1.6	1.7
Total	1.7	1.6	1.6	1.6	1.6	1.6
Percent Change		-5%	-5%	-5%	-5%	0% (SD)

"Novel" Commercial opportunity as selective AR+ targeting agonist

NCCN guidelines- Systemic Tx for ER+HER2- metastatic disease[1]

CDK 4/6 inhibitor
+
Estrogen blocking agent

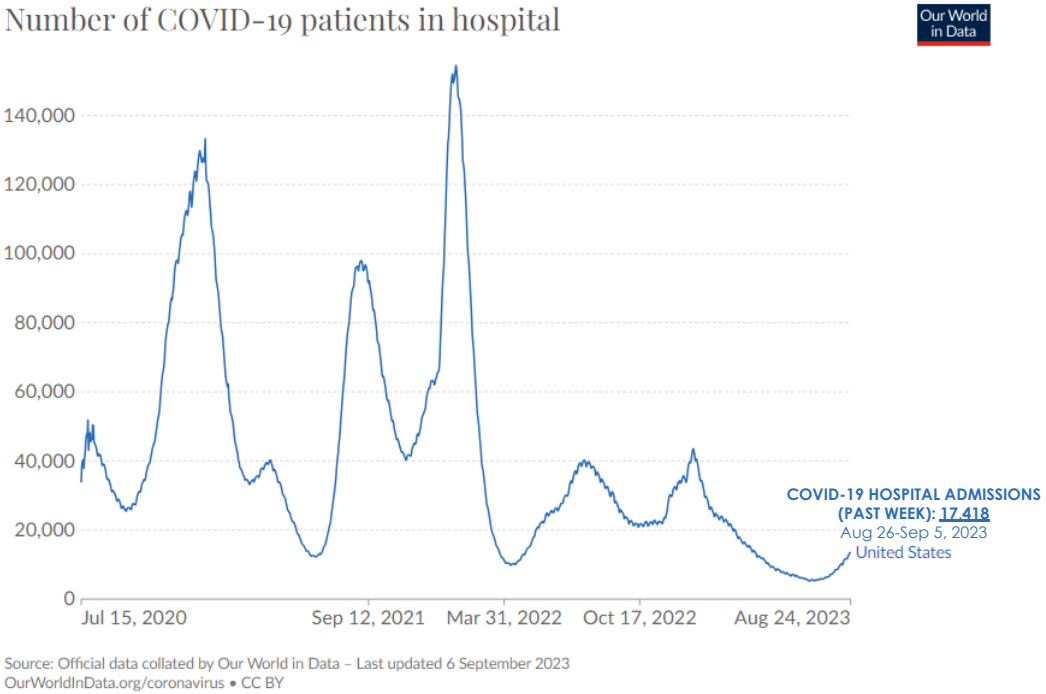
Estrogen blocking agent



Estrogen blocking agent

[1] NCCN Guidelines Breast Cancer V4.2023 March 2023

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



Hospitalizations

Hospital Admissions

17,418

(August 20 to August 26, 2023)

Trend in Hospital Admissions

+15.7% in most recent week

Jul 28, 2023 Aug 26, 2023

Deaths

% Due to COVID-19

2.0%

(August 20 to August 26, 2023)

Trend in % COVID-19 Deaths

+17.6% in most recent week

Jul 8, 2023 Aug 26, 2023

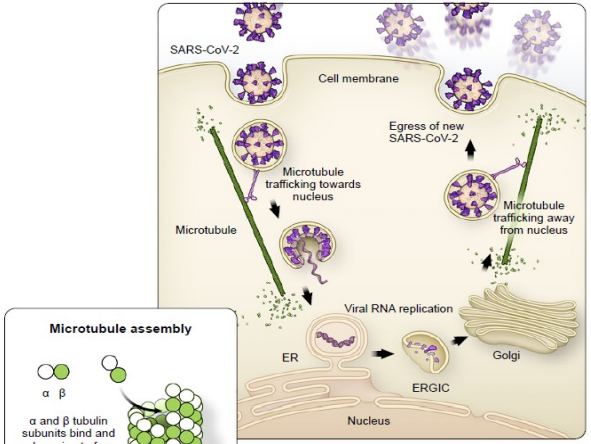
https://covid.cdc.gov/covid-data-tracker/#datatracker-home

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

Sabizabulin Mechanism of action

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

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



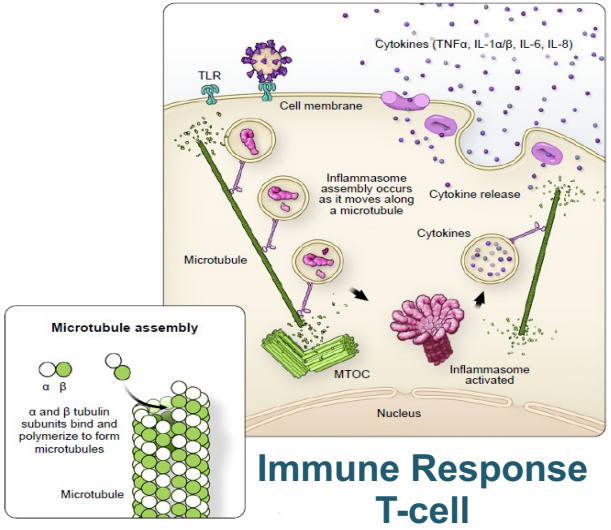
Viral Infection Lung cell

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

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

Sabizabulin Mechanism of action

- 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

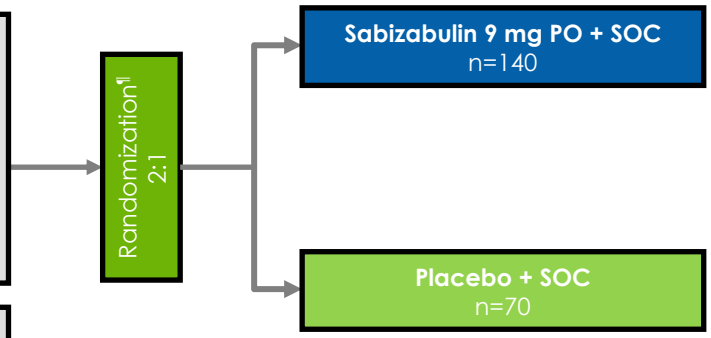
References: 1. Baggin J, et al. *Nat Microbiol*. 2021;6:1219-1232| 2. V'kovski P, et al. *Nat Rev Microbiol*. 2021;19(3):155-170| 3. Bohn MK, et al. *Physiol* (Bethesda). 2020;35(5):288-301| 4. Zhang Q, et al. *Signal Transduct Target Ther*. 2021;6(1):233 | 5. Boechat JL, et al. *Pulmonol*. 2021;27:423-437| 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)|)

Positive Phase 3 study: double blind, placebo-controlled study in hospitalized moderate to severe COVID-19 patients at risk for ARDS and death

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
Day 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.

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

NEJM Evidence

Published July 6, 2022

DOI: 10.1056/EVIDoa2200145

ORIGINAL ARTICLE

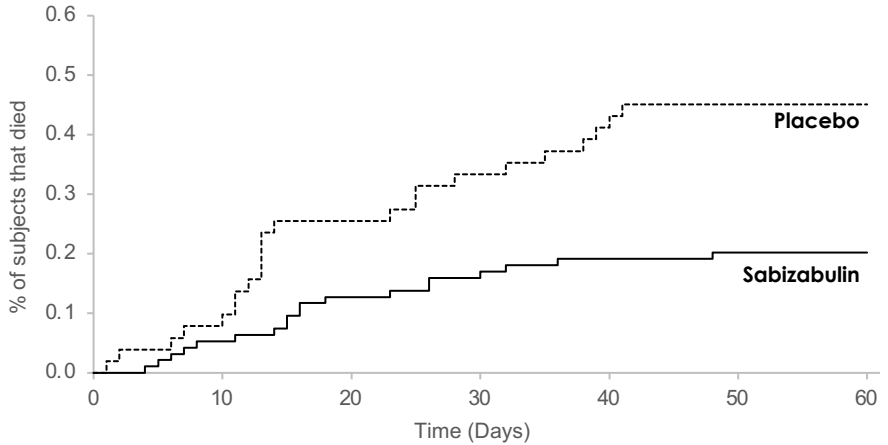
Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis

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*

Interim analysis results
Completed Phase 3

Primary endpoint, mortality rate by Day 60, was met

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



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

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

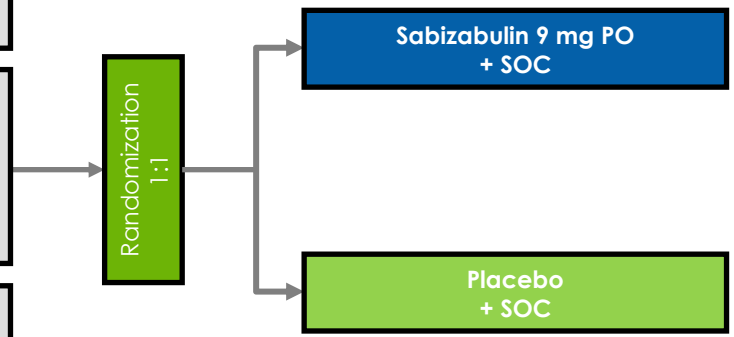
*Statistical analysis per SAP was logistic regression model with multiple imputation

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

N≈408
Sample size calculation
- Placebo 25%
- Sabizabulin 12.5%
- a=0.05 (two-sided)
- Power 90%
- N=408 patients (204/arm)
- Planned interim analysis when 50% (204 patients) and 71% (290 patient) complete the study

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

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



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

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

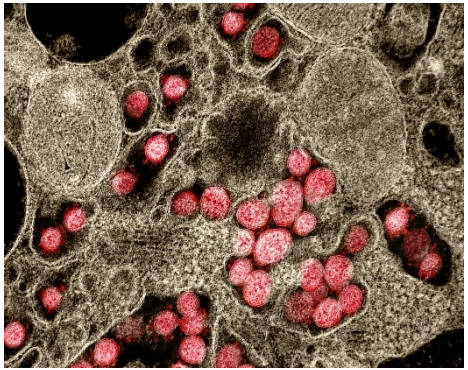
*Recommended by FDA in their review comments on this protocol | WHO 4: Hospitalized, oxygen by mask or nasal prongs; WHO 5: Hospitalized, non-invasive ventilation (NIV) or high-flow oxygen; WHO 6: Hospitalized, intubation and mechanical ventilation.

Sabizabulin has pan antiviral and broad anti-inflammatory activities
Proof of concept: SARS-CoV-2 induced viral pneumonia, ARDS, and multi-organ failure

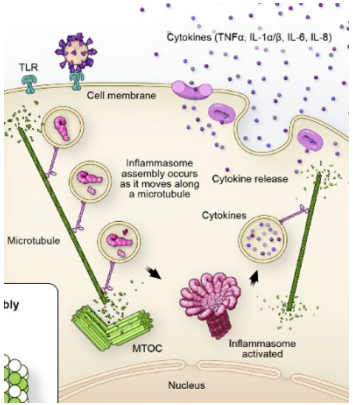
Clinical development plan:

Demonstrate efficacy and safety of sabizabulin in hospitalized COVID-19 patients on oxygen at high risk for ARDS, and then expand to the treatment of viral pneumonia ARDS caused by other respiratory viruses

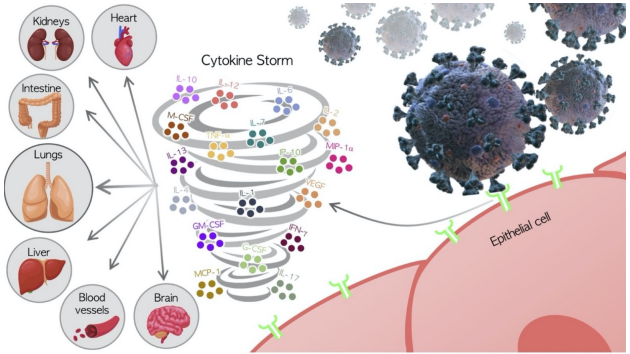
Viral replication



Virus triggers immune response



Hyperimmune response and tissue damage/ARDS/Death



COVID-19 ARDS is a path to viral ARDS

Company seeks to instead expand confirmatory Phase 3 study population to hospitalized patients with any viral pneumonia on oxygen support who are at high risk for ARDS

Moderate to severe viral infection triggers a hyper-immune response leading to ARDS, multi-organ failure, and death

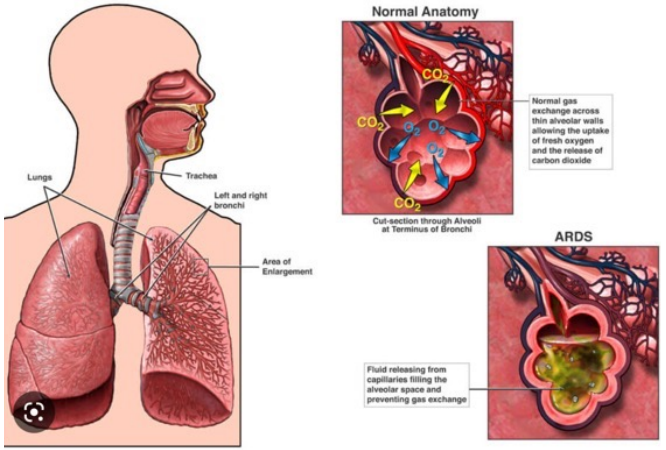
There is no current therapy that has significant mortality benefit in ARDS

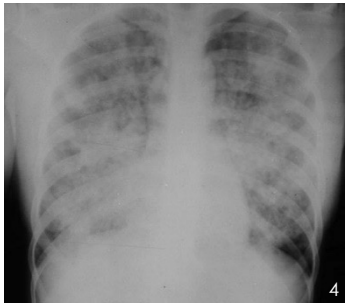
90% of COVID-19 deaths come from patients that had ARDS

Like COVID-19 infection, Influenza A/B and RSV infections also lead to ARDS with similar mortality rates in hospitalized adults on oxygen

Viral induced acute respiratory distress syndrome (ARDS)

- **ARDS- a form of noncardiogenic, pulmonary edema and diffuse alveolar damage associated with systemic inflammatory conditions**
- **ARDS has a high mortality rate and compelling unmet medical need**
- **Mortality rates based on Berlin definitions:**
  - Mild- 27%
  - Moderate- 32%
  - Severe- 45%
- **Viruses cause up to 1/3 of community acquired pneumonia**
  - "Tripledemic viruses" that cause ARDS are SARS-CoV-2, Influenza A/B, and RSV
- ***Viral induced ARDS results from the over-exaggerated immune inflammatory response by patient to the virus infection, rather than by viral mediated direct injury, thus an antiviral agent alone may not be effective***



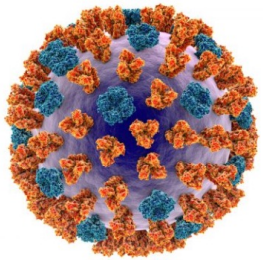


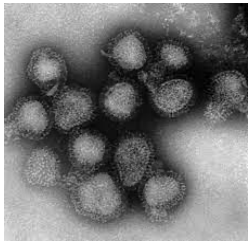
1 Swenson KE et al. Crit Care Clin 37:749-776, 2021 | 2 Ruuskanen O et al. Lancet 377:1264-75, 2011 | 3 Shah RD et al. Clin Chest Med 38:113-125, 2017 | NIH, NHLBI
4: http://learningradiology.com/notes/chestnotes/ards.htm

Influenza viral ARDS

- **Preclinical data evaluated sabizabulin in murine H1N1 influenza pulmonary inflammation model[1]**
  - Sabizabulin treatment reduced the cytokines in bronchoalveolar lavage: KC, IL-6,TNF-alpha, INF-gamma, and CXCL-10
  - Sabizabulin treatment resulted in a reduction in the severity of lung inflammation caused by H1N1 viral challenge (histopathology)
- **Pathogenesis and mortality rates for patients with hospitalized influenza ARDS are similar to COVID-19 ARDS [4-5]**
- **Oseltamivir had no significant effect on mortality in patients with influenza [6]**

Influenza ARDS[2]





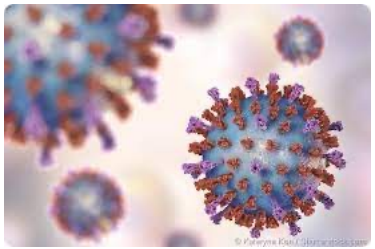
Each year in the United States, Influenza leads to:

CDC 2022[3]

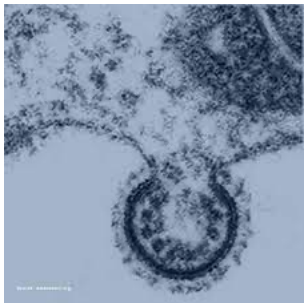
[1] Nonclinical data performed by Labcorp Drug Development 2022 (data on file) | [2] The NativeAntigen Company | [3] Stat News/ED MURPHY/CDC VIA AP | [4] Kronibus N et al. J Clin Med 11:6237, 2022 | [5] Yildirim M et al. Acute and Critical Care 37: 168-176, 2022 | [6] Kwon SK et al. BMC Infect Dis 17:785,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

RSV viral ARDS

Pathogenesis and mortality rates for hospitalized adult patients with RSV ARDS is similar to hospitalized adults with influenza ARDS [1]



2



Each year in the United States, RSV leads, on average[3]:

- 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

[1]Maggi S et al. Vaccines 10:2092, 2022 | [2] The NativeAntigen Company | [3] Stat News/ED MURPHY/CDC VIA

FDA agrees to new Phase 3 clinical study for sabizabulin in broader indication: Hospitalized adult patients with any type of viral ARDS

FDA agreed to a Phase 3, randomized (1:1), multicenter, placebo-controlled, parallel group design study to evaluate the efficacy and safety of sabizabulin 9mg oral daily dose plus standard of care treatment versus placebo plus standard of care treatment in hospitalized adult patients with any type of virus infection ARDS:

- Indication (patient population) for sabizabulin has been expanded to include all hospitalized adult patients with any type of viral ARDS
- Endpoints:
  - Primary efficacy endpoint is all-cause mortality at Day 60
  - Secondary endpoints include Days in the hospital, Days in the ICU, Days on mechanical ventilation, and proportion of patients alive without respiratory failure
- Given the high mortality rate for viral ARDS (27-45%), the expected size of the study is 408 patients
- If Phase 3 study were to demonstrate a benefit on all-cause mortality at Day 60, the primary endpoint, then the study could potentially be sufficient for NDA submission
- As the program has FDA Fast Track designation, a rolling NDA submission is a possibility for sabizabulin

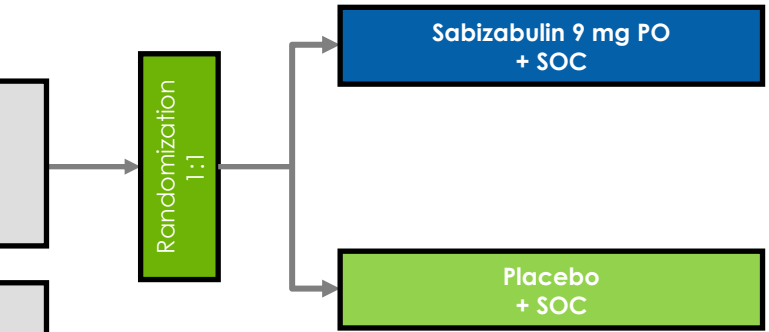
[1] FDA Division of Pulmonary, Allergy, and Critical Care meeting September 21, 2023

"All comers virus" Phase 3 viral- ARDS study design: Double blind, placebo-controlled study in hospitalized patients with viral pneumonia requiring oxygen who have ARDS

Sample size calculation
ARDS mortality rate is 27%-45%[1]
- Placebo 25%
- Sabizabulin 12.5%
- α=0.05 (two-sided)
- Power 90%
- N=408 patients (204/arm)

Key Inclusion criteria:
- Age ≥18 years
- Confirmed viral pneumonia
- Mild, moderate, or severe ARDS by Berlin definition

Key exclusion criteria:
- Pregnant or breastfeeding
- Moderate to severe renal impairment
- Hepatic impairment
- ECMO
- Onset of respiratory failure > 48 hours prior to randomization



Treatment Period
Days 1-21 or until discharge

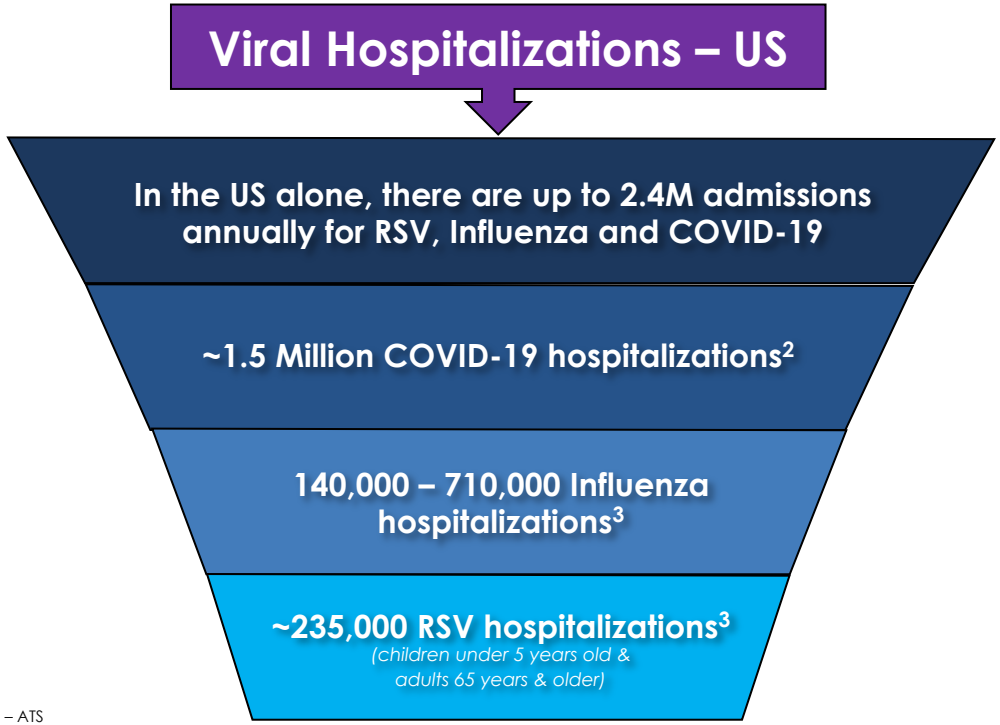
Primary endpoint=
Proportion of patients that die by Day 60

Follow-up Period
Days 22-60

Met with FDA September 2023, FDA has agreed to a single Phase 3 viral ARDS clinical study design for all types of viral pneumonia patients who have ARDS at high risk for death

[1]Matthay MA et al. Lancet Respir Med 9:933-936, 2021

Viral illness causing pneumonia is the NUMBER 1 cause of adult hospitalization in the US next to childbirth[1]



PLUS critically…….

- **~200 million cases of viral community-acquired pneumonia annually** (100M children, 100M adults)[4]
- **Mortality rate** of viral pneumonia is as high as **23% for patients admitted to the ICU**[4]
- In the EU, Norway & UK there are **371,000 hospitalizations due to RSV**[5] *(children under 5 & adults >65*
- In the EU/EEA, there are up to **50 million symptomatic cases of Influenza** annually[6]
- In the US and the rest of the world, **viral pneumonias are the leading cause of hospitalization of infants**[7]

AND placing pressure on the healthcare system

*In a joint statement on 12 October 2022 by the ECDC and the WHO, attention was brought to the **risk of potential co-circulation of COVID-19 and influenza putting increased pressure on both hospitals and healthcare workers. High levels of RSV circulation coinciding with peaks of these viruses could therefore add additional pressure on the system**[8]*

1 – ATS
2 – Clearview data on file
3 – CDC 2002, Stat News/ED MURPHY/CDC VIA AP
4 – https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7138033
5 – NIH
6 - https://www.ecdc.europa.eu/en/news-events/rsv-virus-expected-add-pressure-hospitals-many-eueea-countries-season
7 - https://www.ecdc.europa.eu/en/seasonal-influenza/facts/factsheet
8 - https://www.thoracic.org/patients/patient-resources/resources/top-pneumonia-facts.pdf
9 - 1 - https://www.ecdc.europa.eu/en/news-events/rsv-virus-expected-add-pressure-hospitals-many-eueea-countries-season

ARDS remains a global challenge and represents a large market opportunity

- ARDS carries a high mortality, and FDA views ARDS as a high unmet medical need[1]
- In 2021 the ARDS market was ~1.2B in the 7 Major Markets (US, EU4, UK and Japan)and is expected to grow to ~$12.8B globally by 2029[2]
- Data Bridge Market Research (published Aug/Sept 2022) analyses that the market is growing with a CAGR of 10.6% in the forecast period of 2022 to 2029 and is expected to reach ~$7.5B by 2029 in North America
- Data Bridge Market Research analyses that the market is growing with a CAGR of 9.5% in the forecast period of 2022 to 2029 and is expected to reach ~$5.3B by 2029 in Europe

1 – Veru FDA minutes September 2023
2 – Delve Insights Feb 2022

Sabizabulin as a potential therapeutic for smallpox virus

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

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

veru

UREV
Sexual Health Division

UREV
Sexual Health

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

ENTADFI®
(tadalafil and finasteride)
capsules

Only BPH treatment that prevents BPH progression with low potential for adverse sexual side effects[1-3]

Company has sold asset for $20 million[4] 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| [4] $6mm paid and $14mm notes receivable

FC2 Female Condom® (internal condom) business

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

Sold in U.S. and 149 other countries

Manufacturing plant with annual capacity of 100 million units

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

Increase in US public sector sales

Medical Device

Focus on growing US prescription business for high margin revenues

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

www.fc2condoms.com

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

UREV Sexual Health

FC2 Female Condom® (internal condom) patient portal
FC2Condoms.com

You're on your way to getting your FC2!

You are now leaving fc2condoms.com to visit our telehealth partner site to connect with a physician and get an FC2 prescription for as little as $0* in three easy steps:

1. Fill out a quick questionnaire online
2. Connect virtually with a doctor for $0
3. Get FC2 delivered straight to your door

Important Medicaid Notice:

Unfortunately, due to current limitations, we cannot offer online prescription services to women with Medicaid as their primary insurance in certain states: **TX, MI, NY, GA, NC, IL, SC, AL, TN, CO, MS.****

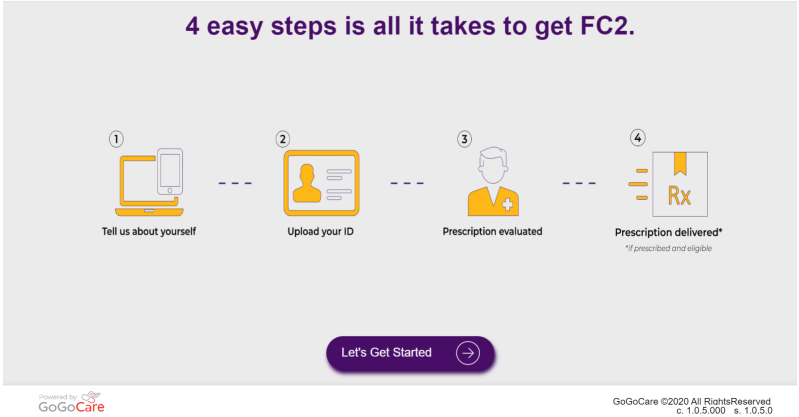
We're actively working towards finding a solution and committed to ensuring access to the FC2 Female Condom, the only female controlled FDA-approved non-hormonal reproductive health choice for preventing pregnancy and STIs.

Continue

By clicking "Continue" you are agreeing to our terms and privacy policy.

**Insurance coverage may vary based upon plan*

***Regarding the Important Medicaid Notice: Varu understands the importance of affordable reproductive health choices for all women, regardless of their insurance coverage. We're actively working towards finding a solution and committed to ensuring access to the FC2 Female Condom, the only female controlled FDA-approved non-hormonal reproductive health choice for preventing pregnancy and STIs. To stay informed on our progress, follow us on Facebook, Instagram and Twitter at @FC2USA. Thank you for supporting our efforts to provide greater access to the FC2 Female Condom and commitment to women's health.*



Financial highlights

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

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

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

Veru – Balance Sheet as of June 30, 2023	
Cash	$ 16.2 mm
Receivables	$ 5.1 mm
Notes Receivables	$ 14.0 mm
US/UK NOL carryforward	$112.7/$63.1 mm
Common Shares Outstanding[1]	~ 89.2 mm

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

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

Drug candidate pipeline
Biopharmaceutical company focused on oncology and infectious disease

Program	Mechanism	Indication	2022	2023	2024	2025
Breast Cancer						
Enobosarm +/- abemaciclib combination (Lilly)	Selective androgen receptor agonist + CDK 4/6 inhibitor	Phase 3 ENABLAR-2 AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Fast Track Designation; Phase 3 FPI; Lilly clinical collaboration and supply agreement	Ongoing; Phase 3 data-stage 1		
Infectious Disease- Acute Respiratory Distress Syndrome						
Sabizabulin	Oral microtubule Disruptor Broad host targeted antiviral and anti-inflammatory agent	Phase 3 (902) study- Hospitalized COVID-19 patients at high risk for ARDS	Fast Track Designation; Positive Phase 3 study	COMPLETED		
		Phase 3 (903) confirmatory study- Hospitalized COVID-19 patients at high risk for ARDS		Phase 3 FPI; Planned Q4 2023		
		Phase 3 (904) study- Hospitalized patients with viral ARDS	Phase 3 study	Planned		
		Smallpox virus	Animal Rule regulatory path	Planned		