UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 13, 2023

VERU INC.
(Exact name of registrant as specified in its charter)

Wisconsin	**1-13602**	**39-1144397**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2916 N. Miami Avenue, Suite 1000, Miami, Florida 33127
Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (305) 509-6897

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	VERU	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement

As previously reported by Veru Inc. (the "Company") in its Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on May 3, 2023, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park" or "Investor") (each, a "Party", and together, the "Parties") dated as of May 2, 2023, which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $100,000,000 of shares (the "Purchase Shares") of the Company's common stock, par value $0.01 per share (the "Common Stock") over the 36 month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park, pursuant to which it agreed to provide Lincoln Park with certain registration rights related to the shares issued under the Purchase Agreement (the "Registration Rights Agreement" and, collectively with the Purchase Agreement, the "Agreements").

On May 3, 2023, the Company filed a prospectus supplement with the SEC under the Company's shelf Registration Statement on Form S-3 (File No. 333-270606), which became effective on April 14, 2023 relating to the purchase and sale of the Purchase Shares pursuant to the Agreements (the "Purchase Agreement Prospectus").

On December 13, 2023, the Company entered into an amendment (the "Amendment") to the Agreements to reduce the amount of shares of common stock subject to the registration under the Agreements from $100 million to $50 million until the Company has sold at least $50 million of shares of common stock under the Purchase Agreement. The Company may sell additional shares of our common stock from time to time under the Purchase Agreement. As of the date of the filing of the Amendment, the Company had sold 3,025,000 shares of its Common Stock covered by the Purchase Agreement Prospectus pursuant to the Purchase Agreement, resulting in proceeds to the Company of $3.1 million.

In connection with the Amendment, the Company plans to file a prospectus supplement to reduce the amount of Purchase Shares which may be sold under the Purchase Agreement Prospectus from $100 million to $50 million. The Company will not make any sales of Purchase Stock under the Purchase Agreement to the extent such sales would cause the aggregate amount of Purchase Shares sold pursuant to the Purchase Agreement to exceed $50 million, unless a new prospectus supplement or registration statement relating to the Purchase Shares has been filed with the SEC.

This Current Report on Form 8-K shall not constitute an offer to sell or a solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, nor shall there be any sale of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction. The foregoing description of the Amendment is qualified in its entirety by reference to the full text of the Amendment, which is attached as Exhibit 10.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 8.01 Other Events

On December 13, 2023, the Company updated its corporate presentation to include a discussion of its planned development of enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a glucagon-like peptide-1 receptor agonist who are at-risk for developing muscle atrophy and muscle weakness (the "Updated Slides"). Selected slides from the updated corporate presentation are attached as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavor," "potential," "continue," and similar expressions, or the negative of these terms, or similar expressions. These forward-looking statements include statements about the Company's plan to reduce the amount of securities which may be sold under the Purchase Agreement Prospectus, the potential safety and anti-tumor activity of any of the Company's current or future product candidates in treating patients, including without limitation enobosarm, the Company's plans to develop enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a glucagon-like peptide-1 receptor agonist who are at-risk for developing muscle atrophy and muscle weakness, the design of its proposed Phase 2b clinical trial evaluating enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a glucagon-like peptide-1 receptor agonist who are at-risk for developing muscle atrophy and muscle weakness and the Company's future expectations, plans and prospects. Accordingly, these statements involve estimates, assumptions, risks and uncertainties which could cause actual results to differ materially from those expressed in them, including: the development of the Company's product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development as well as other operations of the Company; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines, anti-virals and other treatments become widely distributed the need for new COVID-19 or other ARDS treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a viral-induced ARDS treatment, including favoring other treatment alternatives or imposing price controls on viral-induced ARDS treatments; the Company's existing products, including FC2 and, if authorized, sabizabulin, 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 platform, potential regulatory complexity, development costs, and market awareness and acceptance of any telehealth platform we develop; risks relating to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of a large telehealth customer; 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;. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company's business are described in additional detail in the Company's Annual Report on Form 10-K for the year ended September 30, 2023 and other documents filed by the Company from time to time with the SEC. The Company is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed herewith:

Exhibit No.	Document
10.1	Letter Agreement dated December 13, 2023, by and between Veru Inc. and Lincoln Park Capital Fund, LLC.
99.1	Selected Slides from Corporate Presentation of Veru Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 13, 2023

VERU INC.

By: /s/ Michele Greco
Michele Greco
Chief Financial Officer and
Chief Administrative Officer

Exhibit 10.1

December 13, 2023

Lincoln Park Capital, LLC
440 North Wells, Suite 410
Chicago, IL 60654
Attention: Josh Scheinfeld/Jonathan Cope

Gentlemen,

Reference is made to (i) that certain Purchase Agreement (the "Agreement"), dated as of May 2, 2023, by and between Veru Inc., a Wisconsin corporation (the "Company"), and Lincoln Park Fund, LLC, an Illinois limited liability company (the "Investor"), and (ii) that certain Registration Rights Agreement (the "RRA"), dated as of May 2, 2023, by and between the Company and the Investor (collectively, the "Agreements").

Pursuant to Section 12(o) of the Agreement and Section 9 of the RRA, the Company and the Investor hereby amend the Agreements. The Company and the Investor hereby agree that the Agreements shall be amended such that, until such time as Fifty Million Dollars ($50,000,000) of the Purchase Shares, as defined in the Agreements, have been issued upon purchases under the Agreements, the Company shall only be required to register Fifty Million Dollars ($50,000,000) of the Purchase Shares. Except as expressly provided in this letter agreement, all of the terms and provisions of the Agreements are and will remain in full force and effect and are hereby ratified and confirmed by the parties. Capitalized terms not otherwise defined in this letter agreement shall have the meanings ascribed thereto in the Agreements.

Please confirm your agreement by signing below and returning a copy to the undersigned.

Very truly yours,

VERU INC.

By: /s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D.,
Chairman, President and
Chief Executive Officer

Accepted and agreed
as of the date set forth above:

LINCOLN PARK CAPITAL FUND, LLC

BY: Lincoln Park Capital, LLC

BY: Rockledge Capital Corporation

By: /s/ Joshua Scheinfeld
Name: Joshua Scheinfeld
Title: President

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.

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]

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]
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]

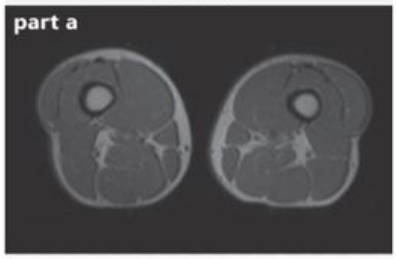
[1] Wilding JPH et al. NEJM 384:989-1002, 2021 | [2] Wegovy FDA PI | [3] Sargeant JA et al. Endocrinol Metab 34:247-262, 2019| Ida S et al. Current Diabetes Rev 17:293-303, 2021 | [5] McGrimmon RJ et al. Diabetologia 63:473-485, 2020 |

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

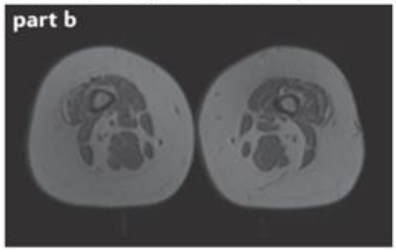
The target population is the at risk obese or overweight patients with low muscle reserves

- **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

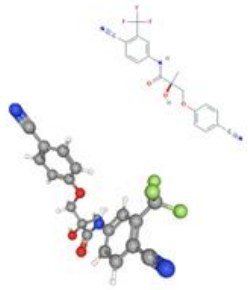
[1] CDC | [2] Wennamethee SG et al. Current Diabetes Reports 2023 | [3] Spanoudaki M et al. Life 13:1242, 2023 | [4] Roh E et al. Front Endocrinol 11: 2020 | [5] Batsis J et al. Nature Reviews Endocrinology 14:513-537, 2018

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

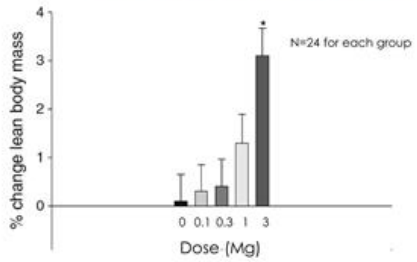


Fig. 1 Percentage change from baseline to day 86/EOS in total lean body mass: evaluable population. *EOS* end of study, **P*<0.001 3 mg vs. placebo (*T* test)

% Change in stair climb power

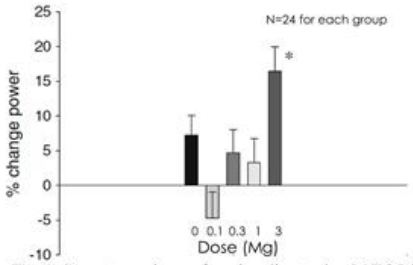
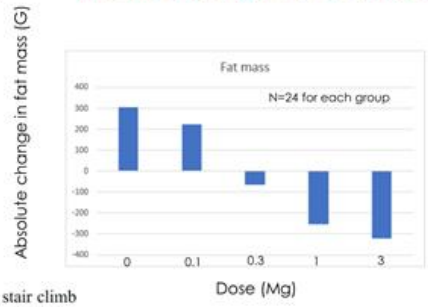


Fig. 2 Percentage change from baseline to day 86/EOS in stair climb power: evaluable population. *EOS* end of study, **P*=0.0133 mg vs. placebo (*T* test)

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]

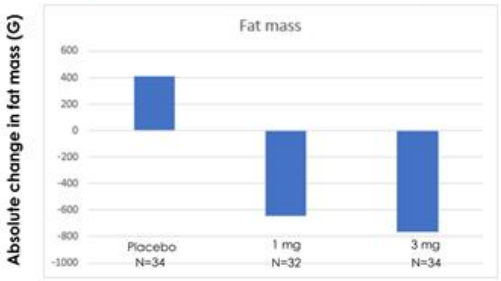
Change in total lean mass at Day 113/EOS compared to baseline

	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

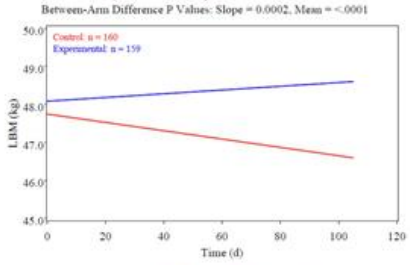
[1] Dobs AS et al. Lancet Oncol 14:335-345, 2013 | [2] G200502 Clinical Study Report

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]

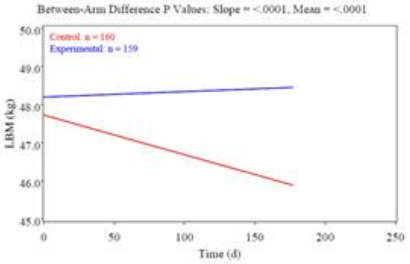
3mg enobosarm treatment in 321 subjects enrolled for 21 weeks

Lean body mass (muscle)

Up to Day 84 visit

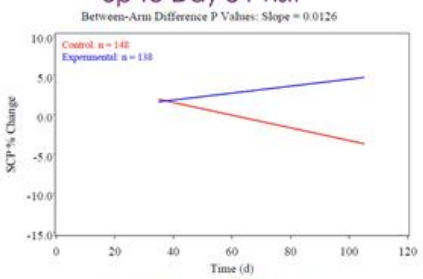


Up to Day 147 visit

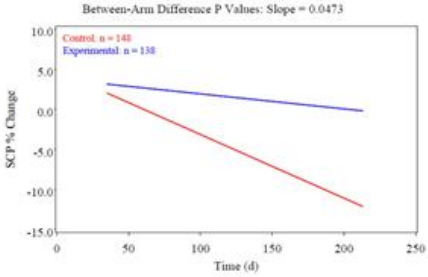


Stair climb power

Up to Day 84 visit

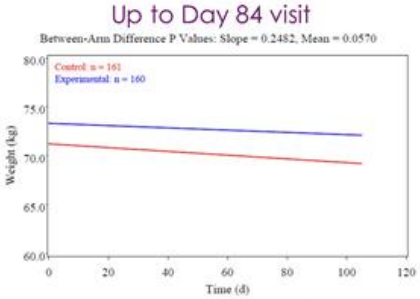


Up to Day 147 visit

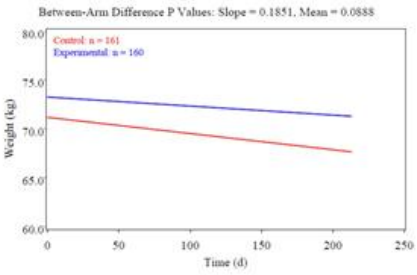


Body weight

Up to Day 84 visit



Up to Day 147 visit

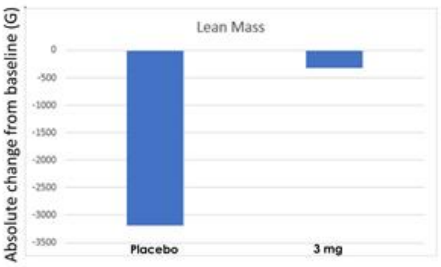


[1] Study G300504 CSR data on file Veru

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]

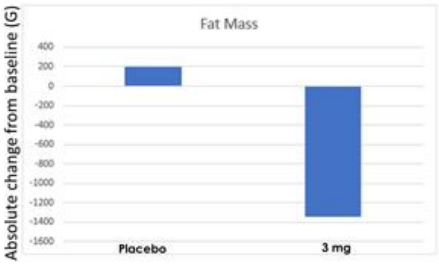
Post-hoc analysis of obese subpopulation (BMI ≥ 30)

Total lean body mass
Up to Day 84 visit



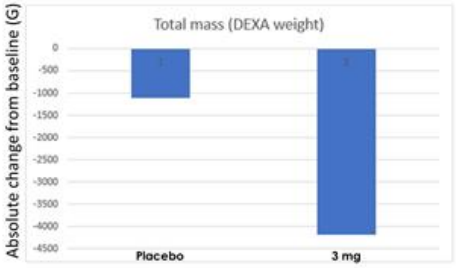
Placebo N=15, Treated N=14
Placebo corrected % change = +4.96%

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



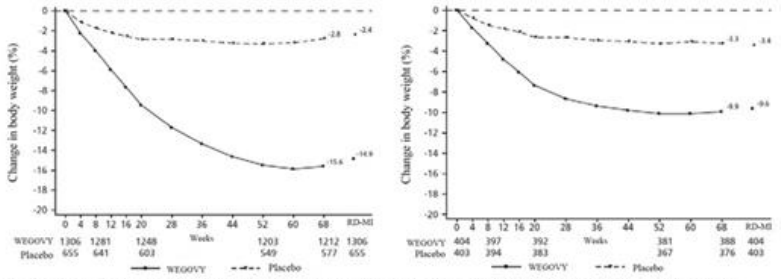
Placebo N=12, Treated N=12
Placebo corrected % change = -4.51%

[1] Study G300504 CSR data on file Veru

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

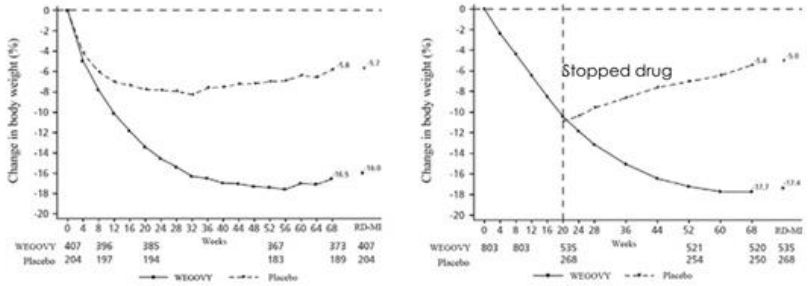
- Patients demonstrated greatest amount of absolute total weight loss (fat + muscle) between weeks 4 and 20
- Patients that discontinued treatment at week 20 had significant weight gain (rebound)
    - The reported weight gain was almost entirely fat mass not muscle

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)

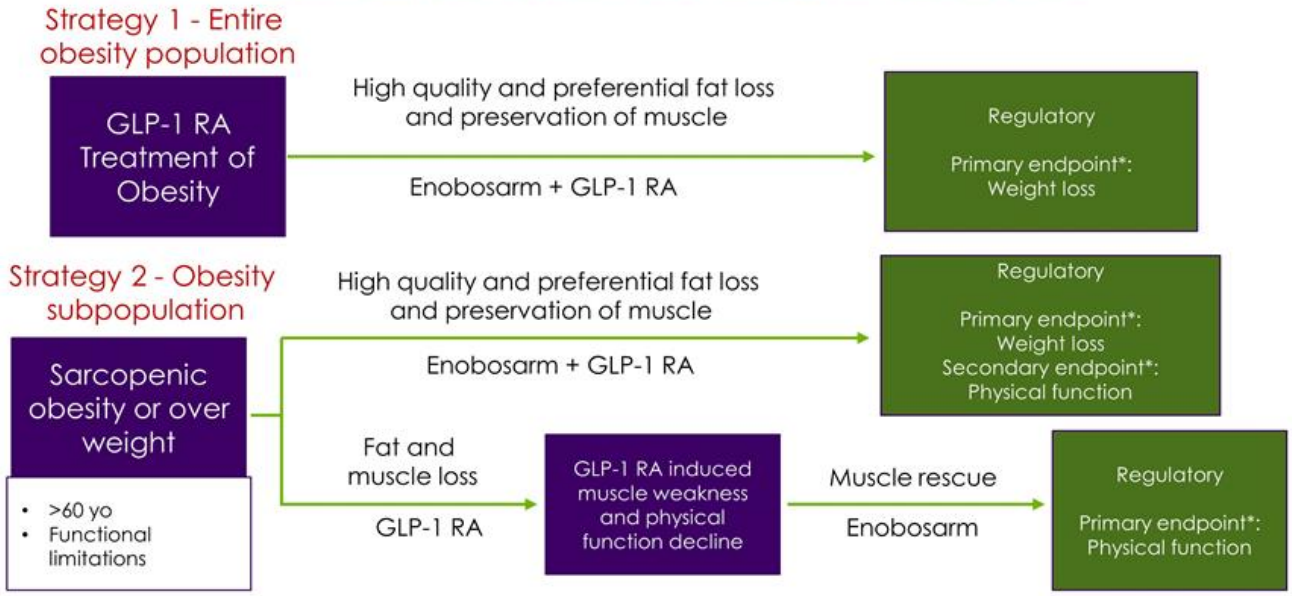
Figure 7. Change from baseline (%) in body weight (Study 3 on left and Study 4[a] on right)



[1]FDA Wegovy PI

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

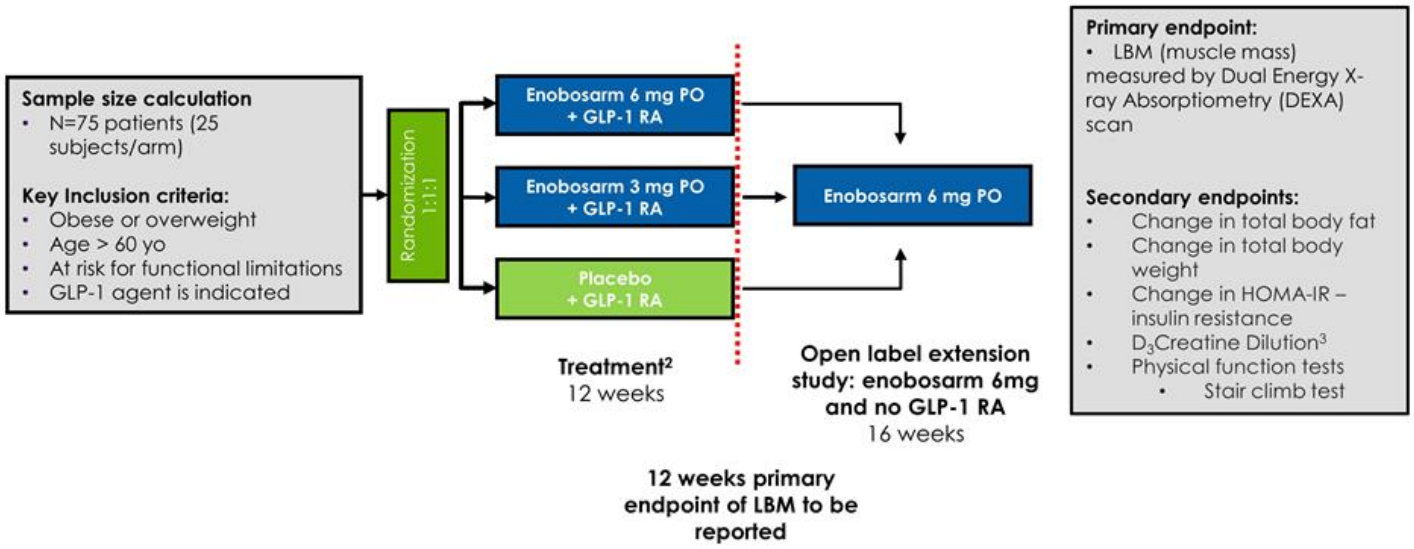
Enobosarm potential direct effects: active protein synthesis in muscle (increasing muscle mass) and increase in lipolysis leads to greater fat loss



*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]



12 weeks primary endpoint of LBM to be reported

[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