



Veru Inc.
Nasdaq:VERU

**Focused on metabolic diseases
and oncology**

**Veru Corporate Presentation
2024 Cantor Global Healthcare Conference
September 17-19, 2024**





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.

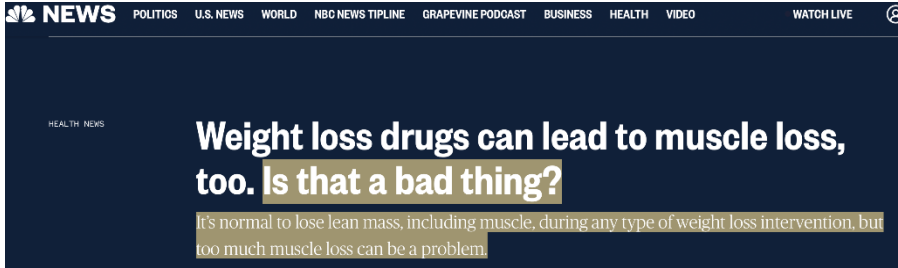
Program	Mechanism	Indication	2023	2024	2025	2026
Metabolic						
Enobosarm and GLP-1 receptor agonist combination	Selective androgen receptor modulator (SARM) + GLP-1 receptor agonist	Obese or overweight elderly patients receiving a GLP-1 RA		Phase 2b QUALITY Trial FPI	Phase 2b QUALITY-Preserve Topline data	Phase 2b Extension Topline data
				●	●	●
						Active
Breast Cancer						
Enobosarm +/- abemaciclib combination	Selective androgen receptor modulator (SARM) + CDK 4/6 inhibitor	Phase 3 ENABLAR-2 AR+ ER+HER2- metastatic breast cancer (2 nd line metastatic setting)*		Phase 3 FPI Stage 1- 160		
				●		
						Paused*
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	
		Phase 3 (904) study - Hospitalized patients with viral ARDS**		Phase 3 FPI -408		
				●		
						Completed
						Paused**

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

HEALTH - WEIGHT-LOSS AND DIET CONTROL INDUSTRY

Weight-loss drugs like Ozempic and Wegovy may be risky for older people because they melt away all-important muscles, experts say

BY [MADISON MULLER AND BLOOMBERG](#)
September 27, 2023 at 4:57 PM EDT



SCIENTIFIC AMERICAN

PHARMACEUTICALS

Ozempic and Other Weight-Loss Drugs Bear Heavy Costs and Questions for Seniors

Limited data on adults age 60 and older raise questions on whether high-priced weight-loss drugs will really help with lowering rates of chronic illness and disability

HEALTH NEWS

✓ Fact Checked

Ozempic Can Cause Major Loss of Muscle Mass and Reduce Bone Density

By [Cathy Cassata](#) on May 2, 2023 — Fact checked by [Jill Seladi-Schulman, Ph.D.](#)



Weight loss medications like Ozempic and Wegovy can help people drop pounds quickly, but they can also cause a rapid loss of muscle mass and bone density unless lifestyle changes are made. anandaBGD/Getty Images

- Rapid weight loss from taking GLP-1 medications like Ozempic and Wegovy can cause a decrease in muscle mass, lessen bone density, and lower your resting metabolic rate, leading to sarcopenia.
- Sarcopenia is the gradual loss of muscle mass, strength, and function and is typically associated with aging.
- Lifestyle changes such as increasing protein intake and incorporating strength and resistance training can help combat muscle and bone density loss while taking GLP-1 medications.

veru | Currently approved GLP-1 receptor agonist drugs have demonstrated significant loss of both fat and muscle in overweight or obese patients

- Weight loss drugs GLP-1 receptor agonists demonstrated a 6.2-17% average total weight loss^{1,2}
- 20-50% of the total weight loss is from muscle loss^{1,3,4,5}

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MARCH 18, 2021 VOL. 384 NO. 11

Once-Weekly Semaglutide in Adults with Overweight or Obesity

John P.H. Wilding, D.M., Rachel L. Batterham, M.B., B.S., Ph.D., Salvatore Calanna, Ph.D., Melanie Davies, M.D., Luc F. Van Gaal, M.D., Ph.D., Ildiko Lingvay, M.D., M.P.H., M.S.C.S., Barbara M. McGowan, M.D., Ph.D., Julio Rosenstock, M.D., Marie T.D. Tran, M.D., Ph.D., Thomas A. Wadden, Ph.D., Sean Wharton, M.D., Pharm.D., Koutaro Yokote, M.D., Ph.D., Niels Zeuthen, M.Sc., and Robert F. Kushner, M.D., for the STEP 1 Study Group*

	Semaglutide 2.4 mg once weekly (N=1306)	Placebo once weekly (N=655)	Treatment comparison for semaglutide vs. placebo [95% CI]
<i>Co-primary endpoint assessed in the overall population</i>			
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]

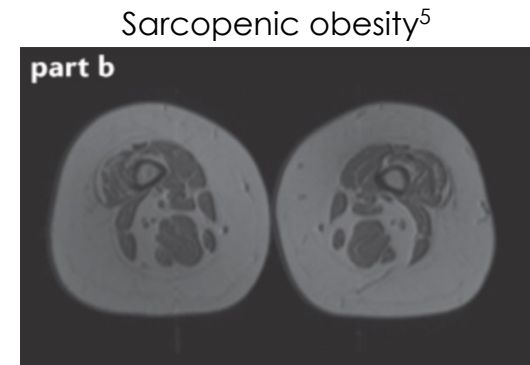
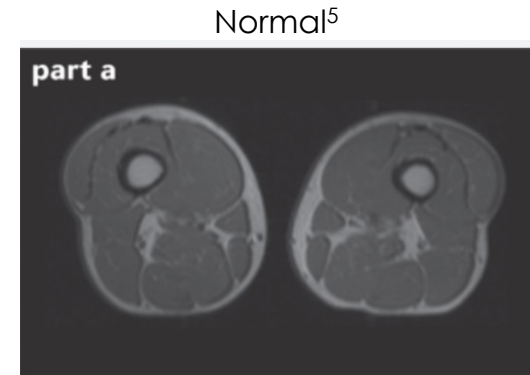


1 pound of muscle for 1 pound of fat

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 | ⁴ Ida S et al. Current Diabetes Rev 17:293-303, 2021 | ⁵ McGrimmon RJ et al. Diabetologia 63:473-485, 2020

veru | **Currently GLP-1 RA drugs result in significant loss of both fat and muscle**
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 drugs¹**
- **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
 - 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 mortality²⁻⁴



MRI 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



WEGOVY FDA label now shows fracture safety data from SELECT Cardiovascular outcomes study

wegovy[®] semaglutide injection 2.4 mg

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use WEGOVY[®] safely and effectively. See full prescribing information for WEGOVY[®].

WEGOVY[®] (semaglutide) injection, for subcutaneous use

Fractures

In the cardiovascular outcomes trial in adults, more fractures of the hip and pelvis were reported on WEGOVY[®] than on placebo in female patients: 1.0% (24/2448) vs. 0.2% (5/2424), and in patients ages 75 years and older: 2.4% (17/703) vs. 0.6% (4/663), respectively.

MDedge® / INTERNAL MEDICINE

LATEST NEWS

Diabetes/Weight Loss Med Linked to Repeat Spinal Surgery

Publish date: May 9, 2024

By [Patrice Wendling](#)



CHICAGO — The diabetes/weight loss drug semaglutide is associated with a significantly greater risk for repeat operations in patients with diabetes who require lumbar surgery, a new study suggests.

The risk for additional surgeries was even higher among patients taking the popular weight loss and diabetes drug for longer periods of time.

Investigators say the study provides the first evidence on the impact of semaglutide on spine surgery.

- Patients from all-payer Mariner database
 - Patients aged 18-74 years with type 2 diabetes who underwent elective transforaminal lumbar interbody fusions (TLIFs) between 1/18- 10/22 and October 2022
 - 447 patients with semaglutide use and 1334 with no semaglutide use. More than half (56%) were female, 62% used insulin, and 81% underwent single-level TLIF

- Results:
 - Patients taking semaglutide were nearly 12 times more likely to have an additional lumbar surgery at 1 year than did those who did not use the drug (27.3% vs 3.1%; OR, 11.79; 95% CI, 8.17-17.33 log-rank p<0.0001)

- *Syed Khalid, MD, study PI, believes that muscle loss from GLP-1 drugs is the cause for repeat operations¹*

¹ Khalid, S. American Association of Neurological Surgeons 2024 Annual Meeting, May 2024

The Atlantic

HEALTH

The Ozempic Plateau

Everyone hits a weight-loss plateau, but the race is on for next-generation drugs that can help patients lose even more weight.

By Sarah Zhang

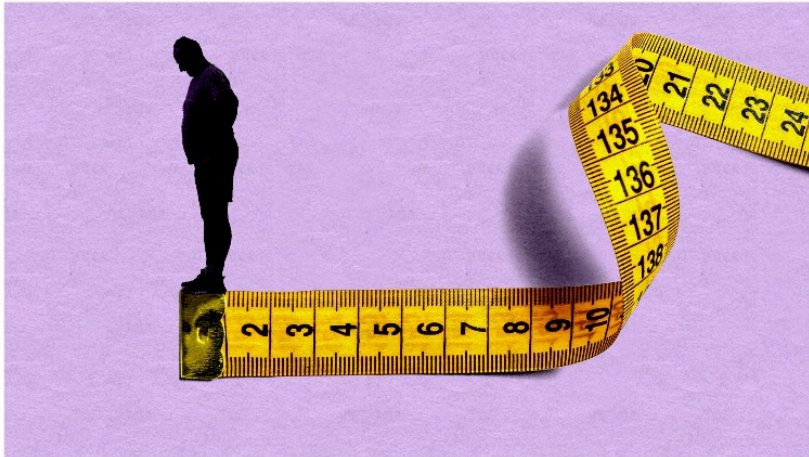


Illustration by The Atlantic. Source: Getty.



The Quest for Treatments to Keep Weight Off After Ozempic

Obesity researchers and companies turn toward helping people maintain losses

her assists Aida Diaz as she undergoes a body composition scan.

By [Retsy McKay](#) [Follow](#) | Photographs by Sarah Blesener for The Wall Street Journal
May 8, 2024 at 5:30 am ET

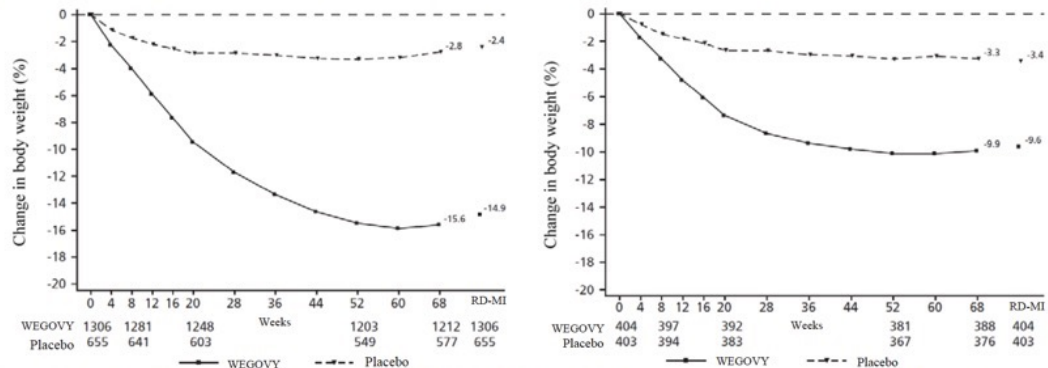


Wegovy approval clinical studies¹: overweight and obese adult patients

Rate of weight loss reaches a plateau

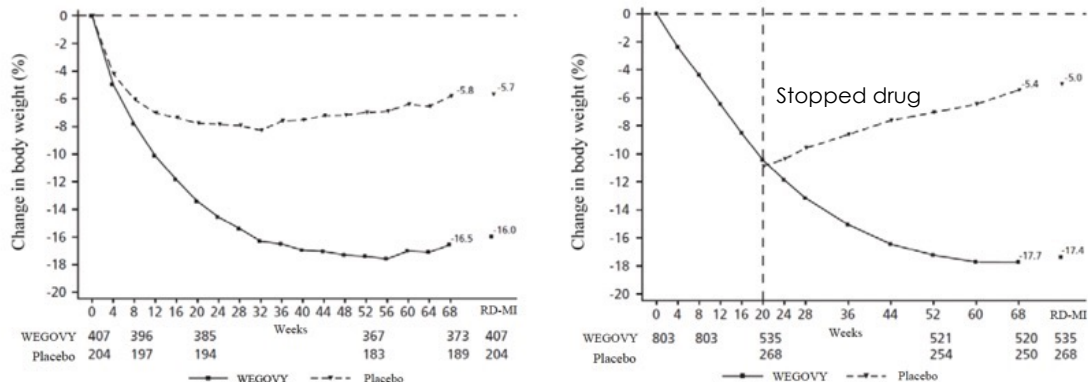
- Greatest amount of absolute total weight loss between weeks 0 and 20
- Patients who discontinued treatment at week 20 had significant weight gain (rebound)
- The reported weight gain was almost entirely fat mass not muscle
- One explanation: deficit in lean body mass (muscle) drives an increase in appetite and fat rebound weight regain^{2,3}

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)

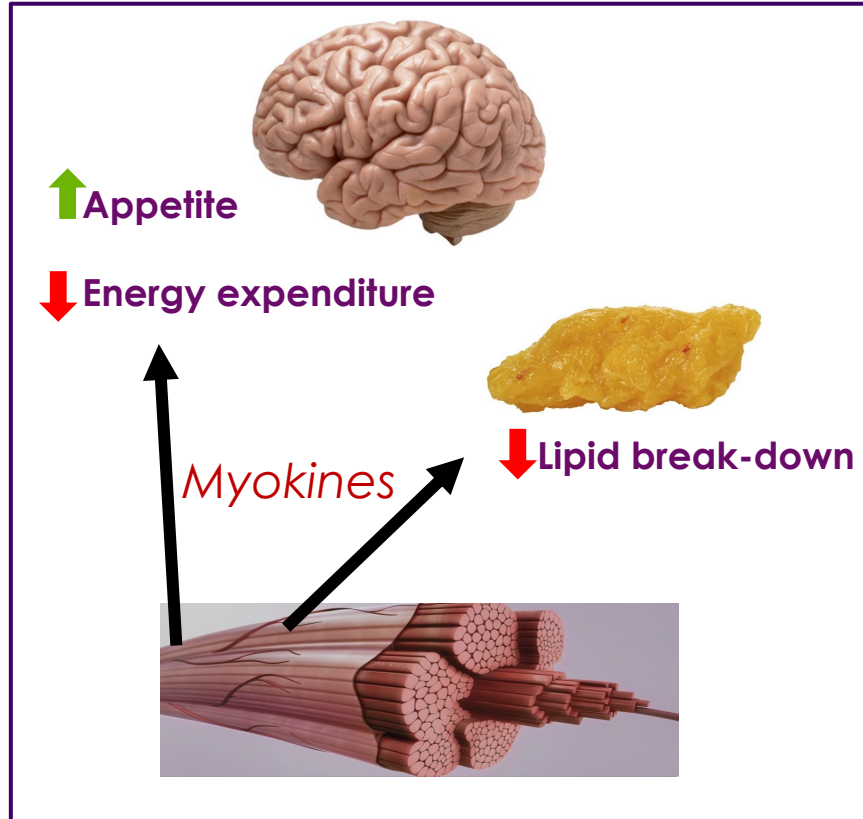
Figure 7. Change from baseline (%) in body weight (Study 3 on left and Study 4^a on right)



¹FDA Wegovy PI | ²Dulloo AG et al. Eur J Clin Nutrition 71:353-357, 2017; ³Dulloo A Obesity 25:277-279, 2017

Muscle produces myokines
Myokines regulate appetite control and energy balance^{1,2}

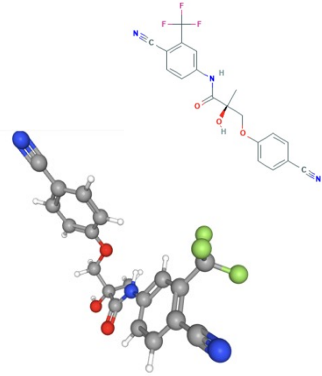
Depleted muscle- low energy balance



¹ Dulloo A Obesity 25:277-279, 2017 | ²Grannell A et al. Muscles 1:26-47, 2022

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

- **Enobosarm (Ostarine, MK2866, GTx-024) is a nonsteroidal, selective androgen receptor modulator^{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/osteoporosis³⁻⁵
 - Safety
 - Lack of masculinizing effects
 - Not converted to estrogen or dihydrotestosterone
 - No liver toxicity- no DILI observed in clinical studies (27 clinical studies)



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 approx. 1,000 patients 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=0.047 at Day 147)	Not reported	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 reported	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 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

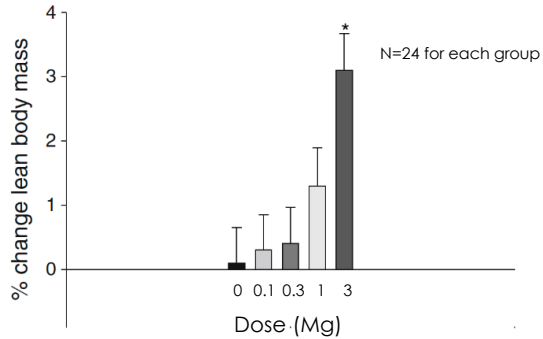


Fig. 1 Percentage change from baseline to day 86/EOS in total lean body mass: evaluable population. EOS end of study, * $P < 0.001$ 3 mg vs. placebo (T test)

% Change in stair climb power

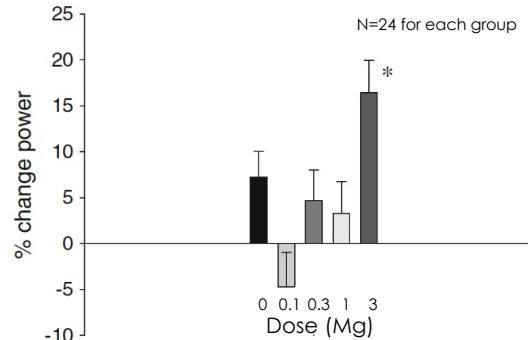
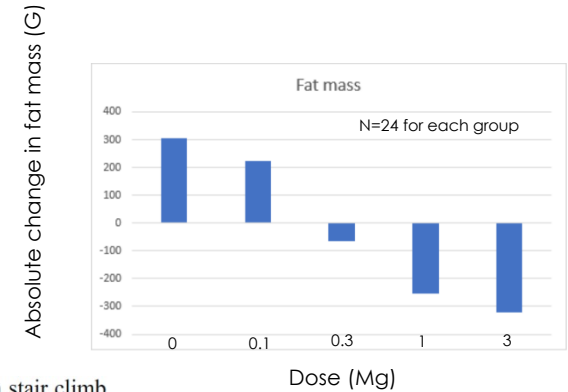


Fig. 2 Percentage change from baseline to day 86/EOS in stair climb power: evaluable population. EOS end of study, * $P = 0.013$ 3 mg vs. placebo (T test)

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 μ U/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 = $2.6\% \pm 8.6$, 1 mg = $-9.3\% \pm 5.5$, 3 mg = $-27.5\% \pm 7.6$) ($P = 0.013$ 3 mg vs. placebo)

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

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

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

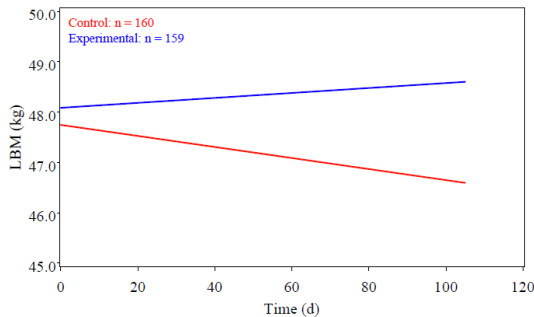
veru | Phase 3 randomized, double-blind, placebo-controlled 504 clinical trial of evaluating the effects of enobosarm on muscle wasting in patients with non-small cell lung cancer on first line platinum plus a taxane chemotherapy¹

3mg enobosarm treatment in 321 subjects enrolled for 21 weeks

Lean body mass (muscle)

Up to Day 84 visit

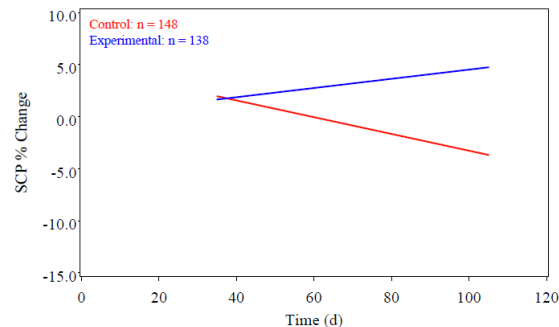
Between-Arm Difference P Values: Slope = 0.0002, Mean = <.0001



Stair climb power

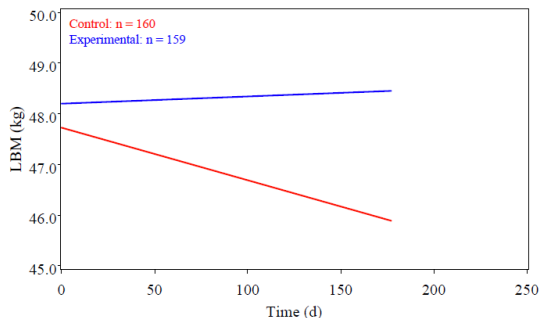
Up to Day 84 visit

Between-Arm Difference P Values: Slope = 0.0126



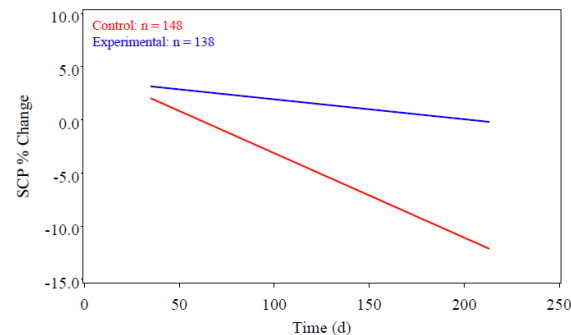
Up to Day 147 visit

Between-Arm Difference P Values: Slope = <.0001, Mean = <.0001



Up to Day 147 visit

Between-Arm Difference P Values: Slope = 0.0473



¹ Study G300504 CSR data on file Veru

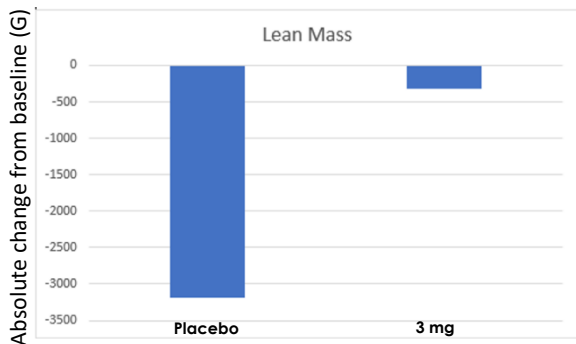


Phase 3 randomized, placebo-controlled 504 clinical trial of evaluating enobosarm on muscle wasting in patients with non-small cell lung cancer on first line platinum plus a taxane chemotherapy¹

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

Total lean body mass

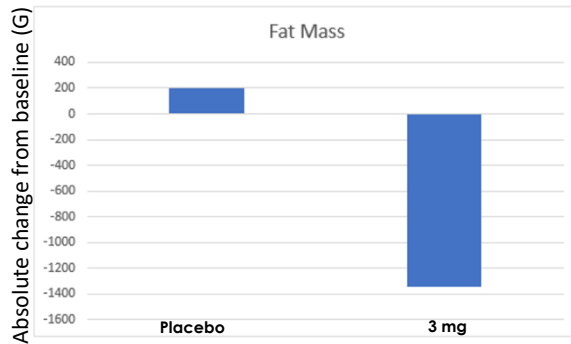
Up to Day 84 visit



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

Total fat mass

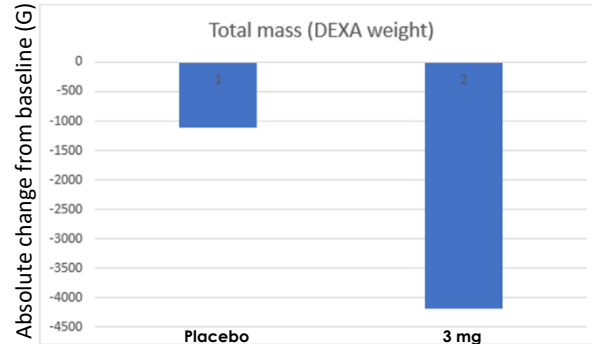
Up to Day 84 visit



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

Total body weight*

Up to Day 147 visit



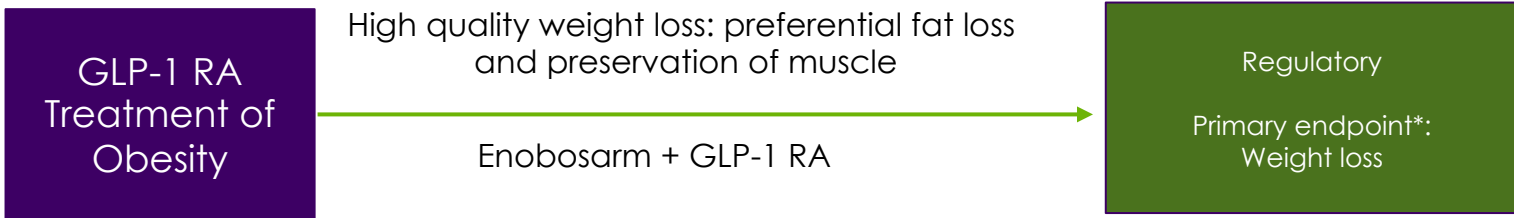
Placebo N=12, Treated N=12
Placebo corrected % change = -4.51%

Total Fat mass
Placebo corrected % change = -14.4%

¹ Study G300504 CSR data on file Veru

- **New drug in combination with GLP-1 RA should show incremental increase in weight loss**
- **Enobosarm potential direct effects:**
 - Prevents muscle loss: active protein synthesis in muscle
 - Increases fat loss: increase in lipolysis and decrease in lipogenesis

Strategy 1 - Entire obesity population



If muscle is preserved, can there still be significant weight loss?

The amount of fat mass compartment is greater than the muscle mass one



Preventing muscle loss (FFM deficit) blocks the trigger to increase in appetite¹

Collateral Fattening: When a Deficit in Lean Body Mass Drives Overeating

Abdul G. Dulloo

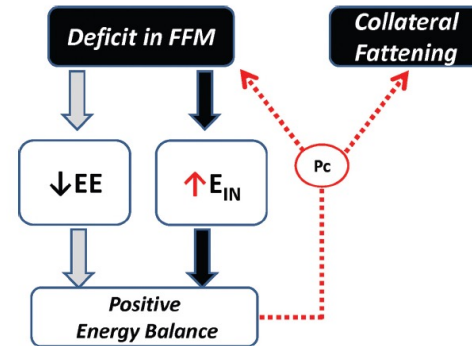
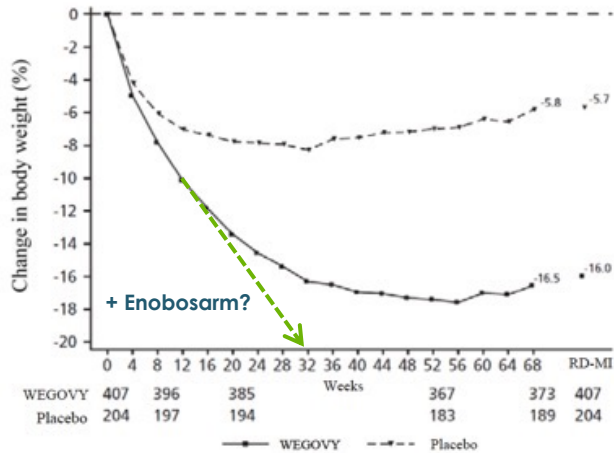


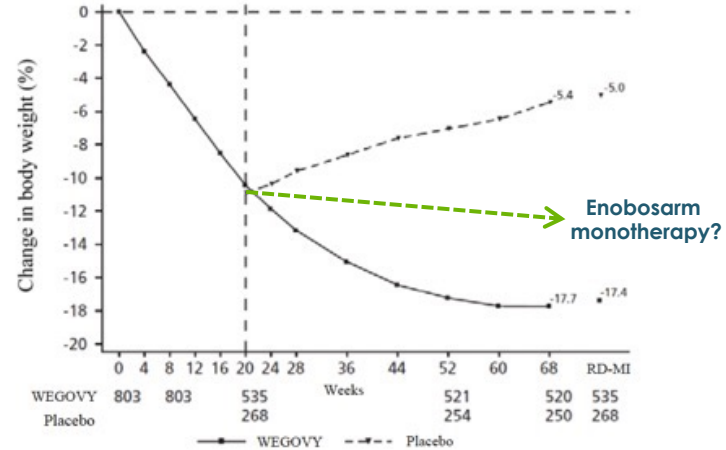
Figure 2 Concept of collateral fattening. A deficit in fat-free mass (FFM) results not only in a lower energy expenditure (EE) and hence lower energy needs for weight maintenance, but also in the activation a feedback loop that drives energy intake (E_{IN}) in an attempt to restore FFM through the lean-to-fat partitioning characteristic (P_c) of the individual (4).

¹ Dulloo A Obesity 25:277-279, 2017

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



Greater amount of fat loss and resultant weight loss on GLP-1RA?

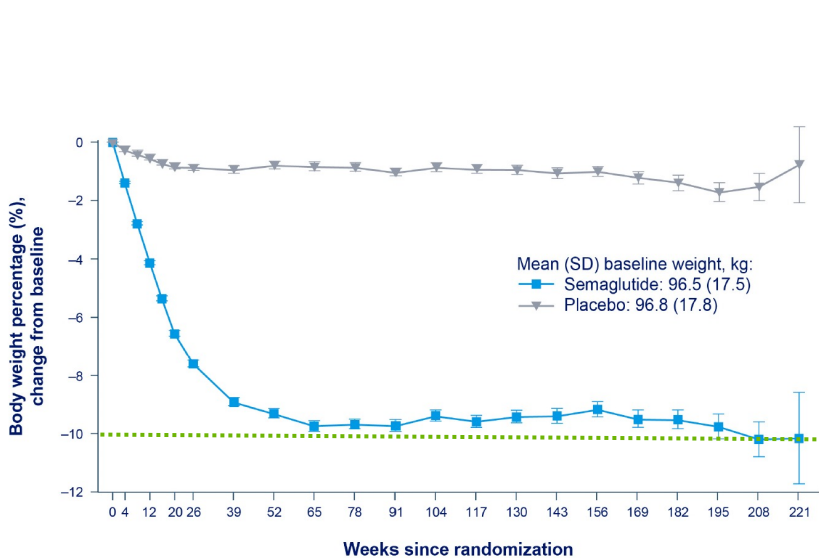


Prevent rebound fat and weight gain and maintain weight loss when off GLP-1RA?



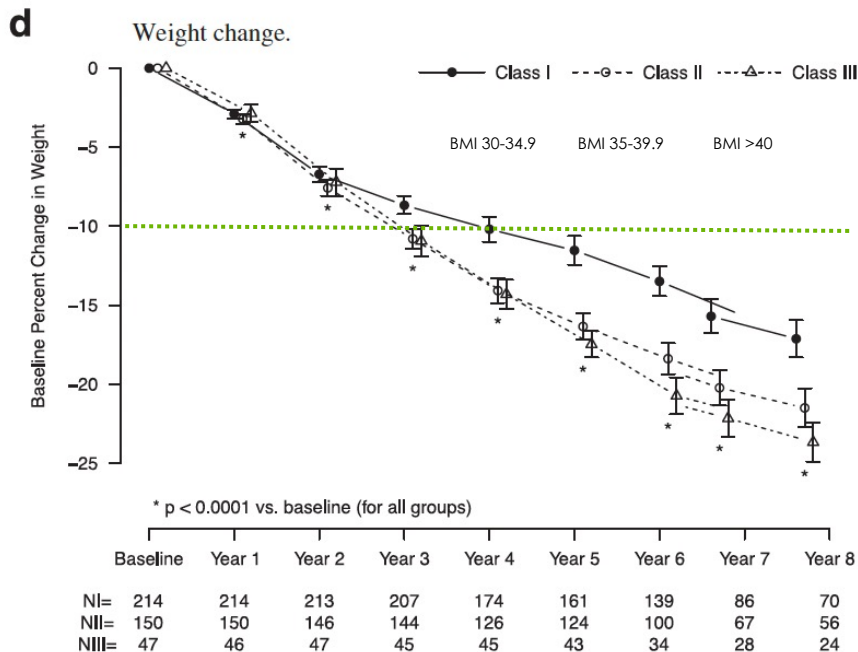
If muscle is preserved, could there be greater weight loss without a plateau ?

SELECT Trial:
Effect of semaglutide vs placebo on body weight
(4.25 years)



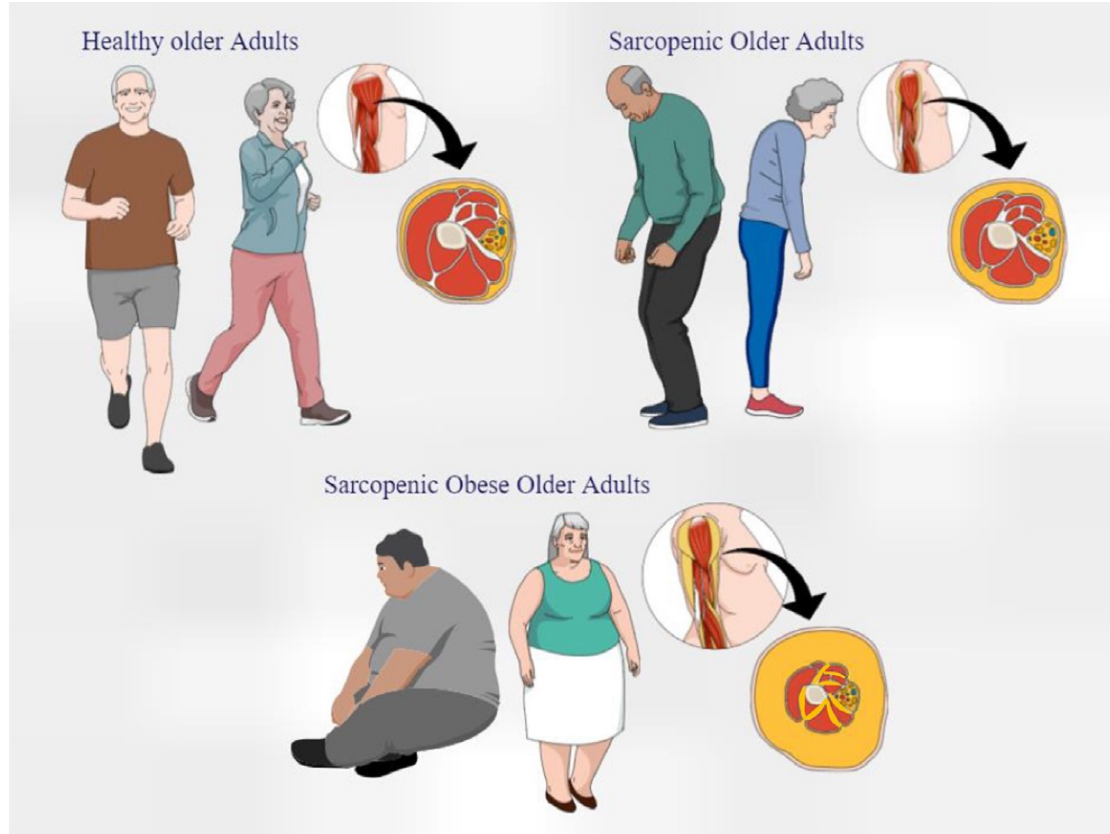
Semaglutide, N	8,803	7,647	7,493	6,690	7,290	6,447	7,282	6,460	7,474	5,991	5,898	4,686	5,085	3,650	2,954	1,737	921	157
Placebo, N	8,801	7,715	7,516	6,704	7,269	6,340	7,272	6,392	7,378	5,871	5,879	4,583	5,014	3,560	2,890	1,698	898	152

Effect of long-term testosterone in hypogonadal men with obesity (8 years)



¹Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and cardiovascular outcomes obesity without diabetes. N Engl J Med 2023;389:2221-32. DOI: 10.1056/NEJMoa2307563 | ² Saad F et al. Int J Obesity 40: 162-170, 2016.

Sarcopenic obese or overweight elderly patients at risk for developing muscle weakness and functional limitations when receiving GLP-1 RA for weight loss

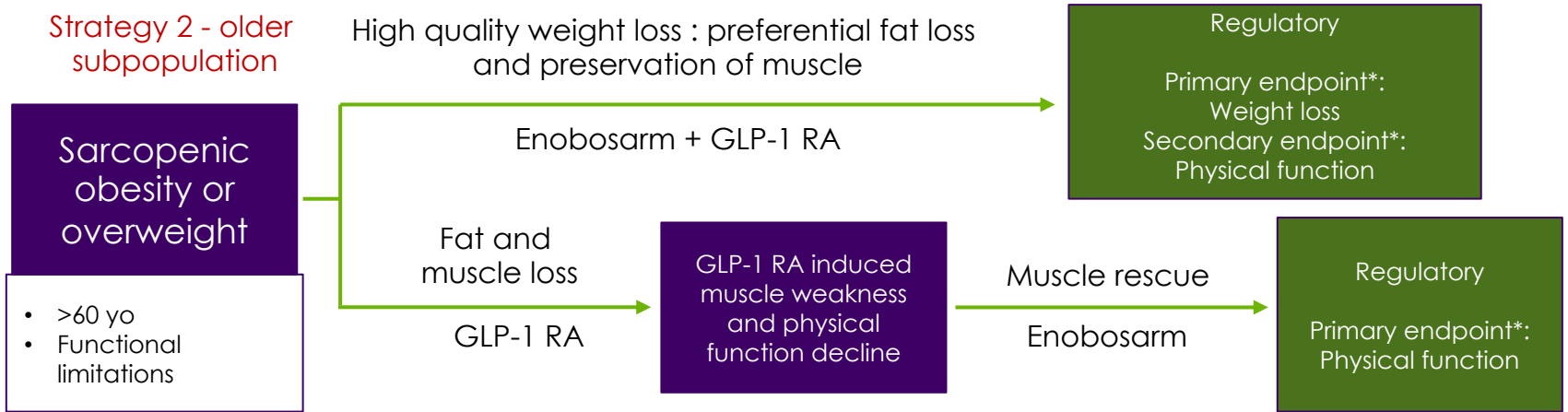


¹ Taken from Malandrino N et al. Endocrinol Metab Clin N Am 52 (2023) 317–339

Enobosarm +/- GLP-1 RA for the treatment of obesity

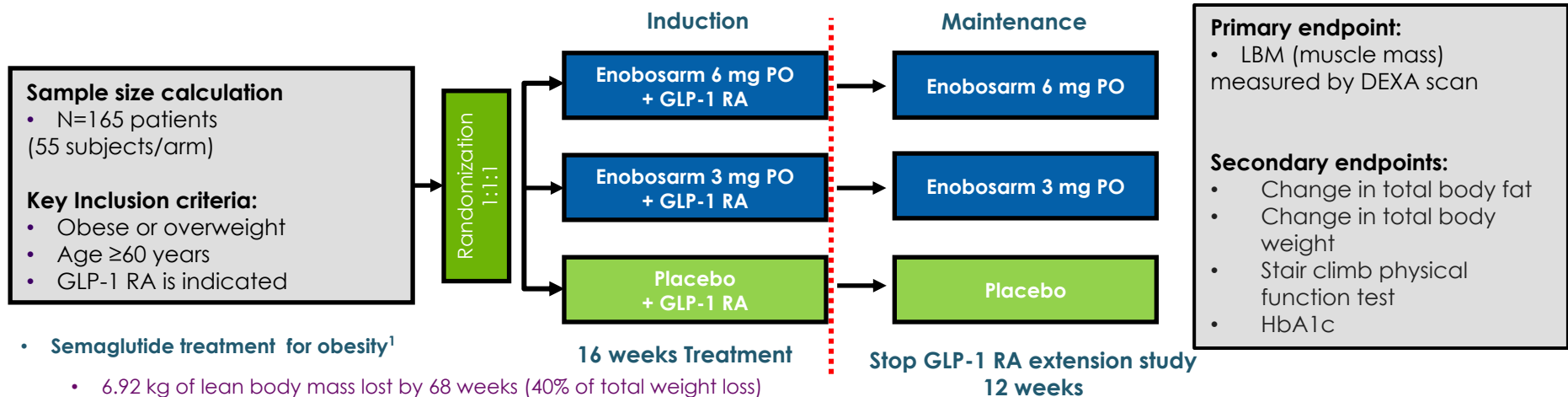
Clinical and regulatory strategy for older patients with low muscle reserve

- New drug in combination with GLP-1 RA should show incremental increase in weight loss and physical function benefit
- **Enobosarm potential direct effects:**
 - Prevents muscle loss: active protein synthesis in muscle
 - Increases fat loss: increase in lipolysis and decrease in lipogenesis



Phase 2b QUALITY Trial- Phase 2 double-blind, placebo controlled, randomized, dose finding trial of enobosarm in preventing muscle loss and increasing fat loss in patients receiving a GLP-1 RA for weight loss- **Enrollment completed**

Primary endpoint of LBM at 16 weeks



Semaglutide treatment for obesity¹

- 6.92 kg of lean body mass lost by 68 weeks (40% of total weight loss)
- 49% of total weight loss at 68 weeks occurred by 16 weeks

Bariatric surgery²

- 55% of 12-month 8.3 kg LBM loss occurred by 12 weeks

Study Power Assumptions

- α=0.05 (two-sided), power = 90%
- 1.6 kg loss in lean mass at 16 weeks in placebo group
- 0.3 kg loss in lean mass at 16 weeks in enobosarm group

Principal Investigator- Steven B. Heymsfield, M.D., a Professor and the Director of the Body Composition-Metabolism Laboratory at the Pennington Biomedical Research Center in Baton Rouge, Louisiana

- **Prevent loss of muscle to preserve physical function**
 - Older adults with sarcopenic obesity are at risk for developing physical function decline; accelerated development of frailty
- **Preserve muscle to stop the GLP-1 weight loss plateau**
 - Loss of muscle creates a muscle deficit that triggers increase in appetite that counters the hypocaloric benefit of GLP-1 drugs leading to the weight loss plateau
 - Without muscle deficit, GLP-1 drugs may potentially remove more fat mass in a maintained hypocaloric state
- **Adequate muscle reserve upon cessation of GLP-1 drugs may prevent fat mass rebound weight regain**
 - Muscle deficit when stopping the GLP-1 drives over-eating and collateral fattening
 - Fat is preferentially regained over muscle; rebound total weight gain is primarily fat



HEALTH

The Ozempic Plateau

Everyone hits a weight-loss plateau, but the race is on for next-generation drugs that can help patients lose even more weight.

By Sarah Zhang



Illustration by the Atlantic. Source: Getty

The Atlantic

JANUARY 17, 2024, 8 AM ET

SHARE SAVE

Enobosarm has an extensive safety database

Combined safety data from double-blind, placebo controlled clinical trials with enobosarm

Treatment-emergent adverse events in at least 2% of patients in placebo or enobosarm 3mg and at least 1% or higher in one of the two groups with a frequency of $\geq 0.5\%$

	Placebo N=515	Enobosarm N=512
Anaemia	123 (23.9%)	131 (25.6%)
Neutropenia	86 (16.7%)	71 (13.9%)
Asthenia	47 (9.1%)	58 (11.3%)
Chest pain	24 (4.7%)	14 (2.7%)
Condition aggravated	12 (2.3%)	7 (1.4%)
Disease progression	63 (12.2%)	51 (10.0%)
Bronchitis	9 (1.7%)	15 (2.9%)
Pneumonia	27 (5.2%)	19 (3.7%)
Urinary tract infection	26 (5.0%)	33 (6.4%)
Blood creatinine increased	20 (3.9%)	35 (6.8%)
Decreased appetite	56 (10.9%)	45 (8.8%)
Dehydration	22 (4.3%)	9 (1.8%)
Back pain	28 (5.4%)	15 (2.9%)
Hypokalaemia	18 (3.5%)	9 (1.8%)
Hypomagnesaemia	5 (1.0%)	10 (2.0%)
Hyponatraemia	5 (1.0%)	13 (2.5%)
Headache	33 (6.4%)	41 (8.0%)
Paraesthesia	17 (3.3%)	3 (0.6%)
Peripheral sensory neuropathy	13 (2.5%)	25 (4.9%)
Dyspnoea	23 (4.5%)	44 (8.6%)
Anxiety	5 (1.0%)	11 (2.1%)
Alopecia	69 (13.4%)	73 (14.3%)
Epistaxis	14 (2.7%)	5 (1.0%)
Haemoptysis	25 (4.9%)	13 (2.5%)
Hiccups	2 (0.4%)	10 (2.0%)
Rash	4 (0.8%)	12 (2.3%)

	Placebo N=515	Enobosarm N=512
Additional Adverse Events of Special Interest		
Alanine aminotransferase increased	7 (1.4%)	19 (3.7%)
Constipation	39 (7.6%)	42 (8.2%)
Deep vein thrombosis	17 (3.3%)	5 (1.0%)
Diarrhoea	49 (9.5%)	38 (7.4%)
Nausea	134 (26.0%)	136 (26.6%)
Vomiting	75 (14.6%)	76 (14.8%)

- **Evaluated in 27 clinical trials comprising >1580 subjects dosed (235 subjects dosed at \geq 9mg)**
- **Data reported from 12 Phase 1 studies:**
 - No QT effects
 - No significant drug-drug interactions²
 - 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

Enobosarm: Lipid profile

Safety of special interest:

Elderly healthy volunteers G200501 Phase 2 study conducted by GTx¹

Lipid profile change from baseline Day 84

Lipids	PBO n=24		3mg n=24		3mg vs. PBO	
HDL (total)(mg/dL)	1.5	3.10%	-16.2	-29.60%	-17.6	-32.70%
VLDL + chylomicron triglycerides (total) (mg/dL)	16.2	52.70%	-4.2	9.50%	-20.4	-43.20%
Direct LDL (total) (mg/dL)	7.5	6.30%	4.6	4.40%	-2.9	-1.90%
Trigs (total) (mg/dL)	17.1	21.70%	-9.7	-1.80%	-26.8	-23.50%
IDL particles (nmol/L)	10	151.70%	-27.2	-19.60%	-37.3	-171.30%
Total Cholesterol (mg/dL)	4.8	2.80%	-15.3	-6.60%	-20.1	-9.40%

Pro-atherogenic

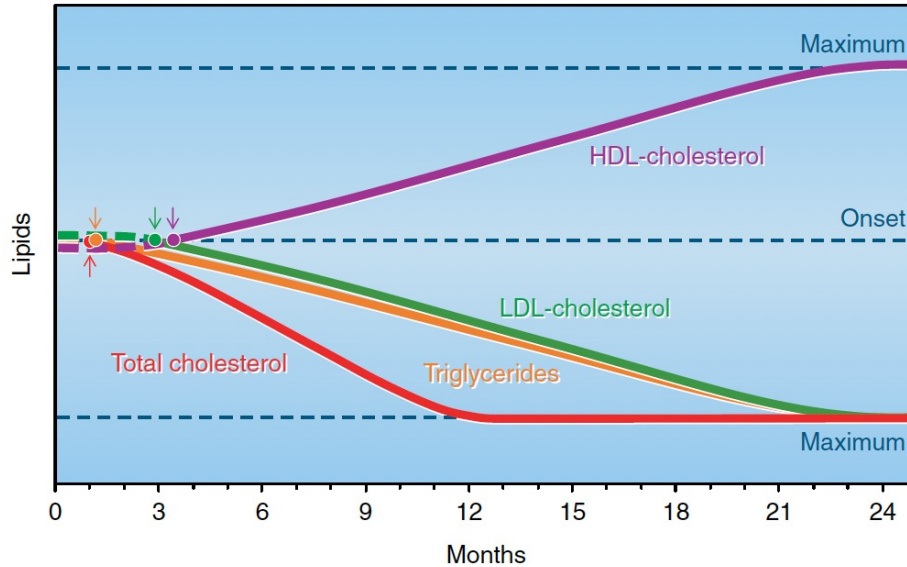
- LDL
- IDL
- VLDL
- Trigs

Anti-atherogenic

- HDL

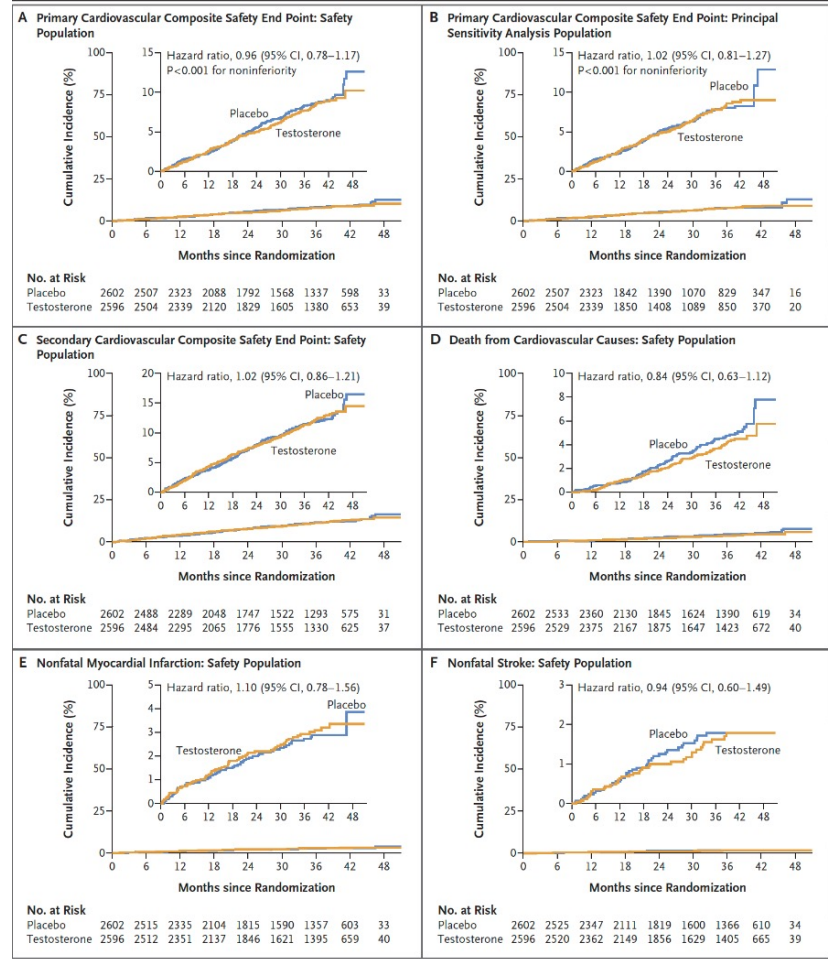
HDL changes are similar to what has been observed for testosterone replacement

Time course of testosterone replacement effects on lipids



2-year cardiovascular study in 5246 men 45 to 80 years of age who had pre-existing or high risk of cardiovascular disease with follow-up of 33 months

- Conclusions:
 - Testosterone therapy was noninferior to placebo with respect to the incidence of major adverse cardiac or stroke events



- **Enobosarm is a nonsteroidal, selective androgen receptor modulator 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/osteoporosis³⁻⁵
 - Safety
 - Large safety database
 - Not converted to estrogen or dihydrotestosterone
 - Lack of masculinizing effects in women
 - No liver toxicity - no DILI observed in clinical studies (27 clinical studies)
 - Minimal GI side effects: frequencies of nausea, vomiting, and diarrhea are similar to placebo⁹

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



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	January 2025		GLP-1 RA combo and GLP-1 RA rescue
Bimagrumab	Anti-myostatin Activin receptor Type 2 antagonist	IV	Phase 2	2025?		Acquired by Lilly for \$2 billion July 2023
Apitegromab	Anti-myostatin Selective anti-latent myostatin	IV	Phase 2	Mid 2025		
Taldefgrobep	Anti-myostatin	SubQ	Phase 2	Study initiating in 2Q 2024		
KER-065	Selective activin receptor ligand trap Anti-myostatin	SubQ	Phase 1	Q1 2025		
Trevogrumab	Anti-myostatin	Injectable	Initiating Phase 2	Not specified		
Azelaprag (BGE-105)	Apelin receptor agonist	Oral	Phase 2	Study initiating in 2024	BioAge Labs (Private)	Doing study with Lilly (Mounjaro)

Louis Aronne, MD- Veru's Chief Medical Advisor

Sanford Weill Professor of Metabolic Research
Director, The Comprehensive Weight Control Center
Division of Endocrinology, Diabetes & Metabolism
Weill Cornell Medical Center
New York City, New York
Founder of the American Board of Obesity Medicine
Past President of The Obesity Society

Shalender Bhasin, MB, BS

Professor of Medicine, Harvard Medical School
Director, Research Program in Men's Health: Aging and
Metabolism
Director, Boston Claude D. Pepper Older Americans
Independence Center
Brigham and Women's Hospital

William J. Evans, PhD

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

Caroline Apovian, MD, FACP, FTOS, DABOM

Co-Director of the Center for Weight Management and
Wellness (CWMW) in the Division of Endocrinology,
Diabetes, and Hypertension at Brigham and Women's
Hospital and Professor of Medicine at Harvard Medical
School

Adrian Dobs, MD, MHS

Professor of Medicine and Oncology and Director of the
Johns Hopkins Clinical Research Network of the Johns
Hopkins Institute for Clinical and Translational Research
(JHCRN)

Preventing muscle loss with weight-loss drugs

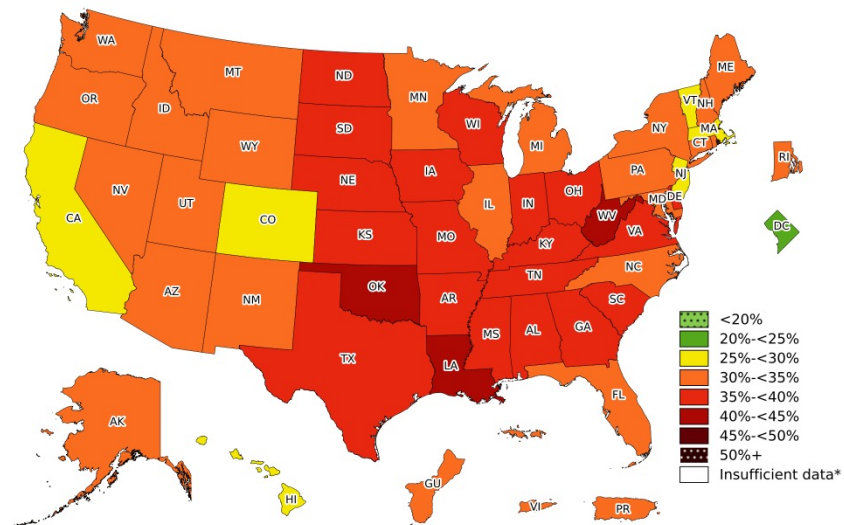
Global obesity and overweight market projected to be \$100 billion by 2030 (Barclays)

Overall obesity¹

Prevalence[†] of Obesity Based on Self-Reported Weight and Height Among U.S. Adults by State and Territory, BRFSS, 2022

US obesity market¹⁻³

- 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



Source: [Behavioral Risk Factor Surveillance System](#)

*Sample size <50, the relative standard error (dividing the standard error by the prevalence) ≥30%, or no data in a specific year.

[†]Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.

¹CDC 2022 | ²Malenfant J J Glob Health Rep 3:e2019045, 2019 | ³Lutski M et al. Prev Chronic Dis 17:200167, 2020

Q3 FYTD 2024 Results of operations	
Q3 FYTD 2024 Net Revenues	\$ 10.2 mm
Q3 FYTD 2024 Gross Profit	\$ 3.2 mm
Q3 FYTD 2024 Operating Loss	\$ 28.7 mm

Q3 FY 2024 Results of operations	
Q3 2024 Net Revenues	\$ 4.0 mm
Q3 2024 Gross Profit	\$ 1.3 mm
Q3 2024 Operating Loss	\$ 10.9 mm

Balance Sheet as of June 30, 2024	
Cash	\$ 29.2 mm
US/UK NOL carryforward	\$138.6/63.0 mm
Common Shares Outstanding ¹	146.4 mm

¹ An aggregate of 18.6 million stock options and stock appreciation rights are outstanding and are, or could potentially be, dilutive in excess of the 146.4 million common shares above

Obesity Program

Drug candidates

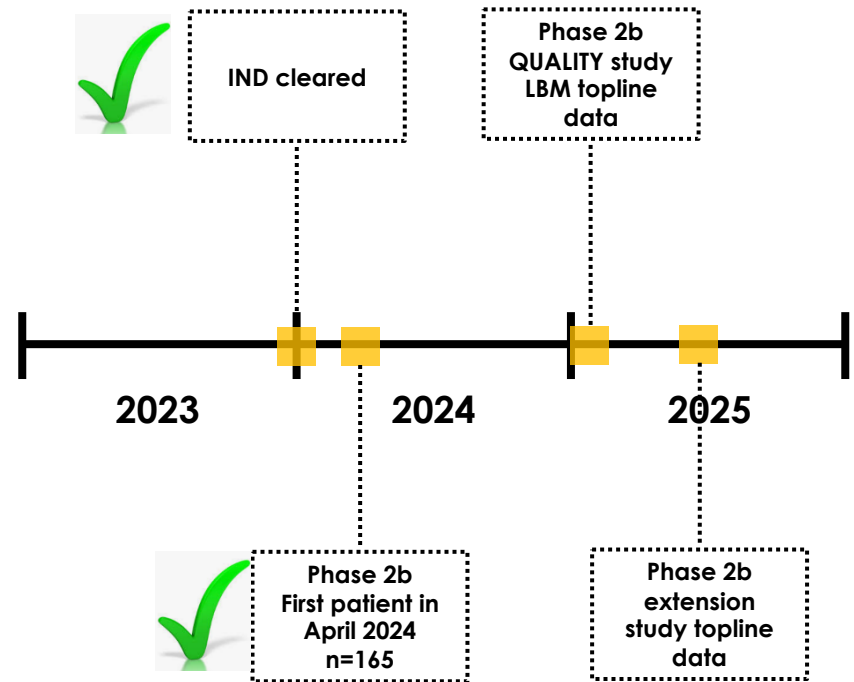
Enobosarm and GLP-1 receptor agonist combination

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



Appendix

Intellectual property

- **Enobosarm qualifies as new chemical entity**

- FDA grants 5 years market exclusivity for first indication
- US Patent and Trademark Office-may qualify for 5 additional years patent term extension

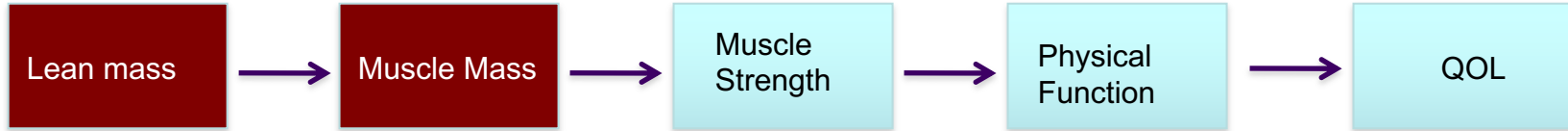
- **Patents**

- Enobosarm issued specific molecule composition of matter patents and issued specific molecule composition of matter polymorphs patents – Last expiry patent term (6 patents) 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 (3 US provisional patents) 2044
- Composition of matter formulation patent: New modified release tablet development in process

- **Additional market exclusivity- As a new chemical entity**

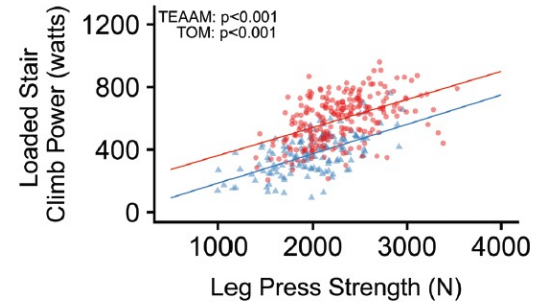
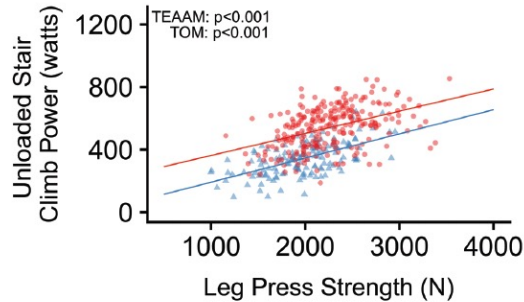
- Europe - may qualify for 10 years market exclusivity term
- Japan - may qualify for 7.5 Years from registration (NDA approval)

Physical function endpoint



• Testosterone replacement in men

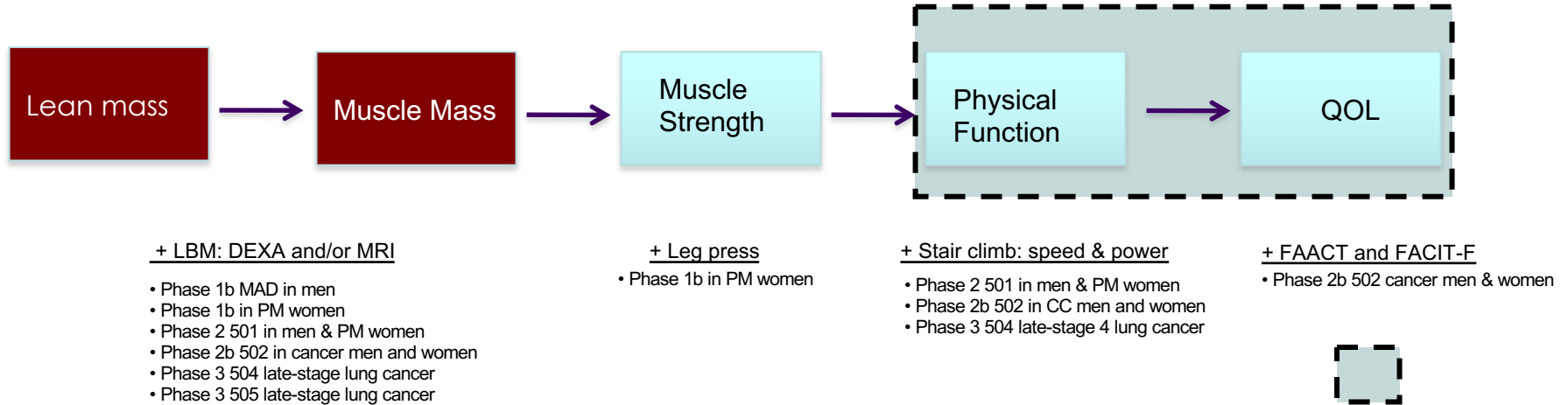
- Increase in lean mass and muscle mass
 - Increase in quadriceps muscles –weight bearing muscles
- Increase chest and leg press strength
- Leg press correlates with stair climb test
- Improves physical function- stair climb test



Stair climb power correlates with leg press strength¹

¹ Gagliano-Juca T et al. J Gerontol A Biol Sci Med Sci 75:1167-1175, 2020 | ² Trivison TG et al. J Gerontol A Biol Sci Med Sci 66A:1090-1099, 2011 | ³ Storer YW et al. J Clin Endocrin and Metab 88:1478-1485, 2003

Physical function: enobosarm is a potent anabolic agent



+ LBM: DEXA and/or MRI

- Phase 1b MAD in men
- Phase 1b in PM women
- Phase 2 501 in men & PM women
- Phase 2b 502 in cancer men and women
- Phase 3 504 late-stage lung cancer
- Phase 3 505 late-stage lung cancer

+ Leg press

- Phase 1b in PM women

+ Stair climb: speed & power

- Phase 2 501 in men & PM women
- Phase 2b 502 in CC men and women
- Phase 3 504 late-stage 4 lung cancer

+ FAACT and FACIT-F

- Phase 2b 502 cancer men & women



Regulatory endpoints

• **Enobosarm 3mg/d therapy in non-obese older men and women (>600 subjects)**

- Increase in lean body mass and muscle mass
 - Increase in quadriceps muscle volume –MRI
- Increase in leg press strength
- Improves physical function- stair climb test-unloaded
- Enobosarm 6mg/d treatment ?



LBM and stair climb test results from 501, 502, and 504 enobosarm clinical studies

Phase 2 501

Elderly men & women

- Mean age >60 yo
- 120 subjects
- 12 weeks of treatment
- No muscle wasting

Phase 2b 502

Multiple cancers wasting

- Mean age >60 yo
- 159 subjects
- 16 weeks of treatment
- Minimal muscle wasting

Phase 3 504

Late-stage lung cancer patients

- Mean age >60 yo
- 321 subjects
- 21 weeks of treatment
- Significant muscle wasting on chemo

% Change in lean mass

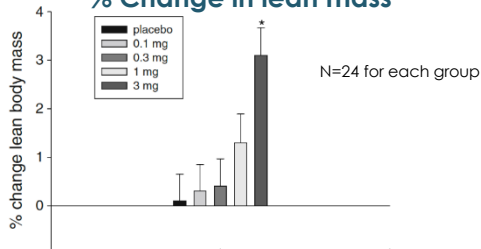


Fig. 1 Percentage change from baseline to day 86/EOS in total lean body mass: evaluable population. EOS end of study, * $P < 0.001$ 3 mg vs. placebo (T test)

% Change in stair climb power

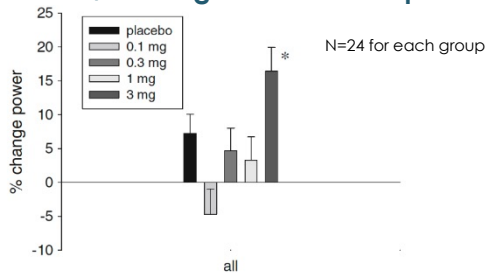


Fig. 2 Percentage change from baseline to day 86/EOS in stair climb power: evaluable population. EOS end of study, * $P = 0.0133$ mg vs. placebo (T test)

Change in total lean mass at Day 113/EOS

	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

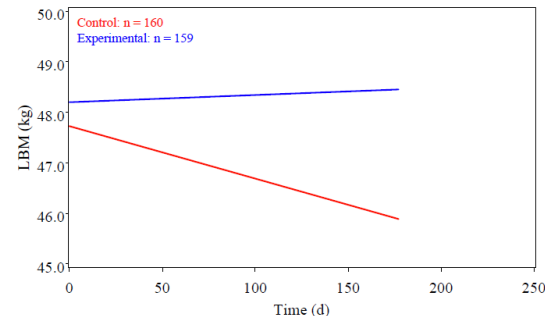
$P < 0.041$ enobosarm 3mg vs placebo

Change in stair climb time & power Day 113/EOS

	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

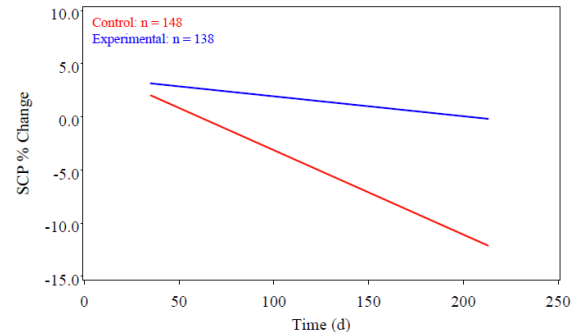
Change in total lean mass at Day 147/EOS

Between-Arm Difference P Values: Slope = $< .0001$, Mean = $< .0001$



Change in stair climb power Day 147/EOS

Between-Arm Difference P Values: Slope = 0.0473



What we know about the obesity population receiving GLP-1 RA?

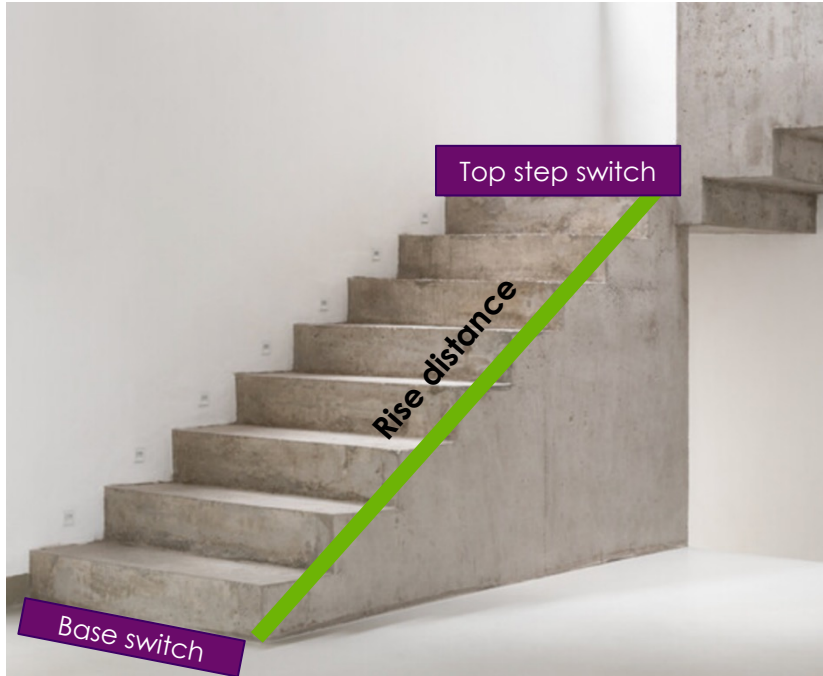
Expected physical function outcomes with enobosarm

- **Patients with obesity receiving semaglutide GLP-1 RA treatment**
 - Actively losing muscle and fat mass while decreasing appetite and inducing a low energy state
 - 40% of weight loss consists of lean body mass (muscle) by 68 weeks¹
 - 49% of total weight loss at 68 weeks occurred by 16 weeks¹
 - Based on bariatric surgery for obesity, 55% of the 12-month 8.3 kg LBM loss occurred by 12 weeks²
 - Extreme weight loss by bariatric surgery leads to loss of lower limb muscle strength by 3 months post-surgery³⁻⁴
 - Recent meta-analysis by Ibacache-Saavedra et al. (2024) reviewed 24 studies consisting of 666 subjects at 3-12 months post bariatric surgery:
 - Significant decrease in absolute lower limb isometric strength ($p=0.002$)
 - Greater reduction in BMI after bariatric surgery resulted in a higher loss of absolute lower-limb strength ($p=0.02$)
- **In our previous studies, enobosarm 3mg/d treatment increased LBM, quadriceps muscle volume, and leg press strength as well as improved physical function by unloaded stair climb test (between 12-21 weeks)**
- **To increase sensitivity, a loaded stair climb test is being used in the Phase 2b QUALITY clinical study**

¹ Wilding JPH et al. NEJM 384:989-1002, 2021 | ² Nuijten M Obes Rev 23:e13370, 2022 | ³ Ibacache-Saavedra P et al. Obs Rev25:e13790, 2024 | ⁴ Reinmann A et al. Front Endo 12:846283, 2021

Loaded stair climb test¹

$$\text{Stair climb power (Watts)} = \frac{(\text{Body weight} + \text{load carried (kg)}) \times 9.81 \text{ m/s}^2 \times \text{total stair rise (m)}}{\text{time (s)}}$$



- 8 step staircase with a computer timer switch pad placed at base and top step
- Subject is loaded by placing iron plates in a backpack equal to 10% of baseline body weight
- Subject wearing loaded backpack climbs stairs as quickly as possible and computer captures time
- The loaded condition raises the ceiling of the test to increase the likelihood of detecting a response to the intervention compared to the unloaded test
- FDA accepts stair climb test as regulatory endpoint²

¹ Trivison TG et al. J Geront A Biol Sci Med Sci 10:1090, 2011 | ² Duvyzat Package Insert |