Tuesday, May 14, 2024 at 12:17:33 Eastern Daylight Time

Subject: MTSR1: Weekly Competitive Intelligence Newsletter (Apr 16-22, 2024)
Date: Monday, April 22, 2024 at 9:50:24 AM Eastern Daylight Time
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Attachments: image002.png

Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: Apr 16-22, 2024

DASHBOARD

KEY TAKEAWAYS OF THE WEEK (Apr 16 - 22, 2024)

- **Clinical –** NeuroBo Pharmaceuticals announced dosing of the first patient in the single ascending dose (SAD) Part 1 of its two-part Phase I clinical trial of DA-1726 for the treatment of obesity [U.S.]
- **Regulatory –** Lexaria Bioscience announced that an independent third-party ethics review board has approved a human pilot study #2 (the "Study"), investigating GLP-1 drugs and DehydraTECH [U.S.]
- **Regulatory –** Laekna Therapeutics announced the U.S. FDA approval of the Investigational New Drug application for LAE102 for the treatment of patients with obesity
- **Commercial –** Biophytis announced the filing of a patent application in the treatment of obesity, a new indication in which the company has positioned itself with the announcement of its Phase II OBA clinical trial [U.S.]

DETAILED NEWS

CLINICAL

1 **Trial Update: Obstructive sleep apnea master protocol GPIF: A study of tirzepatide (LY3298176) in participants with obstructive sleep apnea (SURMOUNT-OSA) [Global]**
Apr 19, 2024

- A Phase III trial sponsored by Eli Lilly titled, *"Obstructive sleep apnea master protocol GPIF: A study of tirzepatide (LY3298176) in participants with obstructive sleep apnea (SURMOUNT-OSA)"* has undergone the following changes:
  - **Overall Status:** Updated from 'Active, not recruiting' to 'Completed'
  - **PCD:** Updated from Mar 1, 2024 [Anticipated] to Mar 12, 2024 [Actual]
  - **SCD:** Updated from Mar 29, 2024 [Anticipated] to Mar 29, 2024 [Actual]
  - **Contacts/Locations:** Multiple sites were added and removed from the location

- **Read more:** NCT05412004

- **Implications:** N/A

2 **Trial Update: A research study comparing how well different doses of the medicine NN0519-0130 help people with excess body weight lose weight [Global]**
Apr 18, 2024

- A Phase II trial sponsored by Novo Nordisk titled, *"A research study comparing how well different doses of the medicine NN0519-0130 help people with excess body weight lose weight"* has undergone the following changes:
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Recruiting'
  - **SCD:** Updated from Apr 28, 2025 [Anticipated] to May 5, 2025 [Anticipated]
  - **Contacts/Locations:** Multiple sites were added to the location

- **Read more:** NCT06326060

- **Implications:** N/A

3 **Trial Update: A study to test whether survodutide (BI 456906) helps people living with overweight or obesity who do not have diabetes to lose weight (SYNCHRONIZE™-1) [Global]**
Apr 16, 2024

- A Phase III trial sponsored by Boehringer Ingelheim titled, *"A study to test whether survodutide (BI 456906) helps people living with overweight or obesity who do not have diabetes to lose weight (SYNCHRONIZE™-1)"* has undergone the following changes:
  - **Overall Status:** Updated from 'Recruiting' to 'Active, not recruiting'
  - **Contacts/Locations:** Multiple sites were added and removed from the location

- **Read more:** NCT06066515

- **Implications:** N/A

4 **Trial Update: A study of LY3541105 (undisclosed) in healthy and overweight participants [U.S.]**
Apr 19, 2024

- A Phase I trial sponsored by Eli Lilly titled, *"A study of LY3541105 (undisclosed) in healthy and overweight participants"* has undergone the following changes:
  - **Overall Status:** Updated from 'Recruiting' to 'Active, not recruiting'
  - **PCD and SCD:** Updated from Sep 18, 2024 [Anticipated] to Aug 2024 [Anticipated]

- **Read more:** NCT05380323

- **Implications:** N/A

5 **New Trial: A study of tirzepatide (LY3298176) plus mibavademab compared with tirzepatide alone in adult participants with obesity [U.S.]**
Apr 18, 2024

- Eli Lilly initiated a Phase II trial where once weekly tirzepatide plus mibavademab compared with tirzepatide alone in adult participants with obesity
  - **Trial details:** N = 360; Status: Not yet recruiting; Start date: May 2024; PCD: Dec 2025, and SCD: Apr 2026; Location: U.S.
  - **Primary Outcome Measures:** Mean Percent Change from Baseline in Body Weight [Time Frame: Baseline, Week 48]

- **Read more:** NCT06373146

- **Implications:** Lilly testing tirzepatide plus mibavademab (leptin receptor agonist monoclonal antibody) combination for superior weight loss over tirzepatide monotherapy.

6 **Biophytis announces new scientific advisory board for its Phase II OBA clinical study in obesity [U.S.]**
Apr 18, 2024

- Biophytis announced the formation of a new Scientific Advisory Board to support the advancement of its Phase II OBA clinical study in obesity
  - This Scientific Advisory Board will be composed of a few worldwide medical experts in the field of obesity, including Professor Dennis Villareal from the U.S. and Professor Francisco Guarner from Spain
- The OBA SAB will guide the company to develop BIO101 (20-hydroxyecdysone) in obesity, in combination with GLP1-RA, and will actively work towards the finalization of the OBA Phase II clinical study design
- Biophytis plans to file for an Investigational New Drug application to start the OBA Phase II clinical study with the U.S. FDA soon

- **Read more:** Biophytis Press Release

- **Implications:** N/A

7 **Lilly plans for ZEPBOUND label expansion into sleep apnea in mid-2024 on back of Phase III win [U.S.]**
Apr 17, 2024

- Eli Lilly announced positive topline results of the SURMOUNT-OSA Phase III clinical trials that showed tirzepatide injection (10 mg or 15 mg) significantly reduced the apnea-hypopnea index (AHI) vs. placebo
  - **The company is planning to submit the data to the U.S. FDA and other agencies for a label expansion beginning in the mid-2024**
- In the 52-week SURMOUNT-OSA Study 1, the injection led to a mean apnea-hypopnea index (AHI) reduction of 27.4 events per hour from baseline in patients who were not on a PAP machine to help them breathe
  - ZEPBOUND (tirzepatide) was also superior over placebo in secondary endpoints in the study, showing a mean AHI reduction from baseline of 62.8% compared to 6.4% from baseline for placebo
- In the SURMOUNT-OSA Study 2, the drug was evaluated in patients who planned to continue using a PAP machine, with Zepbound again hitting the primary endpoint
  - Across both studies, the weight loss seen was almost 20%
- According to a study published in the *Nature*, Novo Nordisk's SAXENDA (liraglutide) or VICTOZA (liraglutide), reduced AHI and had a weight loss effect in patients with sleep apnea

- **Read more:** Endpoints News *(Subscription required),* Eli Lilly Press Release

- **Implications:** Eli Lilly aims to expand the use of ZEPBOUND for sleep apnea treatment following positive Phase III trial results.

8 **Neurobo Pharmaceuticals doses first patient in its Phase I clinical trial evaluating DA-1726 for the treatment of obesity [U.S.]**
Apr 17, 2024

- NeuroBo Pharmaceuticals announced dosing of the first patient in the single ascending dose (SAD) Part 1 of its two-part Phase I clinical trial of DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR), for the treatment of obesity
- The Phase I trial is designed to be a randomized, placebo-controlled, double-blind, two-part study to investigate the safety, tolerability, PK, and PD of single and multiple ascending doses of DA-1726 in obese, otherwise healthy subjects

- The Part 1 SAD study is expected to enroll approximately 45 participants, randomized into one of five planned cohorts
- Part 2 is designed as a MAD study, expected to enroll approximately 36 participants, who will be randomized at the same 6:3 ratio 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
  - Exploratory endpoints will include the effect of DA-1726 on metabolic parameters, cardiac parameters, fasting lipid levels, body weight, waist circumference and body mass index (BMI), among others

- **Read more:** NeuroBo Pharmaceuticals Press Release

- **Implications:** N/A

9 **New Trial: Study of subcutaneously administered ENT-03 (undisclosed) for the treatment of obesity and diabetes [U.S.]**
Apr 17, 2024

- Enterin initiated a Phase I trial to evaluate safety, tolerability, PKs and PDs of subcutaneously administered ENT-03S (undisclosed) for the treatment of obesity and diabetes
  - **Trial details:** N = 49; Status: Recruiting; Start date: Jun 13, 2023; PCD: Jul 31, 2024, and SCD: Oct 30, 2024; Location: U.S.
  - **Arms: Active Comparator:** ENT-03, **Placebo Comparator:** Placebo

- **Read more:** NCT05925920

- **Implications:** New Ph1 with ENT-03, which is a novel, endogenous, centrally acting mammalian aminosterol with Protein Tyrosine Phosphatase 1B (PTP1B) inhibitory activity, which normalizes glucose and causes weight loss by acting on brain circuits that regulate energy and metabolism.

10 **Germany's prescribing guide 'advises against' Lilly's MOUNJARO for weight loss [Germany]**
Apr 18, 2024

- Germany's prescribing guide Arznei-Telegramm has "advised against" the use of Eli Lilly's MOUNJARO (tirzepatide) for weight loss based on the unclear risk-benefit balance based on the current state of knowledge
- Similar to other GLP-1 agonists, MOUNJARO demonstrated many AEs, such as gastrointestinal issues, dizziness and diarrhea and they were also reported more often than with semaglutide
  - All those AEs can lead to dehydration, which, in turn, is dangerous for kidney function
- The guide also highlighted the high cost of MOUNJARO: "€4,183 for one year of weekly 10 mg injections, almost 7% more than the equally expensive GLP-1 agonist semaglutide, which costs €3,926 a year, it is not reimbursed by statutory payers
- It is possible WEGOVY might be reimbursed in Germany if its indication is extended to reduce risk of cardiovascular death, heart attack and stroke prevention based on the SELECT trial data, as it has been in the U.S.
  - However, there are no such data for MOUNJARO

- **Read more:** APM Health *(Subscription required)*

- **Implications:** In Germany there are negative sentiments for reimbursing MOUNJARO (Tirzepatide) for weight loss, while WEGOVY might have bigger chances, due to its positive CV data.

11 **Gubra unveils UCN2 as novel anti-obesity drug candidate for healthy weight loss [Denmark]**
Apr 17, 2024

- Gubra announced the selection of a development candidate and unveils urocortin-2 (UCN2) as a novel anti-obesity drug candidate for healthy weight loss
  - UCN2 is a once weekly peptide which will be developed as a healthy weight loss drug with a favourable cardiac profile
  - This will mark the start of the preclinical toxicology programme

- **Read more:** Gubra Press Release

- **Implications:** The urocortin-2 analogue, a potent CRHR2 agonist designed for weekly dosing, is advancing towards clinical development as a new anti-obesity therapy that maintains lean mass while reducing fat, potentially harmonizing with other drugs.

12 **New Trial: A study of ZT002 (undisclosed) injection in participants with overweight or obesity [China]**
Apr 17, 2024

- Beijing QL Biopharmaceutical initiated a Phase I trial to evaluate the safety, tolerability, and PKs of ZT002 (undisclosed) injection in participants with overweight or obesity
  - **Trial details:** N = 28; Status: Enrolling by invitation; Start date: Nov 21, 2023; PCD: Aug 30, 2024, and SCD: Sep 30, 2024; Location: China
  - **Arms: Experimental:** ZT002 Injection, **Placebo Comparator:** ZT002 Placebo

- **Read more:** NCT06371326

- **Implications:** N/A

13 **Trial Update: A study of once-daily oral orforglipron (LY3502970) in Japanese adult participants with obesity disease (ATTAIN-J) [Japan]**
Apr 19, 2024

- A Phase III trial sponsored by Eli Lilly titled, *"A study of once-daily oral orforglipron (LY3502970) in Japanese adult participants with obesity disease (ATTAIN-J)"* has undergone the following changes:

- **Overall Status:** Updated from 'Recruiting' to 'Active, not recruiting'
- **PCD:** Updated from Jun 3, 2025 [Anticipated] to Jun 2025 [Anticipated]
- **SCD:** Updated from Jun 1, 2025 [Anticipated] to Jun 2025 [Anticipated]
- **Contacts/Locations:** Multiple sites were added and removed from the location

- **Read more:** NCT05931380

- **Implications:** N/A

REGULATORY

14 **Lexaria receives ethics review board approval to begin new GLP-1 study [U.S.]**
Apr 16, 2024

- Lexaria Bioscience announced that an independent third-party ethics review board has approved a human pilot study #2 (the "Study"), investigating GLP-1 drugs and DehydraTECH
- Subject recruitment will begin immediately, and the company will announce as soon as the first dosing has begun, which is expected within 30 days or less
  - The Company anticipates completing the Study in summer 2024
  - The Study will be performed in up to nine healthy volunteers and will study a single 7 mg dose of RYBELSUS (semaglutide) against two different, concentration-matched 7 mg DehydraTECH-enabled semaglutide formulations from crushed RYBELSUS
- Tolerability, blood absorption levels (PK), and blood sugar control will all be evaluated
  - The DehydraTECH compositions for this study will be compound-formulated using commercially available RYBELSUS tablets as the semaglutide input material

- **Read more:** Lexaria Bioscience Press Release

- **Implications:** Ph1 study to test potentially superior oral bioavailability of semaglutide with DehydraTECH vs. RYBELSUS.

15 **Laekna announces IND approval of LAE102 (undisclosed) for the treatment of obesity by FDA [U.S.]**
Apr 15, 2024

- Laekna Therapeutics announced that the U.S. FDA has approved the Investigational New Drug (IND) application for LAE102 (undisclosed), an internally discovered monoclonal antibody against ActRIIA, for the treatment of patients with obesity
  - In Mar 2024, Laekna submitted the IND application to the U.S. FDA for LAE102
- In Q1 2024, Laekna submitted IND applications to the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of China for LAE102 for obesity
  - The IND has been accepted by the CDE

- **Read more:** Laekna Therapeutics Press Release

- **Implications:** N/A

16 **FDA is ready to eliminate the interchangeability designation for biosimilars [U.S.]**
Apr 15, 2024

- The U.S. FDA is calling on Congress to remove the interchangeability designation for biosimilars, claiming that the two-tier system is only causing confusion
- According to Sarah Yim, Director of the U.S. FDA's Office of Therapeutic Biologics and Biosimilars, having two separate classes of biosimilars has been confusing people for a long time as the rest of the world doesn't have two designations
  - Sarah Yim noted that some people wrongly assumed differences in quality between biosimilars and interchangeable biosimilars, even when both are held to the U.S. FDA's highest standard of approval
- The U.S. FDA wants to make all biosimilars interchangeable with a legislative proposal that would eliminate the statutory distinction between biosimilars and interchangeables

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

- **Implications:** This change could streamline the use of biosimilars and potentially improve their uptake.

COMMERCIAL

17 **Biocon Limited signs an exclusive licensing and supply agreement for generic OZEMPIC (semaglutide) commercialization in Brazil with Biomm S.A. [Brazil]**
Apr 17, 2024

- Biocon announced the signing of an exclusive licensing and supply agreement with Biomm in Brazil, for the commercialization of its vertically integrated drug product OZEMPIC (semaglutide), which is used to improve glycemic control in adults with type-2 diabetes
  - Under the terms of this agreement, Biocon will undertake the development, manufacturing and supply of the drug product, and Biomm will be responsible for obtaining regulatory approval and commercialization in the Brazilian market
- The total addressable market opportunity of semaglutide in Brazil is approximately U.S. $580 Mn as per the IQVIA MAT Q4 2023

- **Read more:** Biocon Press Release

- **Implications:** N/A

18 **Biophytis files a patent application and strengthens its intellectual property in obesity [U.S.]**
Apr 15, 2024

- Biophytis announced the filing of a patent application in the treatment of obesity, a new indication in which the company has

positioned itself with the announcement of its Phase II OBA clinical trial
  - This new patent application, which is expected to be granted as soon as 2025, will strengthen BIO101's (20-hydroxyecdysone) position in the treatment of obesity in combination with GLP-1 RAs
  - This new patent will extend the exclusivity period of BIO101 in this indication until 2044
- With promising results in obesity from preclinical studies and in the SARA-INT Phase II study, BIO101 (20-hydroxyecdysone) has demonstrated its potential to become the molecule of choice for preserving muscle function in patients suffering from obesity treated with GLP-1 RAs
  - Subject to regulatory approvals, the drug candidate could help address a critical medical problem, while positioning Biophytis in a large and fast-growing market

- **Read more:** Biophytis Press Release

- **Implications:** The company's movement into the obesity clinical trial space and promising preclinical results suggest BIO101 could be significant for preserving muscle function in obesity treatments, offering strategic positioning in a growing market.

19 **Use of GLP-1 drugs such as OZEMPIC surging among Canadians [Canada]**
Apr 15, 2024

- A new study conducted by Dalhousie University's Agri-Food Analytics Lab and Caddle reveals that between 900,000 and 1.4 Mn Canadians have incorporated these medications into their daily routine
- The survey reveals a varied user demographic, with a slight majority of males (11% vs. 10 % for females) and millennials taking the lead at 12%
  - Ontario boasts the highest usage rate in Canada at 13%, while Prince Edward Island records the lowest at 4%. Most users (79%) have been using these drugs for more than three months, indicating a significant dependence on them
- The primary reasons for usage are managing type 2 diabetes (57.2%) and seeking weight loss (27.2%), which reflects a complex interplay between health needs and body image goals
  - The impact on dietary choices is particularly notable, with 45.5% of users reporting reduced food intake, especially high-calorie items

- **Read more:** Castanet

- **Implications:** Canada sees good acceptance of GLP-1 drugs, especially for treatment of T2D, followed by weight loss.

MISCELLANEOUS

20 **Boehringer preparing to enter the weight-loss drug market [Global]**
Apr 19, 2024

- Boehringer Ingelheim is developing a GLP-1 agonist, BI 456906 (survodutide) in a collaboration with Zealand Pharma, if the company succeeds in bringing its own GLP -1 agonist to the market, it will compete directly with Eli Lilly's MOUNJARO (tirzepatide)
- The top-line data published by Boehringer Ingelheim in 2023 suggest that the patients lose 19% of their body weight on average, which is close to the result shown by tirzepatide, and more than Novo Nordisk's WEGOVY (semaglutide)
  - Boehringer's representatives prefer not to talk about weight loss, but rather about the unmet medical need in the metabolic dysfunction-associated steatohepatitis (MASH) indication
- The company anticipates launching BI 456906 in 2027 or 2028 to compete with MOUNJARO

- **Read more:** APM Health *(Subscription required),* Reuters

- **Implications:** Boehringer emphasizes addressing the broader unmet medical needs in metabolic dysfunction-associated steatohepatitis (MASH) rather than focusing solely on weight loss.

21 **Eli Lilly's edge over GLP-1 rivals tipped to drive MOUNJARO sales to $34 Bn by 2029 [Global]**
Apr 17, 2024

- GlobalData put out a forecast that shows how GLP-1 drugs could rapidly redefine what big looks like in drug sales. The analysts expect MOUNJARO (tirzepatide) to bring in as much in 2029 as Eli Lilly's entire portfolio did in 2023
  - MOUNJARO generated $5.2 Bn in 2023, more than 40% of which landed in Eli Lilly's bank account in Q4 2023
  - ZEPBOUND (tirzepatide) pulled in more than $175 Mn in its first quarter on the market
- The products underpin Lilly's belief that its total revenue will top $40 billion this year, up from $34 billion in 2023
- GlobalData analysts predictined that MOUNJARO sales will hit $34 Bn in 2029. The forecast reflects a belief that Eli Lilly has an edge in the GLP-1 space

- **Read more:** Fierce Pharma

- **Implications:** Eli Lilly's MOUNJARO (tirzepatide) is projected to achieve $34 billion in sales by 2029, an amount that would match the entire revenue of Eli Lilly's portfolio in 2023. This forecast by GlobalData highlights the drug's significant potential impact and competitive edge in the GLP-1 market.

22 **How drugmakers are handling new pressure to recycle plastic injection pens as millions of new patients begin using GLP-1s [Global]**
Apr 16, 2024

- Millions of prescriptions get written leading to millions of discarded pens, the average person may also someday sit on a chair made from the upcycled byproducts of a trending obesity treatment
  - Beyond the expense and complexity of recycling contaminated medical waste like injection pens, in the medical waste big picture, injector pens are a smaller part of the larger problem
- Many new users of Novo Nordisk's WEGOVY (semaglutide) and Eli Lilly's ZEPBOUND (tirzepatide), are starting to raise their voices to help spur pharma recycling. Reddit threads for both drugs include many questions and comments about the wastefulness

of the one-time pens
- Novo Nordisk has a ReMed program, featured recently on its social media channels with videos of piles of bright plastic pellets and the modern furniture the pens are upcycled into
  - ReMed is currently the most extensive upcycling plastic pen effort among the fledgling trials and plans across pharma
- In 2023, Eli Lilly, Sanofi and Merck joined ReMed and the effort has expanded into the UK, Brazil, France and Japan. There are still no plans set for the U.S.

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

- **Implications:** As the use of GLP-1 injections like Novo Nordisk's WEGOVY and Eli Lilly's ZEPBOUND expands, concerns about the environmental impact of disposable injection pens are growing.

23 **Takedowns of websites peddling fake GLP-1 drugs jump as counterfeiters board weight-loss bandwagon [Global]**
Apr 15, 2024
- BrandShield helped remove more than 250 websites peddling the medicines in 2023, as the weight-loss therapies emerged as a major focus of anticounterfeit activity
  - The GLP-1 hype train created opportunities for counterfeiters by fueling demand from people who were unable to get legitimate Eli Lilly and Novo Nordisk's drugs, either because the drugs were in short supply or because they didn't meet the indicated requirements for use
  - Regulators have found fake and substandard GLP-1 medicines in supply Australia, Europe, and the U.S.
- In 2023, the work led to the removal of 1,655 websites that were selling counterfeit drugs, compared to 434 in 2022 and 850 in 2021
  - The number of sites found to be selling GLP-1 drugs rose from 34 in 2022 to more than 250 in 2023
- Websites selling fake GLP-1 drugs accounted for more than 90% of the 279 sites that BrandShield helped to shut down for selling metabolic disease treatments
  - According to BrandShield, no other drug class dominated a therapeutic area like GLP-1 dominated the metabolic space

- **Read more:** Fierce Pharma, Yahoo Finance

- **Implications:** N/A

24 **American college of physicians officially recommends GLP-1s like OZEMPIC for diabetes treatment—despite shortage concerns [U.S.]**
Apr 19, 2024
- The American College of Physicians issued new guidelines for type 2 diabetes treatment, which recommends the use of GLP-1s and another class of diabetes drugs called SGLT-2s alongside metformin
  - This may exacerbate the ongoing drug shortages of several GLP-1s

- **Read more:** Forbes

- **Implications:** American college of physicians continue to back GLP-1s, despite current shortage concerns.

25 **Lawsuits over OZEMPIC, WEGOVY, MOUNJARO and other GLP1-RA drugs may hinge on label warnings [U.S.]**
Apr 19, 2024
- In position papers recently submitted, lawyers involved in lawsuits over OZEMPIC (semaglutide), WEGOVY (semaglutide), MOUNJARO (tirzepatide) and other similar medications detailed their stances on whether manufacturers provided adequate label warnings about the potential stomach paralysis side effects some users are experiencing, and how the growing litigation should be managed during pretrial proceedings
- Patients are now pursuing OZEMPIC lawsuits, WEGOVY lawsuits and MOUNJARO lawsuits against the manufacturers, after developing painful and debilitating injuries, including intestinal blockages and a form of stomach paralysis known as gastroparesis
- Given common questions of fact and law raised in the litigation, the U.S. Judicial Panel on Multidistrict Litigation decided to centralize all GLP-1 lawsuits before the U.S. District Judge Gene E.K. Pratter in the U.S. District Court for the Eastern District of Pennsylvania, and it is widely expected that tens of thousands of lawsuits may ultimately be included in the federal multidistrict litigation

- **Read more:** Aboutlawsuits

- **Implications:** N/A

26 **Patients find weight loss drug ZEPBOUND a game changer, but makers see production delay until 2025 [U.S.]**
Apr 18, 2024
- According to Edgardo Hernandez, EVP & Manufacturing operations resident, Eli Lilly, ZEPBOUND (tirzepatide) will be available from the facility to the pharmacies in Jan 2025 or sometime in 2024
  - The time is not soon enough, as roughly 80,000 people are taking ZEPBOUND due to a shortage just five months after the U.S. FDA approved it
- Rhonda Pacheco, Diabetes & Obesity Group Vice President, Eli Lilly, added that there will be limited availability for the near term, which may cause delays across some of the doses for both MOUNJARO (tirzepatide) and ZEPBOUND

- **Read more:** Benzinga

- **Implications:** ZEPBOUND shortages expected to continue until 2025.

27 **Dario signs two employers for cardiometabolic suite with integrated GLP-1 solution [U.S.]**
Apr 18, 2024

- DarioHealth announced two new contracts to provide integrated chronic condition management solutions for two employers beginning in Q2 2024
- The employers, a national supply chain company and a regional education organization, selected Dario's cardiometabolic suite to help improve outcomes for employees with cardiometabolic health conditions, including diabetes, pre-diabetes, hypertension, and weight management needs, including support for individuals taking a GLP-1 medication

- **Read more:** PR Newswire

- **Implications:** N/A

28 **FDA update to Eli Lilly product availability and estimated shortage duration [U.S.]**
Apr 17, 2024

- The U.S. FDA revised its Drug Shortages and Discontinuations report for the following product availability:
  - ZEPBOUND (tirzepatide): The 5mg, 7.5mg, 10mg, 12.5mg, and 15mg doses are listed as having limited availability through Q2 2024
  - MOUNJARO (tirzepatide): The 5mg, 7.5mg, 10mg, 12.5mg, 15mg doses are listed as having limited availability through Q2 2024

- **Read more:** FDA Drug Shortages, Eli Lilly - Supply, Fierce Pharma

- **Implications:** N/A

29 **Green Circle Life expands availability of healthy weight for life program for the SmartFHR platform [U.S.]**
Apr 16, 2024

- Green Circle Life provider of the innovative communication and engagement platform SmartFHR, announced that its highly successful Healthy Weight for Life program (HWFL) is now available to all users and corporate clients
  - HWFL is an employer-offered weight management program designed to work with individuals to set realistic goals, attain and maintain their desired weight through lifestyle changes
  - The program provides private, personalized coaching, encourages users to engage in physical activities, nutritional adjustments and monitor weight outcomes
  - They can combine the use of prescription medications, such as WEGOVY and SAXENDA by Novo Nordisk or ZEPBOUND by Eli Lilly, with their personalized behavioral therapy to assist in managing chronic weight issues

- **Read more:** Businesswire

- **Implications:** N/A

30 **Prime study finds lower adherence, higher costs for weight loss drugs | AMCP 2024 [U.S.]**
Apr 16, 2024

- According to new analysis from a real-world integrated pharmacy and medical claims data by Prime Therapeutics/MagellanRx Management, only about one third of patients taking the GLP-1 weight loss drugs continued with the medication one year later
  - Additionally, just 27% of members were adherent to their GLP-1 therapy for weight loss at one year
- The Prime/MRx real-world findings focused on commercially insured individuals with an obesity medical claim diagnosis without diabetes
  - The initial results were first released in 2023
  - In 2024 Prime/MRx officials will release new analysis at AMCP 2024

- **Read more:** Managed Healthcare Executive

- **Implications:** The findings, which indicate lower adherence and potentially higher costs, are particularly significant for managing obesity treatments effectively. More detailed results from this study will be discussed at AMCP 2024.

31 **Report: FDA has linked more than 100 deaths to OZEMPIC, WEGOVY and similar drugs [U.S.]**
Apr 15, 2024

- According to a report published by The Daily Mail, the U.S. FDA has received 117 incident reports involving deaths among individuals taking glucagon-like peptide-1 receptor agonists (GLP-1 RA), including OZEMPIC (semaglutide), WEGOVY (semaglutide) and MOUNJARO (tirzepatide)
  - The reports are mostly linked to gastrointestinal issues like masses and stomach paralysis
- OZEMPIC, WEGOVY, MOUNJARO and other GLP-1 RA drugs have become blockbuster treatments over the past year, given the widespread promotion of the medications as safe and effective for weight loss
  - However, evidence has emerged that certain users experience a painful and debilitating stomach paralysis, known as gastroparesis, which lawsuits now allege was not fully disclosed by the drug makers on the warning labels

- **Read more:** AboutLawsuits

- **Implications:** Despite their popularity as blockbuster weight loss treatments, the emergence of severe side effects such as gastroparesis underscores the importance of thorough risk assessment and transparent communication from drug manufacturers.

32 **A good choice to have: Scrip's interview with Viking CEO Brian Lian [U.S.]**
Apr 15, 2024

- In Feb 2024, the company reported that the SC formulation of VK2735, a dual GLP-1/GIP agonist, demonstrated 14.7% weight loss at 13 weeks in Phase II data, which analysts described as competitive with currently marketed obesity drugs as well as other obesity candidates in development
  - Those competitors include Eli Lilly's ZEPBOUND (tirzepatide) as well as Novo Nordisk's WEGOVY (semaglutide)

- Viking Therapeutics went to the financial markets with those data, grossing $550m in a follow-on public offering on 28 February
- On Mar 26, 2024, Viking Therapeutics revealed that VK2735 had demonstrated 5.3% weight loss after four weeks in a Phase Ib study showing a much cleaner gastrointestinal safety and tolerability profile than tirzepatide or semaglutide
  - That study tested doses up to 40mg daily of VK2735 and Viking since launched another cohort testing a 60mg dose in an attempt to find a dose with the optimal therapeutic profile for efficacy and safety
- In 2024, the company intends to take oral VK2735 into Phase II, while the SC formulation already is in Phase II

- **Read more:** Scrip *(Subscription required)*

- **Implications:** Viking is confident in its data and portfolio, especially regarding oral VK2735, which could provide a more convenient option for patients.

33 **French health authorities puzzling over how to manage arrival of weight-loss drugs – press [France]**
Apr 19, 2024

- La Croix and Libération reported, the new weight-loss drugs from Novo Nordisk and Eli Lilly have revolutionized obesity treatment, but are causing headaches for the French health authorities trying to ensure they are used correctly once they are reimbursed
- Novo Nordisk's OZEMPIC (semaglutide) and WEGOVY (semaglutide) have helped people struggling with obesity, including those for whom other options - including weight loss surgery - were not an option
- However, the risk of misuse of these drugs is high
  - French drug regulator ANSM set up a scientific committee in Dec 2023 to manage the issue
  - Its biggest concerns are how to ensure the right people get the drugs - as in those with severe obesity not those wanting to lose a few kilos before summer - and how to manage patients once they have hit their ideal weight using OZEMPIC and WEGOVY
  - OZEMPIC/WEGOVY misuse is not widespread in France vs. other countries, such as the U.S.
- According to the latest health insurance data, only 4,404 people, equivalent to 1.2% of prescriptions, seem to be abusive

- **Read more:** APM Health *(Subscription required)*

- **Implications:** N/A

34 **India's Biocon developing its own version of WEGOVY, clinical trial likely next year [India]**
Apr 18, 2024

- According to Siddharth Mittal, CEO, Biocon, the company is planning to explore weight-loss drug market as early as possible, Biocon is developing its own version of Novo Nordisk's WEGOVY (semaglutide) and is prepared to conduct a clinical trial in 2025
- Biocon also aims to first launch generic versions of the weight-loss drugs in other emerging markets such as Brazil, Mexico, and Saudi Arabia as it derives most of its revenue from foreign markets such as the U.S.

- **Read more:** Reuters

- **Implications:** Biocon's announcement of developing its own version of WEGOVY, with plans for a clinical trial in 2025, indicates a strategic move into the weight-loss drug market.

KEY UPCOMING EVENTS

Q1 2024 Earnings Call:

- **Roche:** Apr 24, 2024 (Roche Investor update)
- **AstraZeneca:** Apr 25, 2024 (AstraZeneca Investor update)
- **Eli Lilly:** Apr 30, 2024 (Eli Lilly Investor update)
- **Pfizer:** May 1, 2024 (Pfizer Investor update)
- **Novo Nordisk:** May 2, 2024 (Novo Nordisk Investor update)
- **Amgen:** May 5, 2024 (Amgen Investor update)

Thank you,
Ben

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