Veru Inc.
Nasdaq:VERU

Focused on metabolic diseases and oncology

Veru Corporate Presentation
December 2023

Forward looking statements and safe harbor

The statements in this document 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 document 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 Phase 2b study of enobosarm in combination with a GLP-1 agonist for the treatment of obesity and related muscle wasting, the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients (if undertaken), the Phase 3 study of sabizabulin in adult hospitalized patients with ARDS (if undertaken), the Phase 2b/3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, and whether any of such studies will meet any of its primary or secondary endpoints; whether and when the IND for the enobosarm/GLP-1 combination study will be filed with the U.S. FDA, whether the FDA will require any additional studies or any preclinical studies, whether the study, if started, will have the same target patient populations as described in this presentation, and whether and when the planned study will commence enrollment and read out data; whether the historical clinical results showing enobosarm's effect on preventing muscle wasting, increasing or maintaining muscle mass and bone density or assisting with preferential fat loss will be replicated to any significant degree or at all in the planned Phase 2b study or in any future study and whether, if approved, any such results would be seen in commercial clinical use; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients or in ARDS patients or in 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 an NDA for sabizabulin for any indication; whether and when any potential NDA would be granted; 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 COVID-19 and ARDS or any other indication; whether the current and future clinical development efforts of the Company, including all studies of sabizabulin in COVID-19, ARDS, or any other infectious disease indications or enobosarm in obesity or 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 government and private payors will provide sufficient coverage for enobosarm for obesity or any of the Company's other drugs, if approved in each case; whether the companies that develop and commercialize GLP-1 drugs for obesity will accept the use of enobosarm in combination with their respective products; whether the intellectual property portfolio for enobosarm is sufficient to protect the Company's interest in enobosarm in obesity, breast cancer or any other indication and whether it will prevent competitors from developing SARMs for the same indication or whether the Company will have the resources or be successful in enforcing its intellectual property rights; whether and how long the relative lack of competition in the obesity market for drugs and drug candidates that might help mitigate muscle wasting will continue and what the effects of any such competition might be on the Company's prospects in the sector; whether enobosarm will become a treatment, in combination or alone, for obesity or breast cancer, and whether sabizabulin will become a treatment for broad ARDS or COVID-19; 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 and whether the Company will ever be able to liquidate the preferred stock that it owns in Blue Water; whether, when and how many shares may be sold under the Lincoln Park Capital Fund equity line; whether the cash raised by any future equity offering will be sufficient for the Company's planned or expected operations; 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 Company's existing product, FC2 and any future products, if approved, possibly not being commercially successful; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, 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, 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, 2023 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.

Drug candidate pipeline
Biopharmaceutical company

Program	Mechanism	Indication	2023	2024	2025	2026
Metabolic						
Enobosarm and GLP-1 receptor agonist combination	Selective androgen receptor modulator (SARM) + GLP-1 Receptor agonist	Obese or overweight elderly patients receiving a GLP-1 RA	IND; Phase 2b FPI -75	Phase 2b Protect muscle loss from GLP-1 data	Phase 2b Rescue Open-label data	Planned
Breast Cancer						
Enobosarm +/- abemaciclib combination (Lilly)	Selective androgen receptor modulator (SARM) + CDK 4/6 inhibitor	Phase 3 ENABLAR-2 AR+ ER+HER2- metastatic breast cancer (2nd line metastatic setting)*	Lilly clinical collaboration and supply agreement; Phase 3 FPI Stage 1- 160		Phase 3 data- stage 1	Open and active
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	Positive Phase 3 study Fast Track Designation			Completed
		Phase 3 (904) study - Hospitalized patients with viral ARDS**	Phase 3 FPI -408		Phase 3 data	Planned

*Subject to availability of funds **Subject to funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources

Currently approved GLP-1 receptor agonist drugs for the treatment of obesity have demonstrated significant loss of both fat and muscle in obese patients

- **Weight loss drugs GLP-1 receptor agonists demonstrated a 6.2-12.4% average total weight loss in third-party clinical trials[1,2]**
- **20-50% of the total weight loss reported by patients in those third-party clinical trials was attributed to muscle loss[1,3,4,5]**

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Once-Weekly Semaglutide in Adults with Overweight or Obesity

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	Semaglutide 2.4 mg once weekly (N=1306)	Placebo once weekly (N=655)	Treatment comparison for semaglutide vs. placebo [95% CI]
Co-primary endpoint assessed in the overall population			
Body weight change from baseline to week 68 – %	−16.86	−2.44	ETD: −14.42 [−15.29; −13.55]
Body weight reduction ≥5% – proportion of participants (%) at week 68	92.4	33.1	OR: 37.0 [28.0; 49.0]

Supportive secondary endpoints assessed in the DEXA subpopulation

	N=95	N=45	
Body composition change from baseline to week 68 (DEXA)			
Total fat mass			
Kg change	−10.40	−1.17	ETD: −9.23 [−12.72; −5.74]
Percentage-points change in total fat mass proportion§	−4.19	−0.19	ETD: −4.00 [−6.27; −1.73]
Regional visceral fat mass¶			
Kg change	−0.47	−0.03	ETD: −0.45 [−0.60; −0.30]
Percentage-points change in regional visceral fat mass proportion‖	−2.65	0.58	ETD: −3.23 [−5.35; −1.10]
Total lean body mass			
Kg change	−6.92	−1.48	ETD: −5.44 [−7.07; −3.81]
Percentage-points change in total lean body mass proportion§	3.61	0.11	ETD: 3.50 [1.35; 5.64]

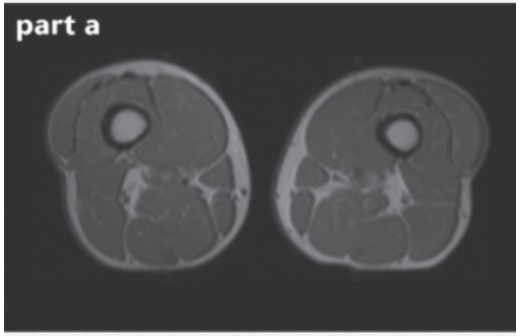
[1] Wilding JPH et al. NEJM 384:989-1002, 2021 | [2] Wegovy FDA PI | [3] Sargeant JA et al. Endocrinol Metab 34:247-262, 2019 | Ida S et al. Current Diabetes Rev 17:293-303, 2021 | [5] McGrimmon RJ et al. Diabetologia 63:473-485, 2020 |

Currently approved GLP-1 RA drugs for the treatment of obesity have demonstrated significant loss of both fat and muscle in clinical trials

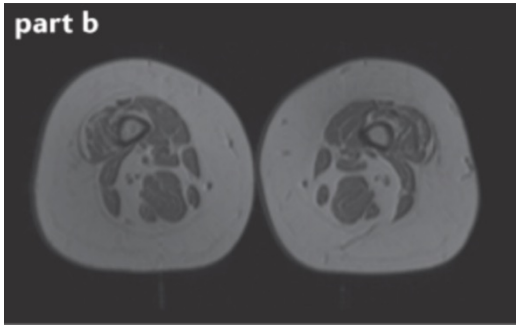
The target population is the at risk obese or overweight patients with low muscle reserves

- **Approximately 42% of older adults (>60 yo) have obesity or overweight and could benefit from weight-loss drugs[1]**
- **Subpopulation: older obese or overweight patients with low muscle mass/ functional limitations**
  - 30% of people over 60 years old and more than 50% of those over 80 years old have sarcopenia
  - Patients with sarcopenic obesity, high fat mass with very low muscle mass, have the greatest risk to develop ***muscle weakness*** because of critically low muscle mass with weight-loss drug treatment[2-4]
  - Elderly patients with sarcopenia obesity have a higher risk of frailty/***muscle weakness***, *which can* lead to poor balance, decrease in gait, loss of muscle strength, functional limitations, mobility disability, falls and fractures, higher hospitalization rate, and increased mortality [2-4]

Normal[5]



Sarcopenic obesity[5]



CT scans

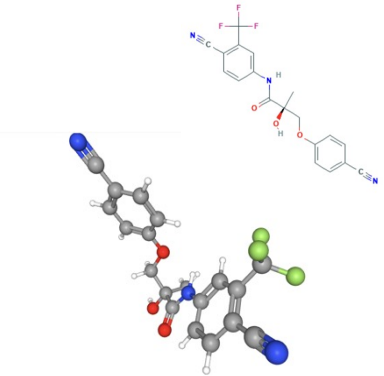
[1] CDC |[2] Wennamethee SG et al. Current Diabetes Reports 2023|[3] Spanoudaki M et al. Life 13:1242, 2023|[4] Roh E et al. Front Endocrinol 11: 2020|[5] Batsis J et al. Nature Reviews Endocrinology 14:513-537, 2018

Enobosarm is a novel oral selective androgen receptor modulator (SARM) designed to reduce fat mass and increase lean mass (muscle and bone)

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

Data from clinical trials and preclinical studies support enobosarm's potential:

- Once-a-day oral dosing
- Activates the androgen receptor, a well-established mechanism
- Tissue selective
  - Improves muscle mass and physical function[2,6]
  - Stimulates lipolysis, inhibits lipogenesis, and decreases fat mass[7,8]
  - Builds and heals bone-potential to treat bone loss/osteoporosis[3-5]
- Safety
  - Lack of Masculinizing effects
  - No liver toxicity



Chemical structure of enobosarm

[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 Metab 37:243-255, 2019 | [5] Kearbey JD et al Pharm Res 26:2471-2477, 2009 | [6]Dobs AS et al. Lancet Oncol 14:335-45, 2013 | [7]Dalton JT et al. J Cachexia Sarcopenia Muscle 2:153-161, 2011 | [8] Leciejewska N et al. J Phys and Pharma 70:525-533, 2019

Enobosarm clinical data from 5 clinical trials conducted by GTx or Merck in subjects with and without muscle wasting

Subjects (n=)	Phase	Population	Purpose	Muscle (LBM)	Muscle strength/ function	Fat Mass	Duration	Source
120 (24 received enobosarm 3mg)	2	Males over 60 years of age and postmenopausal women (Study G200501)	Dose-finding (0.1mg-3mg) placebo controlled	3mg=1.25 kg increase (p< 0.001 compared to placebo) 3.1% increase from baseline	3mg Increase SCP (p=0.049 compared to placebo)	3mg=0.32 kg decrease (p=0.049 compared to placebo) 2-5% decrease in fat mass	12 weeks	Dalton JT J Cachexia Sarcopenia Muscle 2:153, 2011 and CSR
48 (12 received enobosarm 3mg)	2	Sarcopenic postmenopausal women (Study 003)	Double-blind placebo controlled (3mg)	3mg=1.54 kg increase (p<0.001 compared to placebo) 3.7% increase from baseline.	Bilateral leg press 3mg 21.96 lbs. increase from baseline vs placebo 1.5 lbs. increase from baseline	Not collected	12 weeks	Merck study Clinical study report (on file)
159 (41 received enobosarm 3mg)	2b	Muscle wasting cancer (Study G200502)	Double-blind placebo controlled (1 and 3 mg)	3mg = 1.27 kg (2.8%) increase (p=0.041 compared to baseline)	3mg 16.8 watt increase SCP. (p=0.001 compared to baseline)	3mg= 0.76 kg decrease in total fat mass (p=0.086 compared to placebo) 4% decrease of total fat mass	16 weeks	Dobs AS Lancet Oncology 14:335, 2013 And CSR
321 (160 received enobosarm 3mg	3	Lung cancer muscle wasting receiving cisplatin + taxane chemotherapy (Study G300504)	Double-blind placebo controlled (3mg)	0.8 kg Increase in LBM at Day 84 (p<0.001 from baseline) Higher mean slope of the change from baseline than placebo (p=0.0002 Day 84 and p<0.0001 Day 147)	5.17% Increased in SCP at Day 84 vs. -1.27% in the placebo Higher mean slope of the change from baseline (p=0.0147 at Day 84, p=0.049 at Day 147)	Not collected	21 weeks	Clinical study report (on file)
320 (159 received enobosarm 3mg)	3	Lung cancer muscle wasting receiving cisplatin + nontaxane chemotherapy (Study G300505)	Double-blind placebo controlled (3mg)	0.73 kg Increase in LBM Day 84 and 0.67 kg increase at Day 147 (p=0.013) Higher mean slope of the change from baseline compared to placebo (p=0.0111 at Day 84, and p=0.0028 at Day 147)	SCP N.S.	Not collected	21 weeks	Clinical study report (on file)

Sarcopenic= presence of low muscle mass; LBM= lean body mass; SCP= stair climb power (Watts), power exerted in a 12-step stair climb; CSR=clinical study report ; N.S.=not significant

Healthy elderly men (60 yo) and postmenopausal women receiving enobosarm in GTx conducted Phase 2 double-blind placebo controlled clinical trial (G200501) demonstrated improved lean body mass and physical function

- 120 subjects enrolled
- 12 weeks of treatment

% Change in lean mass

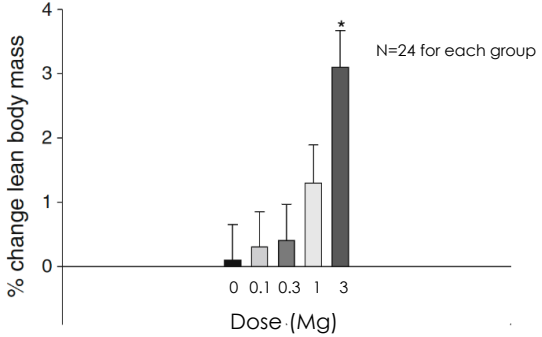


Fig. 1 Percentage change from baseline to day 86/EOS in total lean body mass: evaluable population. *EOS* end of study, *P<0.001 3 mg vs. placebo (T test)

% Change in stair climb power

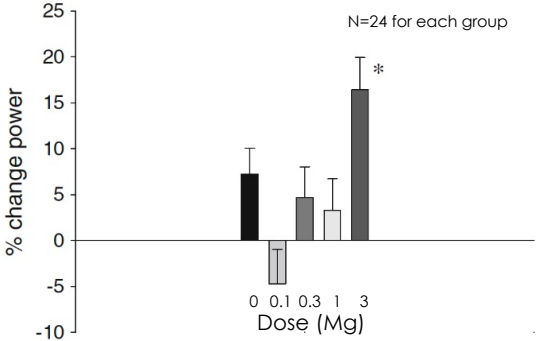
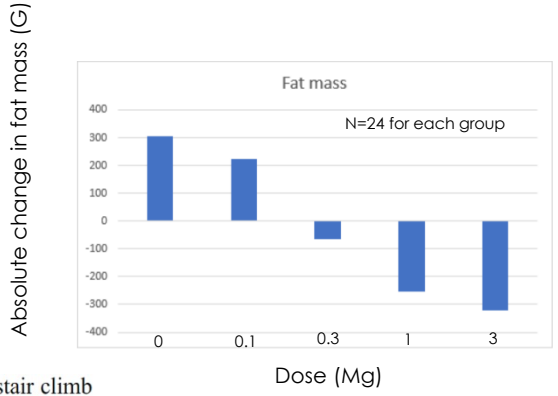


Fig. 2 Percentage change from baseline to day 86/EOS in stair climb power: evaluable population. *EOS* end of study, *P=0.0133 mg vs. placebo (T test)

Mean change in fat mass



Metabolic changes

Blood glucose was significantly decreased by an average of 6.9 ± 2.5 mg/dL in the enobosarm 3mg versus placebo (n=24; P = 0.006)

Blood insulin was reduced by 2.2 ± 1.1 µIU/mL in the enobosarm 3mg versus placebo (n=24; P = 0.052)

Insulin resistance (HOMA-IR) was reduced in the enobosarm 1-mg and 3-mg treatment groups (placebo = 2.6% ± 8.6, 1 mg = −9.3% ± 5.5, 3 mg = −27.5% ± 7.6)(P = 0.013 3 mg vs. placebo)

[1] Dalton JT et al. J Cachexia Sarcopenia Muscle 2:153-161, 2011 | [2] G200501 Clinical Study Report

Reported effects of enobosarm on muscle and physical function in patients with cancer: a double-blind, randomized controlled Phase 2b (G200502) clinical trial conducted by GTx[1,2]

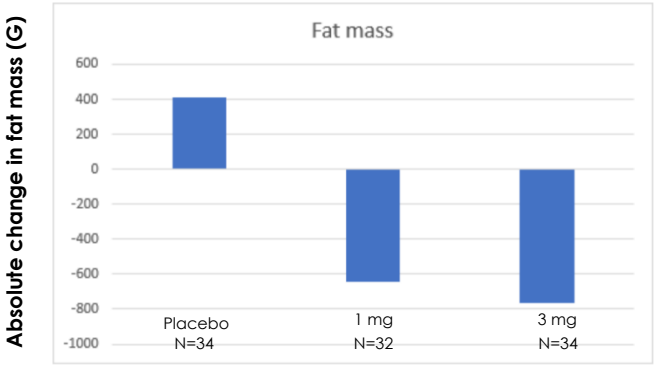
Change in total lean mass at Day 113/EOS compared to baseline

	Placebo	Enobosarm 1 mg	Enobosarm 3 mg
N	34	32	34
Mean (SD), kg	0·1 (2·7)	1·5 (2·7)	1·3 (3·5)
Median (range), kg	0·02 (–5·8 to 6·7)	1·5 (–2·1 to 12·6)	1·0 (–4·8 to 11·5)
p value *	0·88	0·0012	0·046

P< 0.041 enobosarm 3mg vs placebo

- Mean age >60 yo
- 159 subjects enrolled
- 16 weeks of treatment

Mean change in fat mass at Day 113/EOS compared to baseline



Change in stair climb time and power at Day 113/EOS compared to baseline

	Placebo	Enobosarm 1 mg	Enobosarm 3 mg
Stair climb time (s)			
N	36	32	28
Mean (SD)	0·20 (2·98)	–1·63 (3·39)	–2·22 (7·05)
Median (range)	–0·14 (–4·61 to 14·54)	–0·84 (–12·67 to 5·56)	–0·46 (–31·01 to 5·06)
p value *	0·26	0·0019	0·0065
Stair climb power (watts)†			
N	36	31	28
Mean (SD)	2·21 (39·30)	14·26 (53·77)	16·81 (31·08)
Median (range)	11·34 (–156·36 to 56·37)	19·93 (–235·34 to 110·14)	12·84 (–77·74 to 93·15)
p value *	0·11	0·0008	0·0006

Change in body weight at Day 113/EOS compared to baseline

	Placebo	Enobosarm 1 mg	Enobosarm 3 mg
Total bodyweight (scale weight)			
n	36	34	35
Mean (SD)	0·93 (4·13)	1·00 (4·27)	1·12 (4·02)
Median (range)	0·90 (–9·6 to 12·0)	0·80 (–7·3 to 12·3)	0·40 (–7·7 to 9·9)
p value	0·091	0·205	0·169
Total bodyweight (DXA weight)			
n	34	32	34
Mean (SD)	0·52 (3·79)	0·85 (4·29)	0·51 (4·20)
Median (range)	0·68 (–8·55 to 10·45)	0·30 (–6·53 to 9·71)	0·21 (–9·97 to 9·39)
p value	0·270	0·400	0·586

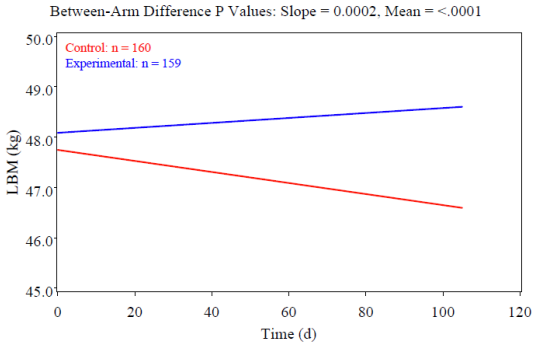
[1] Dobs AS et al. Lancet Oncol 14:335-345, 2013 | [2] G200502 Clinical Study Report

Phase 3 randomized, double-blind, placebo-controlled 504 clinical trial of evaluating the effects of enobosarm on muscle wasting in patients with non-small cell lung cancer on first line platinum plus a taxane chemotherapy conducted by GTx[1]

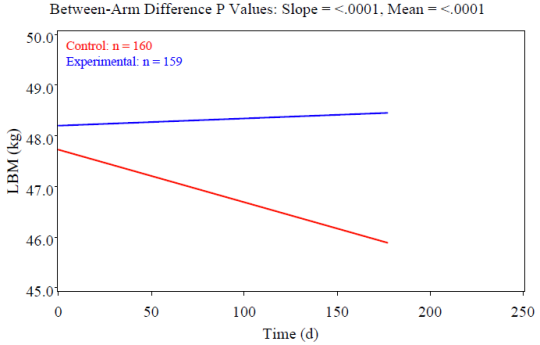
3mg enobosarm treatment in 321 subjects enrolled for 21 weeks

Lean body mass (muscle)

Up to Day 84 visit

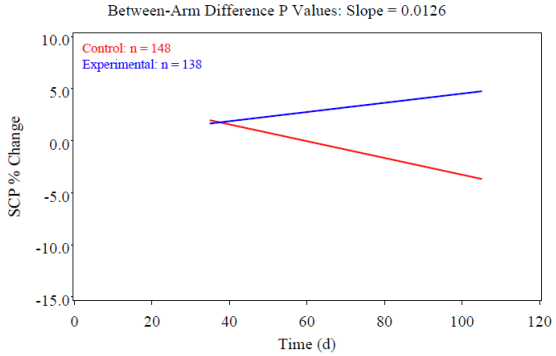


Up to Day 147 visit

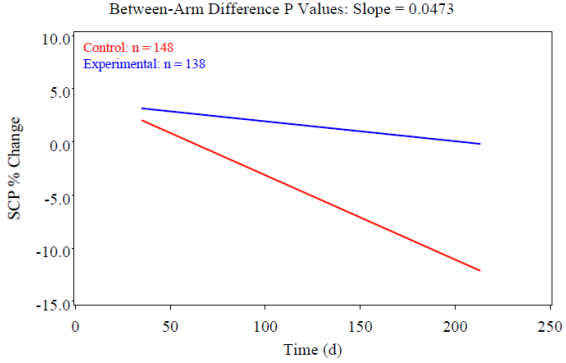


Stair climb power

Up to Day 84 visit

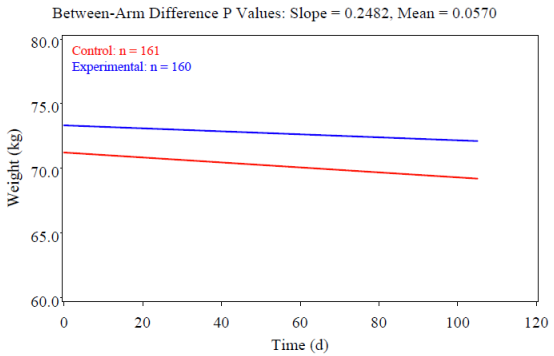


Up to Day 147 visit

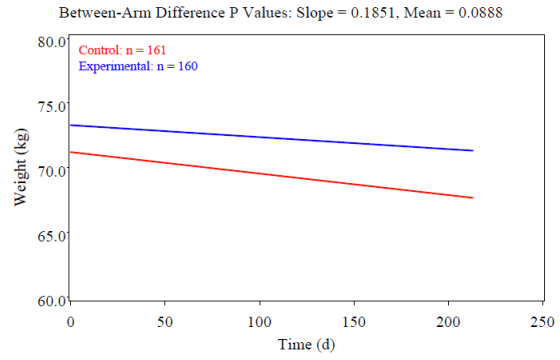


Body weight

Up to Day 84 visit



Up to Day 147 visit

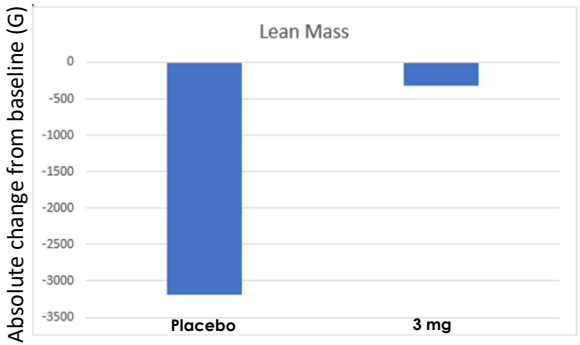


[1] Study G300504 CSR data on file Veru

Phase 3 randomized, placebo-controlled 504 clinical trial of evaluating enobosarm on muscle wasting in patients with non-small cell lung cancer on first line platinum plus a taxane chemotherapy conducted by GTx[1]

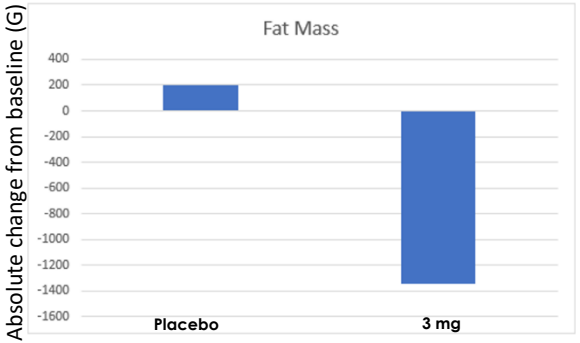
Post-hoc analysis of obese subpopulation (BMI ≥ 30)

Total lean body mass
Up to Day 84 visit



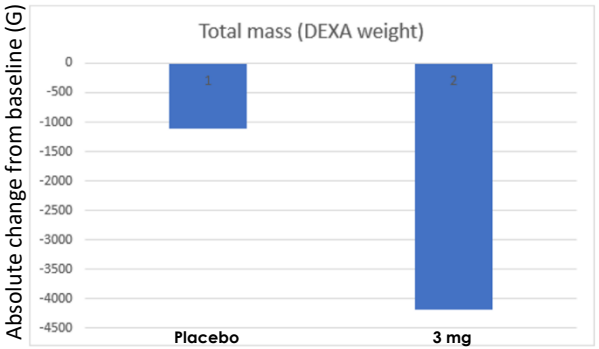
Placebo N=15, Treated N=14
Placebo corrected % change = +4.96%

Total fat mass
Up to Day 84 visit



Placebo N=15, Treated N=14
Placebo corrected % change = -5.77%

Total body weight
Up to Day 147 visit



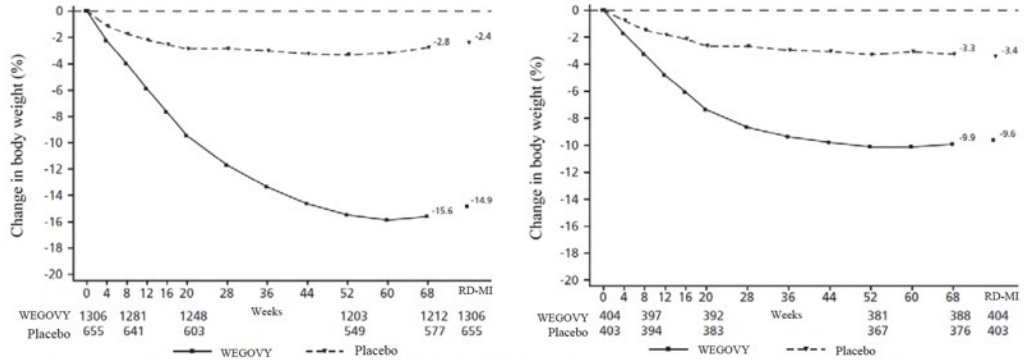
Placebo N=12, Treated N=12
Placebo corrected % change = -4.51%

[1] Study G300504 CSR data on file Veru

Data from third-party clinical trials of currently approved GLP-1 RAs

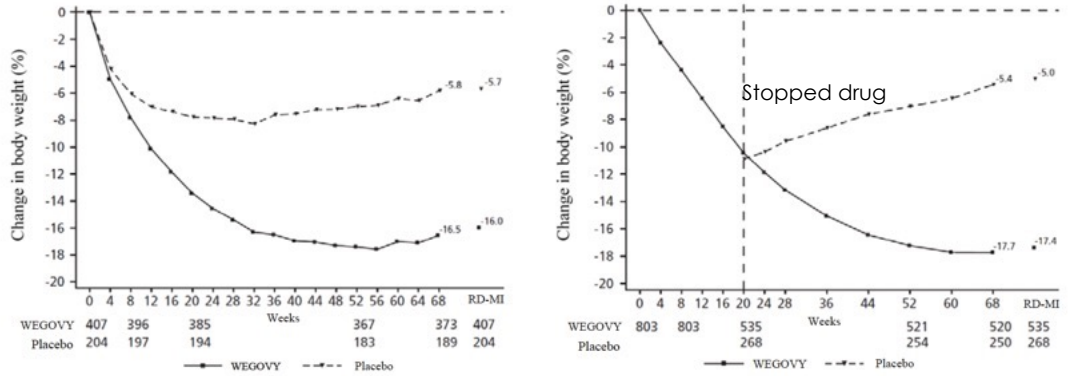
- Patients demonstrated greatest amount of absolute total weight loss (fat + muscle) between weeks 4 and 20
- Patients that discontinued treatment at week 20 had significant weight gain (rebound)
    - The reported weight gain was almost entirely fat mass not muscle

Figure 6. Change from baseline (%) in body weight (Study 1 on left and Study 2 on right)



Observed values for patients completing each scheduled visit, and estimates with multiple imputations from retrieved dropouts (RD-MI)

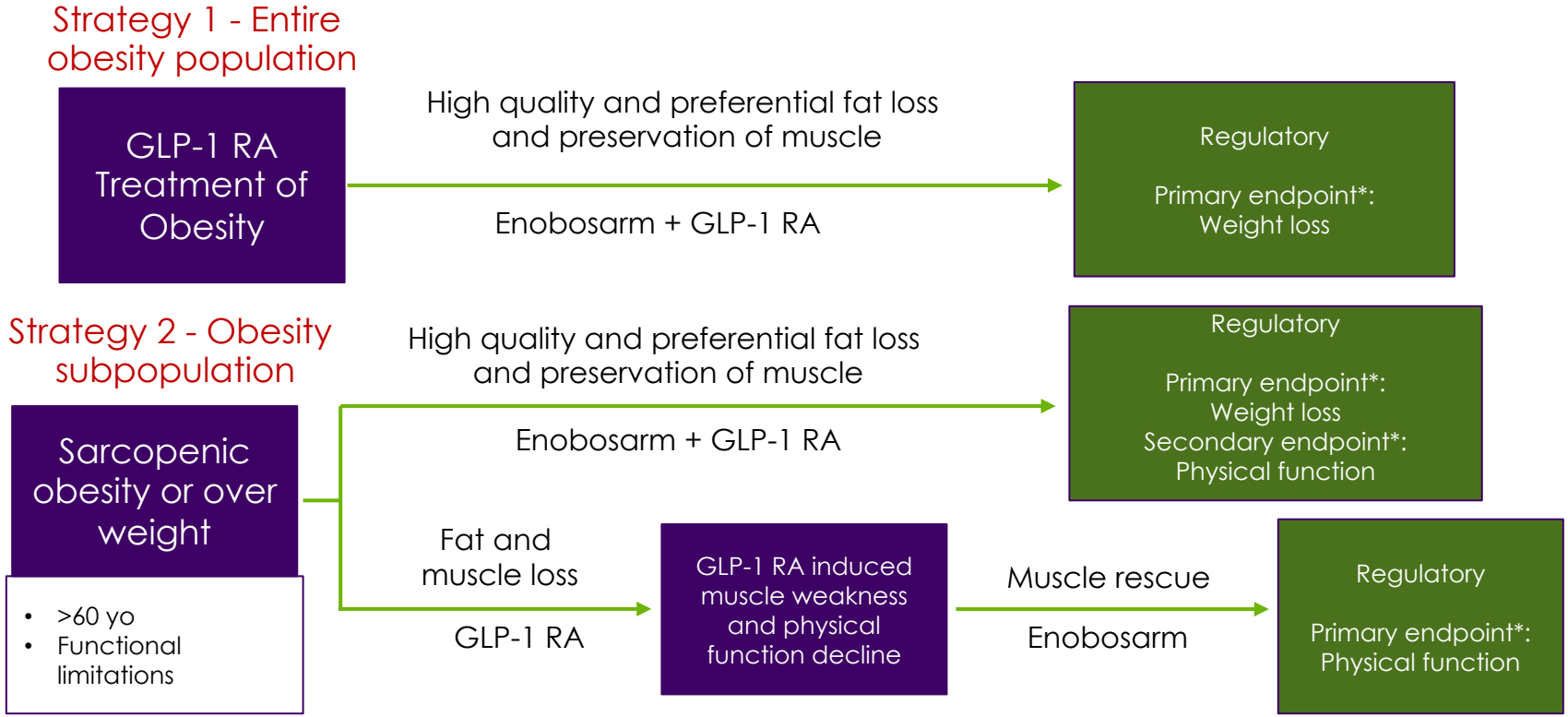
Figure 7. Change from baseline (%) in body weight (Study 3 on left and Study 4[a] on right)



[1]FDA Wegovy PI

Enobosarm +/- GLP-1 RA for the treatment of obesity
Clinical and regulatory strategy

Enobosarm potential direct effects: active protein synthesis in muscle (increasing muscle mass) and increase in lipolysis leads to greater fat loss



*Trial design are preliminary and are subject to discussion with FDA

Phase 2b double-blind, placebo controlled, randomized, dose finding trial to evaluate the efficacy and the safety of enobosarm in preventing muscle loss and increasing fat loss in patients receiving a GLP-1 RA to treat obesity

Enobosarm and GLP-1 RA combination study[1]

Sample size calculation
- N=75 patients (25 subjects/arm)

Key Inclusion criteria:
- Obese or overweight
- Age > 60 yo
- At risk for functional limitations
- GLP-1 agent is indicated

Randomization 1:1:1

- Enobosarm 6 mg PO + GLP-1 RA
- Enobosarm 3 mg PO + GLP-1 RA
- Placebo + GLP-1 RA

Treatment[2]
12 weeks

Enobosarm 6 mg PO

Open label extension study: enobosarm 6mg and no GLP-1 RA
16 weeks

12 weeks primary endpoint of LBM to be reported

Primary endpoint:
- LBM (muscle mass) measured by Dual Energy X-ray Absorptiometry (DEXA) scan

Secondary endpoints:
- Change in total body fat
- Change in total body weight
- Change in HOMA-IR – insulin resistance
- D_3Creatine Dilution[3]
- Physical function tests
  - Stair climb test

[1]Trial design is preliminary and subject to change if FDA provides input | [2] Based on FDA Guidance 2010 M3(R2) pg 21-22, no animal toxicology studies for drug combination studies are required to support Phase 2 study for 90 days duration | [3]Evans JE et al. Calcified Tissue International. Doi.org/10.1007/s00223-023-01124-w 2023 |

Scientific advisory board

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Duke University Medical Center
Durham, NC
Adjunct Professor of Human Nutrition
Department of Nutritional Sciences & Toxicology
University of California, Berkeley

Additional names pending NDA execution

Enobosarm has an extensive safety database

Combined Safety data from 5 Phase 2 and 3 clinical trials in cancer and healthy subjects and Phase 1 studies

Percentage of healthy and cancer subjects in all 5 clinical and Phase 1 clinical trials reporting a treatment-emergent adverse event with a frequency of ≥0.5%

MedDRAPreferred Term	Enobosarm (N=896)	Placebo (N=437)	All subjects (N=1333)
	n(%)	n(%)	n(%)
Any treatment related adverse event	*219 (24.4)*	*73 (16.7)*	*292 (21.9)*
Headache	51 (5.7)	10 (2.3)	61 (4.6)
Nausea	27 (3.0)	12 (2.7)	39 (2.9)
Alanine aminotransferase increased	19 (2.1)	2 (0.5)	21 (1.6)
Diarrhoea	19 (2.1)	12 (2.7)	31 (2.3)
Dizziness	18 (2.0)	2 (0.5)	20 (1.5)
Back pain	13 (1.5)	2 (0.5)	15 (1.1)
Constipation	12 (1.3)	3 (0.7)	15 (1.1)
Vomiting	12 (1.3)	4 (0.9)	16 (1.2)
Pain In extremity	11 (1.2)	4 (0.9)	15 (1.1)
Hyperhidrosis	9 (1.0)	1 (0.2)	10 (0.8)
Pruritus	9 (1.0)	3 (0.7)	12 (0.9)
Somnolence	9 (1.0)	0 (0)	9 (0.7)
Dyspnoea	8 (0.9)	0 (0)	8 (0.6)
Fatigue	8 (0.9)	5 (1.1)	13 (1.0)
Abdominal Pain	7 (0.8)	2 (0.5)	9 (0.7)
Hot Flush	6 (0.7)	2 (0.5)	8 (0.6)
Muscle Spasms	6 (0.7)	1 (0.2)	7 (0.5)
Myalgia	6 (0.7)	1 (0.2)	7 (0.5)
Dizziness Postural	5 (0.6)	0 (0)	5 (0.4)
Insomnia	5 (0.6)	1 (0.2)	6 (0.5)
Rash	5 (0.6)	0 (0)	5 (0.4)

Percentage of healthy and cancer subjects in all 5 clinical and Phase 1 clinical trials reporting a treatment-emergent serious adverse event with a frequency of ≥ 1%

MedDRAPreferred Term	Enobosarm (N=896)	Placebo (N=437)
	n(%)	n (%)
Any serious adverse event	*157 (17.5)*	*145 (33.2)*
Disease progression	34 (3.8)	45 (10.3)
Anaemia	18 (2.0)	14 (3.2)
Pneumonia	15 (1.7)	11 (2.5)
Neutropenia	14 (1.6)	14 (3.2)
Malignant neoplasm progression	12 (1.3)	8 (1.8)
Febrile neutropenia	10 (1.1)	6 (1.4)
Thrombocytopenia	10 (1.1)	6 (1.4)
Pulmonaryhaemorrhage	4 (0.4)	5 (1.1)
Dehydration	3 (0.3)	7 (1.6)

[1]Taken from GTx Investigator Brochure 2017

Enobosarm has an extensive safety database

- **Evaluated in 27 clinical trials comprising >1580 subjects dosed (235 subjects dosed at ≥ 9mg)**

- **Data reported from 12 Phase 1 studies:**
  - No QT effects
  - No significant drug-drug interactions[2]
  - No significant food effect
  - No significant renal or hepatic effects
  - Major metabolites analysis and route of elimination- renal elimination and only metabolite is enobosarm glucuronide
  - Cytochrome P450 3A4- enobosarm is not an inhibitor

Safety of special interest:

Elderly healthy volunteers G200502 Phase 2 study conducted by GTx[1]

	Baseline	SD	Absolute change	SD	*P* value
Total cholesterol (mg/dL)					
Placebo	195.9	35.83	4.8	17.46	
0.1 mg	197.8	27.31	−6.3	20.03	0.088
0.3 mg	204.4	29.84	−14.3	19.88	0.004*
1 mg	197.1	29.87	−19	26.34	<.001*
3 mg	203.1	35.1	−15.3	26.95	0.003*
HDL (mg/dL)					
Placebo	49.9	10.2	0	4.88	
0.1 mg	50.9	9.49	−4.3	4.72	0.027*
0.3 mg	55.3	13.99	−6.3	4.86	0.001*
1 mg	52.1	10.44	−8.9	6.18	<.001*
3 mg	52.8	10.99	−14.7	10.58	<.001*
LDL (mg/dL)					
Placebo	130	34.02	7.5	13.95	
0.1 mg	128	22.91	5.5	16.48	0.734
0.3 mg	130.7	31.57	−0.2	15.67	0.206
1 mg	125.2	23.83	3.9	27.16	0.564
3 mg	130.6	29.68	4.6	27.44	0.629
Triglycerides (mg/dL)					
Placebo	114.8	39.66	7.2	34.43	
0.1 mg	137.4	76.17	5.8	46.96	0.952
0.3 mg	126	80.69	2.4	50.18	0.838
1 mg	112.9	49.14	−12.8	31.14	0.4
3 mg	153.5	182.89	−36.6	155.64	0.06

HDL changes are similar to what has been observed for testosterone replacement

[1]Dalton JT et al. J Cachexia Sarcopenia Muscle 2:153-161, 2011 | 2: Enobosarm has not been evaluated for adverse drug-drug interactions in combination with GLP-1

Enobosarm for weight loss–IP portfolio and regulatory protection create significant barriers to entry

- Enobosarm is a novel SARM
- Enobosarm issued specific molecule composition of matter patents and issued specific molecule composition of matter polymorphs patents – Last expiry patent term (6 patents) 2028-2029 (latest is US 7,968,603 directed to composition of matter of enobosarm polymorph form)
- Enobosarm and SARMS pending methods of use (combination with GLP-1 receptor agonist / use in chronic weight management) – Last patent expiry (1US provisional) 2044
- Enobosarm – USPTO/FDA – May qualify for 5 additional years patent term extension
- Japan - enobosarm new chemical entity (NCE) exclusivity - May qualify for 7.5 Years from registration (NDA approval)
- Europe - enobosarm as a new chemical entity - May qualify for 10 years market exclusivity term
- Composition of matter formulation patent: New modified release tablet development in process

Clinical drug candidates to prevent muscle loss with GLP-1 RA for obesity
Competitive Landscape

Drug	Class	Delivery	Clinical stage with GLP-1 RA	Data expected	Company	Comments
Enobosarm	Selective androgen receptor modulator	Oral	Phase 2b	2H 2024	veru	GLP-1 RA combo and GLP-1 RA rescue
Bimagrumab	Anti-myostatin Activin receptor Type 2 antagonist	IV	Phase 2	5/2025	Versanis	Acquired by Lilly for $2 billion July 2023
Apitegromab	Anti-myostatin Selective anti-latent myostatin	IV	Phase 2	Mid 2025	ScholarRock	
Azelaprag (BGE-105)	Apelin receptor agonist	Oral	Phase 2	Study initiating in 2024	BioAge Labs (Private)	Doing study with Lilly (Mounjaro)

Enobosarm and GLP-1 receptor agonists
Target product profile

- **Enobosarm is a nonsteroidal, selective androgen receptor agonist that targets the androgen receptor, a well-established mechanism of action[1,2]**
- **Data from clinical trials and preclinical studies support enobosarm's potential:**
  - Administration: Once-a-day oral dosing
  - Efficacy
    - Avoidance of muscle loss - improves muscle mass and physical function[2,6]
    - Reduction of fat mass - stimulates lipolysis and inhibits lipogenesis[7,8]
    - Metabolic effects- decrease glucose, lowers insulin, and reduces insulin resistance
    - Builds and heals bone-potential to treat bone loss/osteoporosis[3-5]
  - Safety
    - Lack of masculinizing effects in women
    - No liver toxicity
    - Minimal GI side effects: frequency of nausea, vomiting, and diarrhea are similar to placebo[9]
- **Potential therapeutic benefits of enobosarm in the treatment of obesity:**
  - In combination with GLP-1 RA- prevents muscle loss and increases fat loss in patients receiving a GLP-1 RA
  - Upon discontinuation of GLP-1 RA- restores muscle mass and function & avoids rebound fat and weight gain

[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 Metab 37:243-255, 2019 | [5] Kearbey JD et al Pharm Res 26:2471-2477, 2009 | [6]Dobs AS et al. Lancet Oncol 14:335-45, 2013 | [7]Dalton JT et al. J Cachexia Sarcopenia Muscle 2:153-161, 2011 | [8] Leciejewska N et al. J Phys and Pharma 70:525-533, 2019 | 9: Taken from GTx Investigator Brochure 2017

Preventing muscle loss in patients receiving treatment for obesity

US obesity market[1-3]

- 45.9% of adult men aged 40-59 yo
- 38.4% of adult men aged 60+ yo

- 42.8% of adult women aged 40-59 yo
- 44.2 of adult women agreed 60+ yo

- 41.5% of adults > 60 yo
  - 34.4% also have sarcopenia

[1]CDC 2017-2020 | [2] Malenfant J J Glob Health Rep 3:e2019045, 2019 | [3]Lutski M et al. Prev Chronic Dis 17:200167, 2020

Enobosarm for AR+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]

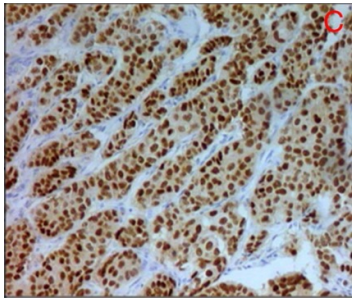
What is the androgen receptor's function in breast tissue?

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.

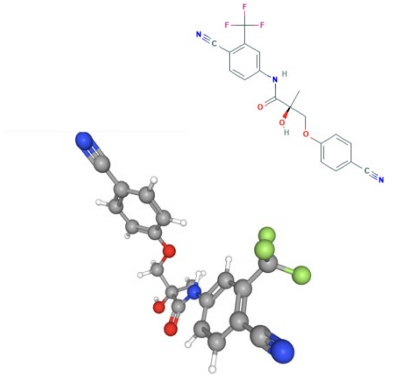
[1] Ponnusamy et al, iScience 21:341-358, 2019 | [2]Peters et al, Cancer Res 69: 6131-40, 2009 | [3]Hickey et al, Nature Medicine 2021 | [4]Moinfar et al, Cancer 98:703–11, 2003 | [5]Hu et al, Clin Cancer Res 17:1867–74, 2011| [6]Ricciardelli et al, Clin Cancer Res 24:2328-41, 2018 | [7]Bronte et al, 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 increases 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 27 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

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

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

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

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

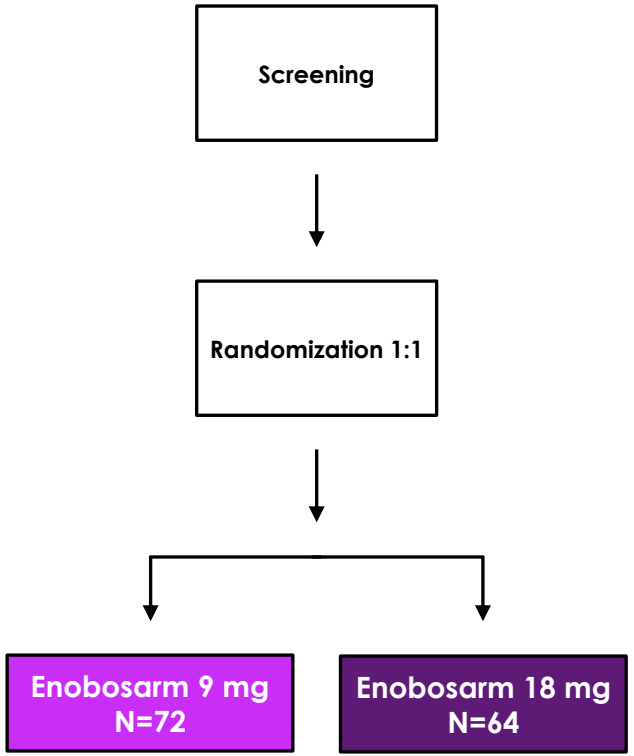
Clinical trial design – heavily pretreated population
Phase 2 (G200802)

Trial design

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

Patient population - 136 heavily pretreated women enrolled

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



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

Patient baseline demographics
Phase 2 (G200802)

Demographics	9 mg cohort	18 mg cohort
Age (median), years (range)	60.5 (35-83)	62.5 (42-81)
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)
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**	**3**

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%)

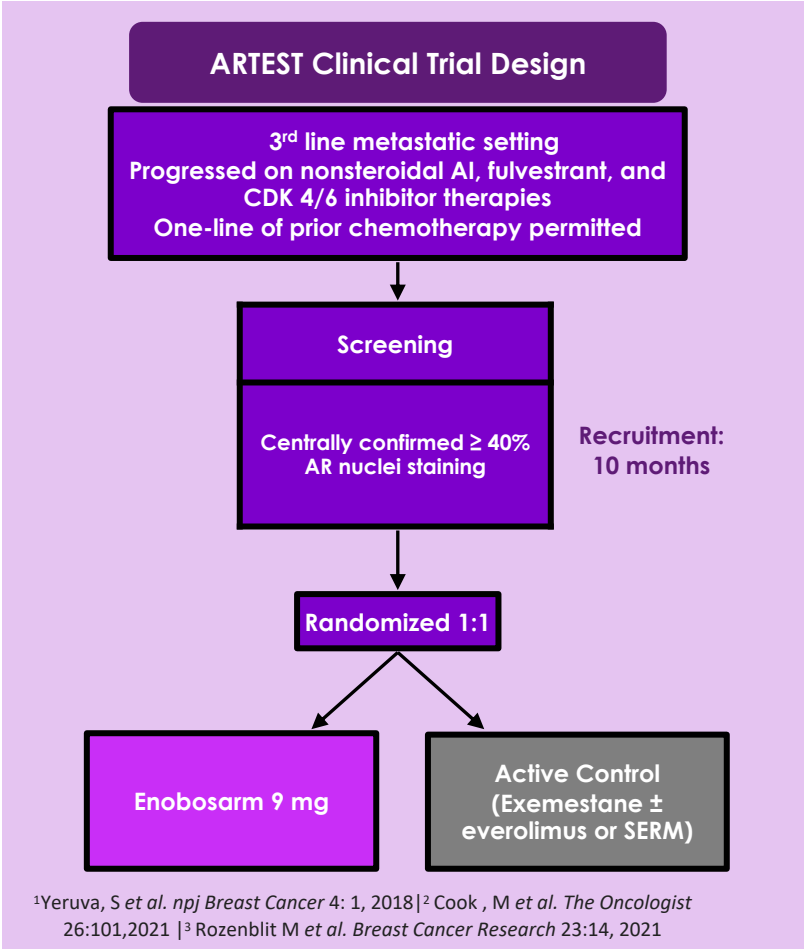
Conclusions
Phase 2 (G200802) study

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

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

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

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

CDK4/6 inhibitor resistance after first line metastatic Tx

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

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

Primary endpoint= ORR

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

- Estrogen blocking agent n=32
- Enobosarm 3mg n=32
- Enobosarm 9mg n=32
- Abemaciclib + Enobosarm 3mg n=32
- Abemaciclib + 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 12+ 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	D364 10/05/2023	
TL1 – Adrenal gland	3.3	1.3	0.8	0.7	0.6	0.6	0.6	
TL2 – Adrenal Gland	2	1.3	0.4	0.5	0.5	0.5	0.8	
Total	5.3	2.6	1.2	1.2	1.1	1.1	1.4	
Percent Change		-51%	-77%	-77%	-79%	-79% (PR)	-74%	

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 - Progressed 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	D-336 9/13/2023	
T1 - Liver	1.7	1.6	1.6	1.6	1.6	1.7	1.7	ET due new bone Mets
Total	1.7	1.6	1.6	1.6	1.6	1.6	1.7	
Percent Change		-5%	-5%	-5%	-5%	0% (SD)	0%	

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

Enobosarm for breast cancer – Robust IP portfolio and regulatory protection create significant barriers to entry

- Enobosarm issued specific molecule composition of matter patents and issued specific molecule composition of matter polymorphs patents – Last expiry patent term (6 patents) 2028-2029 (latest is US 7,968,603 directed to composition of matter of enobosarm polymorph form)
- Enobosarm issued methods of use (enobosarm specific) – Last patent expiry (8 patents) 2033-2034 (latest is US 9,969,683 directed to use of enobosarm for treatment of refractory ER+ breast cancer)
- Enobosarm pending methods of use (combination with CDK4/6 inhibitor) – Last patent expiry (1 US pending & 1 PCT pending) 2033 and 2042
- Enobosarm – USPTO/FDA - 5 additional years patent term extension
- Japan- enobosarm new chemical entity (NCE) exclusivity - 7.5 Years from Registration (NDA approval)
- Europe - enobosarm as a new chemical entity -10 years market exclusivity term

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

Demonstrated sabizabulin's mortality benefit in hospitalized COVID-19 patients on oxygen at high risk for ARDS
Plan to now expand to the treatment of viral induced ARDS caused by any respiratory viruses

NEJM Evidence

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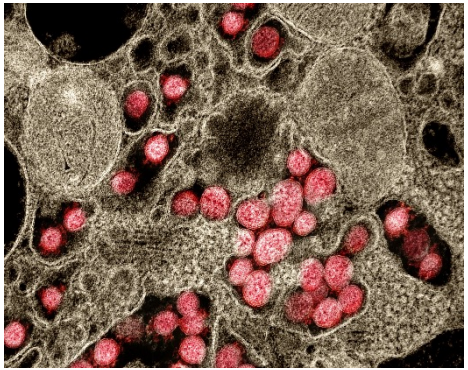
ORIGINAL ARTICLE

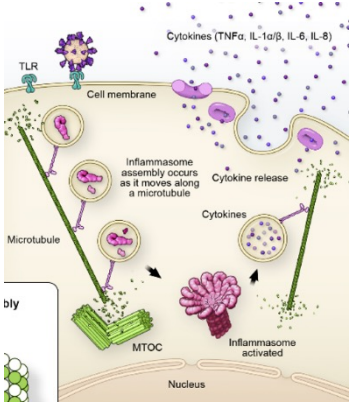
Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis

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

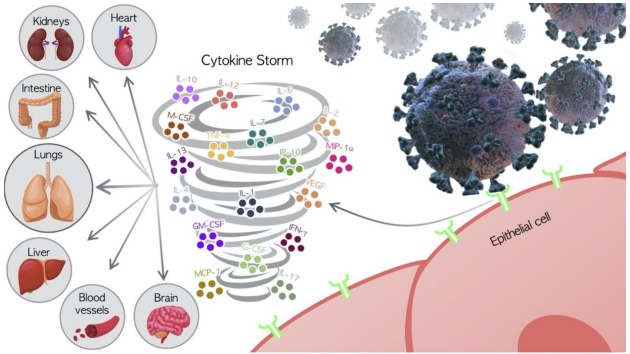
Viral replication



Virus triggers immune response



Hyperimmune response and tissue damage/ARDS/Death

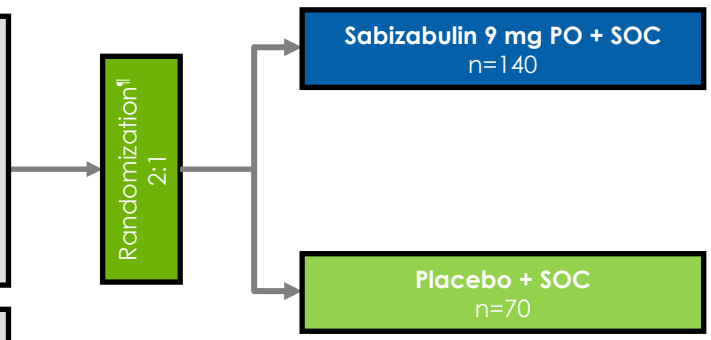


Positive Phase 3 study : double blind, placebo-controlled study in hospitalized moderate to severe COVID-19 patients at risk for ARDS and death

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

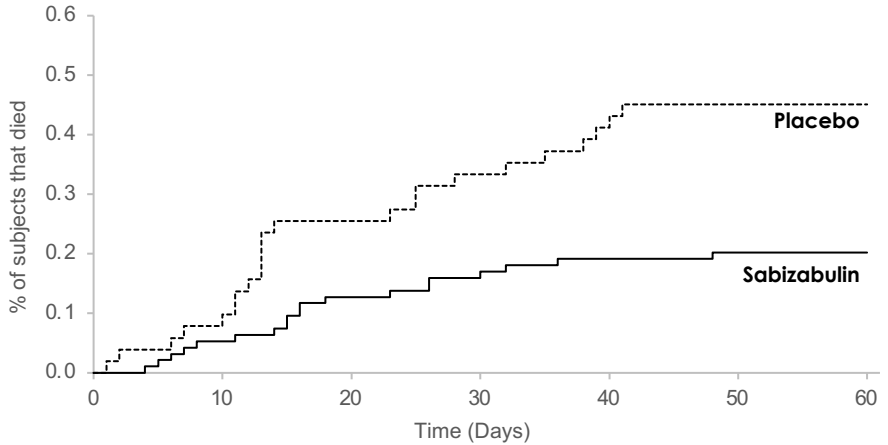
Follow-up Period
Day 22-60

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.

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

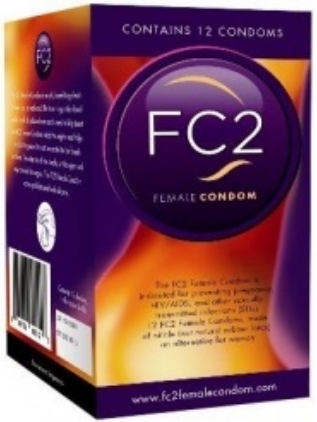
FDA agreed to a Phase 3, randomized (1:1), multicenter, placebo-controlled, parallel group design study to evaluate the efficacy and safety of sabizabulin 9mg oral daily dose plus standard of care treatment versus placebo plus standard of care treatment in hospitalized adult patients with any type of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

Company will initiate study only after securing external funding via governmental or pharma partnership funding

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] $7mm cash +$3mm stock paid and $10mm promissory 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

Public sector sales: UNFPA, USAID, Brazil, and South Africa

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
- Increase business with existing and anticipated new contracts with additional telemedicine and internet pharmacy partners

www.fc2condoms.com

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

Financial highlights

Net Revenues	
FY 2023 Net Revenues	$ 16.3 mm
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

Fiscal Year 2023 Results of operations	
FYTD 2023 Net Revenues	$ 16.3 mm
FYTD 2023 Gross Profit	$ 7.6 mm
FYTD 2023 Operating Loss	$ 93.7 mm

Q4 Fiscal Year 2023 Results of operations	
Q4 FY 2023 Net Revenues	$ 3.9 mm
Q4 FY 2023 Gross Profit	$ 1.5 mm
Q4 FY 2023 Operating Loss	$ 10.8 mm

Balance Sheet as of September 30, 2023	
Cash	$ 9.6 mm
Receivables	$ 4.5 mm
US/UK NOL carryforward	$140.5/63.0 mm
Common Shares Outstanding[1]	91.8 mm

Total cumulative net revenues from FY 2017-2023 $220.8 million

[1] An aggregate of 17.4 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 91.8 million common shares above

Metabolic diseases program
Clinical milestones

Obesity Program

Drug candidates
Enobosarm and GLP-1 receptor agonist combination

Mechanism
Selective androgen receptor modulator (SARM) + GLP-1 Receptor agonist

Indication
Prevent muscle loss in obese or overweight elderly patients receiving a GLP-1 RA