Subject: MTSR1: Weekly Competitive Intelligence Newsletter (Jan 29 – Feb 5, 2024)
Date: Monday, February 5, 2024 at 10:52:25 AM Eastern Standard Time
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Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: Jan 29 – Feb 5, 2024

DASHBOARD

KEY TAKEAWAYS OF THE WEEK (Jan 30 – Feb 5, 2024)

- **Clinical –** Eli Lilly initiated a Phase II, to investigate weight management with LY3841136 (undisclosed) vs. placebo in adult participants with obesity or overweight [U.S.]
- **Regulatory –** The U.S. FDA has cleared NeuroBo Pharmaceuticals' IND application for DA-1726 (undisclosed) [U.S.]
- **Commercial –** Roche completed acquisition of Carmot Therapeutics [U.S.]

DETAILED NEWS

CLINICAL

1 New Trial: A study of LY3841136 (undisclosed) compared with placebo in adult participants with obesity or overweight [U.S.]
Jan 30, 2024

- Eli Lilly initiated a Phase II trial, the main purpose of this study, performed under the master protocol W8M-MC-CWMM (NCT06143956), is to investigate weight management efficacy and safety with LY3841136 (undisclosed) vs. placebo in adult participants with obesity or overweight
- **Trial details:** N = 225; Status: Not Yet Recruiting; Start date: Feb 16, 2024; PCD: Jun 27, 2025; SCD: Sep 05, 2025; Location: U.S.

- **Read more:** NCT06230523
- **Implications:** The study represents a potential advancement in obesity treatment options. Amylin agonists like LY3841136 could offer a new mechanism of action compared to existing weight management medications. This could fill a gap in current treatment modalities, providing more options for patients who may not respond well to existing therapies. Novo Nordisk's CagriSema, a combination treatment of obesity and weight-loss drug semaglutide and amylin analogue, cagrilintide entered Phase III trials

2 Pfizer Q4 FY23 Earnings Call
Jan 30, 2024

- Pfizer announced topline data from the Phase IIb clinical trial investigating its oral glucagon-like peptide-1 receptor agonist (GLP-1RA) candidate danuglipron in adults with obesity and without type 2 diabetes in Dec 2023
  - The study met its primary endpoint demonstrating statistically significant change in body weight from baseline. While the most common AEs were mild and gastrointestinal in nature consistent with the mechanism, high rates were observed
  - No new safety signals were reported, and treatment with danuglipron was not associated with increased incidence of liver enzyme elevation vs. placebo
- Future development of danuglipron will be focused on a once-daily formulation, with PK data anticipated in H1 2024, which will help to inform a potential path forward

- **Read more:** Pfizer Q4 FY23 Earnings Call – Press Release

- **Implications:** Pfizer remains interested in entering the obesity market despite the setbacks experienced with both lotiglipron and danuglipron (twice daily), which failed to advance to phase 3 trials. In December 2023, Pfizer decided to discontinue the development of danuglipron, even though it achieved its primary goal in a placebo-controlled Phase 2b trial by leading to a statistically significant weight loss. However, the extent of weight reduction was less than that observed in trials for competing drugs targeting the same GLP-1 pathway. Additionally, a significant number of patients reported side effects, leading to a high dropout rate from the trial.

3 **Trial update: A study of LY3437943 (retatrutide) on renal function in participants with overweight or obesity and chronic kidney disease with or without type 2 diabetes [U.S.]**
Jan 31, 2024

- A Phase II study sponsored by Eli Lilly titled, *"A study of LY3437943 (retatrutide) on renal function in participants with overweight or obesity and chronic kidney disease with or without type 2 diabetes"* has undergone changes
  - **Secondary outcome measures:** Updates were made in secondary outcome measures
  - **Contacts/Locations:** Multiple sites have been removed and added to the U.S. location

- **Read more:** NCT05936151

- **Implications:** Tightening the HbA1c requirement from ≤10.5% to ≤9.5% for those with T2D could exclude patients with poorer glycemic control. This shift potentially narrows the participant pool to those with moderately controlled T2D, possibly aiming for a group whose condition might respond more predictably to the intervention

4 **Trial update: A chronic weight management master protocol study LY900038 (mazdutide) of multiple intervention-specific-appendices (ISAs) in adult participants with obesity or overweight [U.S.]**
Jan 31, 2024

- A Phase II study sponsored by Eli Lilly titled, *"A chronic weight management master protocol study LY900038 (mazdutide) of multiple intervention-specific-appendices (ISAs) in adult participants with obesity or overweight"* has undergone changes
  - **Overall status:** Updated from 'Not yet recruiting' to 'Recruiting'
  - **Enrollment:** Updated from 165 [Anticipated] to 390 [Anticipated]
  - **Contacts/Locations:** Multiple sites have been removed and added to the U.S. location

- **Read more:** NCT06143956

- **Implications:** The anticipated enrollment increase from 165 to 390 participants suggests a more extensive study scope, allowing for more robust data collection and analysis. This could enhance the statistical power of the study, potentially leading to more definitive conclusions about mazdutide's efficacy and safety

5 **Trial update: A research study comparing WEGOVY (semaglutide) to other weight management drugs in people living with obesity in America [U.S.]**
Jan 31, 2024

- A Phase IV study sponsored by Novo Nordisk titled, *"A research study comparing WEGOVY (semaglutide) to other weight management drugs in people living with obesity in America"* has undergone changes
  - **Overall status:** Updated from 'Recruiting' to 'Active, not recruiting'
  - **Contacts/Locations:** A site was removed and added to the U.S. location

- **Read more:** NCT05579249

- **Implications:** Novo Nordisk tries to differentiate WEGOVY (semaglutide) from other commercially available medications for weight management in the U.S.

6 **Trial update: A research study on how NNC0487-0111 (undisclosed) works in people with overweight or obesity [U.S.]**
Jan 31, 2024

- A Phase I study sponsored by Novo Nordisk titled, *"A research study on how NNC0487-0111 (undisclosed) works in people with overweight or obesity"* has undergone changes
  - **Overall status:** Updated from 'Recruiting' to 'Completed'
  - **PCD and SCD:** Updated from Jan 9, 2024 [Anticipated] to Jan 9, 2024 [Actual]
  - **Enrollment:** Updated from 116 [Anticipated] to 144 [Actual]
  - **Contacts/Locations:** Sites were removed and added to the U.S. location

- **Read more:** NCT05369390

- **Implications:** Recruitment completed for Phase I trial for NNC0487-0111, which is a new medicine similar to two hormones that are produced in human body: amylin and glucagon-like peptide-1.

7 **Roche Q4 FY23 Earnings Call**
Feb 1, 2024

- According to Roche Q4 FY23 Earnings Call presentation early-stage clinical readouts for all incretins acquired from Carmot Therapeutics is expected in 2024 and new trials are to be initiated
    - CT-388: Final Phase I trial data readout is expected in the end of 2024 and Phase II trial in obesity +/- T2D to be initiated in 2024
    - CT-868: Phase II trial interim data readout expected in 2024
    - CT-996: Phase I trial interim data readout expected in 2024
- **Read more:** Roche Q4 FY23 Earnings Call – Press Release, Roche Q4 FY23 Earnings Call – Presentation
- **Implications:** Roche enters the competition in the obesity drug market through a $2.7 billion acquisition of Carmot. The deal marks a return to a GLP-1 field that Roche abandoned in 2018, when its subsidiary Chugai was sold to Lilly. Carmot's once-a-week injection called CT-388, is a dual GLP-1/GIP receptor agonist similar to Lilly's Mounjaro, or Zepbound.

8 **Trial update: Safety and efficacy of bimagrumab and semaglutide in adults who are overweight or obese [Global]**
Feb 1, 2024

- A Phase II study sponsored by Eli Lilly titled, "*Safety and efficacy of bimagrumab and semaglutide in adults who are overweight or obese"* has undergone changes
    - **Secondary IDs:** Updated from VER201-PH2-031 [Eli Lilly and Company] to J4Z-MC-GIDA [Eli Lilly and Company] VER201-PH2-031 [Versanis]
    - **PCD:** Updated from May 31, 2024 [Anticipated] to May 20, 2024 [Anticipated]
    - **SCD:** Updated from Jun 30, 2025 [Anticipated] to Jun 17, 2025 [Anticipated]
    - **Contacts/Locations:** Multiple sites were removed and added to the U.S. location
- **Read more:** NCT05616013
- **Implications:** Lilly acquired bimagrumab, Versanis Bio's asset last year. Bimagrumab is a monoclonal antibody that blocks activin type II receptors and stimulates skeletal muscle growth, which might help to reduce body fat, while increasing muscle mass. Combining incretins with bimagrumab has the potential to further reduce fat mass while preserving muscle mass

REGULATORY

9 **NeuroBo Pharmaceuticals announces FDA clearance of IND for a Phase I clinical trial of DA-1726 (undisclosed) for the treatment of obesity [U.S.]**
Feb 1, 2024

- NeuroBo Pharmaceuticals announced that the U.S. FDA has cleared its IND application for DA-1726 (undisclosed). The company plans to initiate a Phase I clinical trial, for the treatment of obesity, in H1 2023
- The Phase I trial is designed to be a randomized, placebo-controlled, double-blind, sequential parallel group study to investigate the safety, tolerability, PK, and PD of single and multiple ascending doses of DA-1726 in obese, otherwise healthy subjects
    - Part 1: Single ascending dose (SAD) study, expected to enroll approximately 45 participants, randomized into one of five planned cohorts. Each cohort will be randomized in a 6:3 ratio of DA-1726 or placebo
    - Part 2: Multiple ascending dose (MAD) study, expected to enroll approximately 36 participants, who will be randomized into four planned cohorts, each to receive four weekly administrations of DA-1726 or placebo
- The primary endpoint will assess the safety and tolerability of DA-1726 by monitoring AEs, SAEs, TEAEs and AEs leading to treatment discontinuation
    - Secondary endpoints include the PK of DA-1726, assessed via serum concentrations over time and metabolite profiling at the highest doses of DA-1726
- **Read more:** NeuroBo Pharmaceuticals Press Release
- **Implications:** Phase I expected to start for DA-1726 a novel, dual oxyntomodulin (OXM) analog agonist that functions as a GLP1R and GCGR to test safety and tolerability. Company plans to dose first patient in first half of 2024 and expects to announce results in first half of 2025

10 **Japan to revise Ad guidelines to address GLP-1 use for cosmetic weight loss [Japan]**
Jan 31, 2024

- The Ministry of Health, Labor and Welfare (MHLW) will revise its advertising guidelines for medical institutions in response to an increase in illicit ads touting the off-label use of GLP-1 RAs for aesthetic weight loss
- A draft revision of the guidelines proposed by the MHLW was approved by its panel of experts on medical advertising on Jan 29,

2024

- The ministry aims to enforce the revised guidelines by the end of Mar, 2024 after taking public comments

- Medical advertising is regulated by the Medical Care Act, while specific requirements are stipulated in the guidelines and Q&As. Violations could be subject to administrative guidance

- **Read more:** Pharma Japan *(Subscription required)*

- **Implications:** N/A

11 **Bahrain among first countries to authorise 'MOUNJARO' injection [Bahrain]**
Feb 2, 2024

- According to the licensing mechanisms in force in Bahrain, the National Health Regulatory Authority (NHRA) has authorised the use of the MOUNJARO (tirzepatide) injection

  - The move is within the framework of the Kingdom's keenness to provide all medications that contribute to the treatment of chronic diseases related to obesity and diabetes

- The NHRA indicated that the MOUNJARO needle is available in the kingdom's pharmacies, and should be used in accordance with medical prescriptions and after undergoing the necessary medical examinations, adding that Bahrain is among the first countries to provide this medicine in its markets

- **Read more:** Bahrain News Agency

- **Implications:** This initiative is part of the Kingdom's measures to offer medications that help manage chronic diseases linked to obesity and diabetes.

COMMERCIAL

12 **Novo Nordisk Q4 FY23 Earnings Call**
Jan 31, 2024

- Total sales within Diabetes and Obesity care in 2023 increased by 38% in Danish kroner to DKK 215.1 Bn (42% at CER), mainly driven by GLP-1 diabetes sales growth of 48% in Danish kroner (52% at CER) and Obesity care growing by 147% in Danish Kroner to DKK 41.6 Bn (154% at CER)
- Total Obesity care sales in FY 2023 increased by 147% measured in Danish kroner and by 154% at CER, from DKK 16,864 Mn in 2022 to DKK 41,632 Mn in 2023

Q4 2023 sales split per area

	Total DKK Mn (% change at CER)	North America Operations DKK Mn (% change at CER)	The U.S. DKK Mn (% change at CER)	International Operations DKK Mn (% change at CER)	EMEA DKK Mn (% change at CER)	Region China DKK Mn (% change at CER)	Rest of World DKK Mn (% change at CER)
OZEMPIC (semaglutide)	30,065 (85%)	23,524 (101%)	21,807 (106%)	6,541 (44%)	3,536 (26%)	1,008 (77%)	1,997 (69%)
WEGOVY (semaglutide)	9,614 (311%)	8,608 (277%)	8,608 (277%)	1,006 -	1,006 -	-	-
SAXENDA (liraglutide)	1,615 (45%)	325 (73%)	144 (85%)	1,290 (23%)	704 (27%)	17 (17%)	569 (17%)

FY 2023 sales split per area

	Total DKK Mn (% change at CER)	North America Operations DKK Mn (% change at CER)	The U.S. DKK Mn (% change at CER)	International Operations DKK Mn (% change at CER)	EMEA DKK Mn (% change at CER)	Region China DKK Mn (% change at CER)	Rest of World DKK Mn (% change at CER)
OZEMPIC (semaglutide)	95,718 (66%)	69,340 (69%)	63,010 (67%)	26,378 (58%)	14,327 (40%)	4,821 (137%)	7,230 (61%)
WEGOVY (semaglutide)	31,343 (420%)	29,430 (393%)	29,430 (393%)	1,913 -	1,913 -	-	-
SAXENDA (liraglutide)	10,289 (0%)	3,887 (17%)	3,306 (22%)	6,402 (14%)	3,780 (10%)	146 (17%)	2,476 (20%)

- **Read more:** Novo Nordisk Q4 FY23 Earnings Call – Press Release, Novo Nordisk Q4 FY23 Earnings Call – Presentation

- **Implications:** The 147% growth in Obesity care sales, translating to 154% at CER, from DKK 16.864 billion in 2022 to DKK 41.632 billion in 2023, underscores the explosive demand and the effectiveness of new obesity treatments.

13 **Carmot Therapeutics announces completion of acquisition by Roche [U.S.]**
Jan 29, 2024

- Carmot Therapeutics announced that its acquisition by Roche has been completed
- The acquisition gives Roche access to Carmot's differentiated portfolio of incretins including:
    - **CT-388:** The lead asset which is currently in Phase I, is a Phase II ready, dual GLP-1/GIP receptor agonist for the treatment of obesity in patients with and without type 2 diabetes. Injected subcutaneously once a week, it has potential as a standalone and combination therapy to improve weight loss and to be expanded to other indications
    - **CT-996**: A once-daily oral, small molecule GLP-1 receptor agonist currently in Phase I intended to treat obesity in patients with and without type 2 diabetes
    - **CT-868:** A Phase II, once-daily SC injectable, dual GLP-1/GIP receptor agonist intended for the treatment of type 1 diabetes patients with overweight or obesity
- **Read more:** Carmot Therapeutics Press Release
- **Implications:** Roche completed acquisition of Carmot Therapeutics, which will place another big pharma player in the obesity space. Carmot's attempt to differentiate its candidates from the competition rests on "biased signaling" that is designed to minimize recruitment of ß-arrestin

14 **North Carolina ends coverage for obesity drugs [U.S.]**
Jan 29, 2024

- On Jan 25, 2024, the State Health Plan Board of Trustees voted to cut coverage for GLP-1 receptor agonists WEGOVY (semaglutide), SAXENDA (liraglutide), and ZEPBOUND (tirzepatide) when prescribed for weight loss for individuals on the State Health Plan
    - The plan covers over 740,000 state employees, teachers, retirees, and their family members
- The decision will take effect on Apr 01, 2024. However, the State Health Plan will continue covering GLP-1 receptor agonists for type 2 diabetes
    - GLP-1 receptor agonists have soared in popularity in recent years and cost the State Health Plan $102 Mn in 2023, accounting for 10% of all prescription costs
- The trustees who voted to drop coverage cited an unexpected increase in costs and said only a small number of all plan beneficiaries need coverage for obesity drugs
- **Read more:** Healthnews
- **Implications:** The discontinuation of obesity drug coverage in North Carolina also raises concerns about access to effective treatments for patients battling obesity, amidst warnings of the potential return of weight after stopping the medication. This decision could set a precedent for how the State Health Plan and possibly other insurers manage the coverage of medications for weight loss versus other conditions, influencing future health care and insurance policy decisions

15 **Newtopia launches "GLP-1 sustain" program to affordably preserve and extend valuable health benefits of novel weight loss drugs [U.S.]**
Jan 29, 2024

- Newtopia announced "**GLP-1 Sustain**", a companion program to specifically support and extend the dramatic clinical outcomes produced by glucagon-like-peptide-1 (GLP-1) receptor agonists and other related agonist drugs once a user first encounters a "weight loss plateau" and even if users cease taking the medication entirely
    - Newtopia's GLP-1 Sustain ensure that the many short-term health benefits of these medications may be long-lasting and that the significant costs to invest in them may in fact yield a positive return on investment for payers, employers, value-based providers, and patients
    - Newtopia's GLP-1 Sustain combines genetic testing for risk factors and key behaviours with individualized live coaching, curated content, and remote monitoring from smart devices to help any GLP-1 user identify, develop, and internalize constructive lifestyle habits necessary to sustain weight loss, health, and well-being over time – whether users remain on, or ultimately stop taking these medications
- GLP-1 Sustain will also produce significant annual cost savings for Newtopia clients of ~$10,000+ per participant
- **Read more:** Newtopia Press Release
- **Implications:** Incorporating genetic testing, coaching, and remote monitoring, may offer a holistic approach to long-term weight management.

16 **Health, wellness, fitness, and nutrition brands gain instant GLP-1 market entry with CareValidate's CareGLP obesity telehealth marketplace [U.S.]**
Jan 30, 2024

- CareValidate announced the launch of its new program, CareGLP
    - This initiative is to transform the landscape of weight loss healthcare by providing businesses with unprecedented access to GLP-1 therapies, including OZEMPIC (semaglutide) and WEGOVY (semaglutide)

- CareGLP integrates CareValidate's cutting-edge and compliant case management platform with a network of trusted suppliers and providers, making it easy and efficient to offer GLP-1 medications to your user base
- CareGLP equips brands with a comprehensive SOC2, GDPR, HIPAA and CCPA-certified platform that seamlessly integrates every aspect of obesity care, from initial diagnosis to ongoing support and medical treatment

- **Read more:** PR Newswire

- **Implications:** Telehealth in obesity is becoming popular. It offers a level of privacy and comfort that may be particularly valued by individuals living with obesity. The experience of bias, shame, and stigma can be significant obstacles to seeking healthcare for people with obesity, obstacles that are frequently encountered even in medical environment

17 **Eli Lilly said to be in talks with Germany to win coverage for weight loss drugs [Germany]**
Jan 29, 2024

- According to *Spiegel magazine*, Eli Lilly started discussions with German authorities to obtain public health reimbursement for its weight-loss treatments, a decision that will end the country's restrictive coverage for weight-loss treatments
- While the company has implemented a staggered rollout of MOUNJARO/ZEPBOUND (tirzepatide) in Germany, Poland, and Switzerland so far, EU governments have taken a restrictive stance on new weight-loss drugs, including Novo Nordisk's WEGOVY (semaglutide) due to budgetary concerns
- During the interview, Ilya Yuffa, President, Lilly International also announced that the company is planning to build its first manufacturing plant in Germany. The plant will be built at a cost of €2.3Bn to manufacture Eli Lilly's diabetes and obesity drugs

- **Read more:** Seeking Alpha (Subscription required), Pharma Live

- **Implications: :** Lilly aims to obtain reimbursement by German authorities, as a weight-loss treatment and also invests in a manufacturing plant in Germany

18 **Launches and prices of Novo Nordisk's weight-loss drug WEGOVY (semaglutide) [EU]**
Jan 30, 2024

- Novo Nordisk is working to convince European governments and insurers to reimburse WEGOVY (semaglutide), seeking to position it as more than a lifestyle drug
- Company officials mentioned that the factories are running 24 hours per day but it has struggled to keep up with demand
    - The weekly injections start at 0.25 milligrams of active ingredient semaglutide and gradually increase to the maintenance dose of 2.4 mg

- **Read more:** Aol

- **Implications:** Novo Nordisk tries to get reimbursement for WEGOVY (semaglutide) in Europe, aiming to have it recognized for uses beyond just a lifestyle medication.

19 **According to an article, Novo Nordisk 'surprised' by high European demand for weight-loss drugs [EU] [Article]**
Feb 4, 2024

- Novo Nordisk has been "surprised" by the readiness of European consumers to pay for weight-loss drugs from their own pockets, as the region's largest company invests in new supply to meet runaway demand
- WEGOVY's (semaglutide) effectiveness — participants lost an average 15% of their body weight in a trial lasting more than a year and a string of celebrity endorsements have made it very popular
- In Europe, WEGOVY is not yet generally available in public health systems, 80% of sales are paid for personally by consumers, with the remainder reimbursed by health insurance or states
    - In the U.S., more than 90% of sales are completely or partially covered by health insurance
    - In Denmark, 1.5% adult population are paying for the drug
    - In the UK, WEGOVY is available in limited supply on the NHS but patients using private healthcare can pay up to €300 for a month's supply
- High demand has led to supply problems, with the company committing $6.5 Bn in capital spending in 2024 to increase production

- **Read more:** Financial Times (Subscription required), Yahoo Finance

- **Implications:** Novo Nordisk's Wegovy is increasingly popular in Europe, with consumers readily paying out of pocket, frequently resulting in shortages.

20 **Ontario limiting access to OZEMPIC (semaglutide) to conserve supply for those with diabetes [Canada]**
Jan 31, 2024

- The Ontario government is taking steps to restrict access to OZEMPIC (semaglutide) and conserve its supply for people with Type 2 diabetes under a province-funded program amid shortages due to popular demand for the drug for weight loss
- According to the Ministry of Health, people who don't have Type 2 diabetes will no longer have coverage for the drug under the Ontario Drug Benefit (ODB) program from Jan 31, 2024
- Hannah Jensen, Ministry of Health, Canada, spokesperson stated that, *"This move has been taken to conserve supply for those who need OZEMPIC most and aligns Ontario with many other provinces who have taken steps to protect their supply"*

- **Read more:** CBC News

- **Implications:** Semaglutide and tirzepatide shortages are seen frequently as the drugs are now used for both T2D and weight loss patients. Ozempic which is approved for T2D is often used off-label by patients with obesity therefore adding to the growing shortage of supply and prompting the Ontario government to take action

GENERAL

21 **Exclusive: Weight loss app Noom lays off employees including coaches and engineers [U.S.]**
Jan 30, 2024

- Noom made another round of layoffs following a series of cuts over recent years as it leans more heavily into weight loss drugs and works to improve its margins
- The cuts to Noom's coaching staff are happening as Noom pushes further into the business of prescribing medications for weight loss, including GLP-1 medications
  - That business is a shift from Noom's start helping people lose weight through behavior changes, aided by coaches
- **Read more:** Endpoints News (Subscription required)
- **Implications:** N/A

22 **Q&A: Regulatory reform necessary to improve obesity drug access [EU]**
Jan 31, 2024

- In an exclusive interview with *Pharmaceutical Technology*, Dr. Nicholas Finer, Former Senior Principal Clinical Scientist, Novo Nordisk, discussed issues with determining the cost-benefit of obesity drugs and barriers to patient access
- According to Finer, even though SAXENDA (liraglutide), WEGOVY (semaglutide), and XENICAL (orlistat) have been approved to manage obesity by the National Institute for Health and Care Excellence (NICE), there is virtually no funding for them, so doctors are not able to prescribe them
  - The access to WEGOVY is soon going to be trialed in half a dozen centres across the UK, funded by €40 Mn coming from the Department of Health (in a pilot programme). Otherwise, they are not yet available in the National Health Service (NHS)
- In the UK, there is no government funding for weight loss drugs. There are very few centres that can prescribe WEGOVY within their NHS services
  - Most UK WEGOVY prescriptions are done privately, so it is up to the individual to pay the full cost of it
- **Read more:** Global Data (Subscription required)
- **Implications:** A pilot program funded by the Department of Health aims to trial WEGOVY access in the UK, indicating a move towards integrating these drugs into national healthcare. The absence of government funding for weight loss drugs in the UK limits their prescription through NHS services

23 **According to a recent study, many patients maintain weight loss a year after stopping semaglutide, liraglutide**
Feb 1, 2024

- According to a recent study from *Epic Research*, over half of patients who stopped taking liraglutide or semaglutide were able to maintain their weight for a year
- In the most recent analysis, researchers studied 17,733 patients prescribed SAXENDA (liraglutide) and 20,274 patients prescribed WEGOVY (semaglutide), all of whom lost five pounds while on the medications
  - They found that 18.7% of liraglutide users and 17.7% of semaglutide users regained all the weight they had lost or more after one year of discontinuation
  - However, 56.2% of patients who took semaglutide and 55.7% of patients who took liraglutide remained around the same weight they were at during the time of medication stoppage or even continued to lose additional weight
- According to the researchers, the reasons for discontinuing GLP-1 receptor agonists can vary among patients
- **Read more:** Healio
- **Implications:** Weight maintenance poses a significant challenge with GLP-1 drugs: the question is how patients can sustain their weight loss without needing to rely on weekly injections indefinitely.

24 **Opinion: Amid GLP-1 mania, health tech's weight loss startups are trying to prove their services matter [Article]**
Feb 1, 2024

- The opinion piece discussed Calibrate's relevancy challenges amid prescription drugs for weight loss and tech competitors. Calibrate and companies like it have to show evidence that their approaches go further than providing access to weight loss medications
- According to a report published, Calibrate found that by 24 months, those who stayed on Calibrate's program which includes medication, coaching and lifestyle changes lost an average of 18% of their weight

- The results are slightly better than in the pivotal trial used for the approval of Novo Nordisk's WEGOVY, including in patients who got lifestyle therapy

- Calibrate also released data for its customers who stopped taking the drugs while sticking with the company's coaching program. In that group, 92% of people kept off at least 10% of the weight they lost

- Scott Honken, President, and Chief Commercial Officer, Calibrate, stated that, *"Calibrate anticipates growing its business by continuing to sell its services to health plans and employers in 2024, though it also continues to operate the direct-to-consumer business where it got its start"*

- **Read more:** Endpoints News *(Subscription required)*

- **Implications:** Calibrate's ability to demonstrate significant, sustainable weight loss through a comprehensive program can position it strongly in the weight loss market

25 **In obesity, Regeneron wants to fill gaps. But for cell therapy? Yancopoulos wants to try something new [Article]**
Feb 2, 2024

- The obesity drugs taking the market by storm are great leading to substantial weight loss for patients and potentially changing the course of future disease. But George Yancopoulos, Chief Scientific Officer, Regeneron, sees plenty of room for improvement
- Regeneron wants to fill the gaps in care with a combo approach from its pipeline, adding trevogrumab or garetosmab to WEGOVY (semaglutide) to improve the quality of weight loss that patients experience

  - Regeneron is also testing a solution for what happens after treatment with Novo Nordisk's semaglutide ends. Once a patient has lost the weight, how can they keep it off without continuing with the weekly injections forever?

- According to Yancopoulos, a Phase II study is expected to get underway in May 2024

  - The trial will test the addition of the anti-myostatin trevogrumab to semaglutide with and without the anti-activin A medicine garetosmab to improve the quality of weight loss, as well as maintenance post-semaglutide

  - Once results from an early safety study are available in healthy volunteers, enrollment is set to start midway through 2024,

- **Read more:** Fierce Biotech

- **Implications:** Regeneron wants to create a combination approach from Regeneron's pipeline, adding trevogrumab or garetosmab to semaglutide in a bid to improve the way a patient loses weight

KEY UPCOMING EVENTS

Q4 and FY2023 Earnings Call:

- **Eli Lilly:** Feb 6, 2024 (Eli Lilly Investor update)
- **Amgen:** Feb 6, 2024 (Amgen Investor update)
- **AstraZeneca:** Feb 8, 2024 (AstraZeneca Investor update)

Thank you!
Kind regards,
Diksha Matta

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