**Subject:** MTSR1: Weekly Competitive Intelligence Newsletter (May 14 - May 20, 2024)
**Date:** Monday, May 20, 2024 at 11:29:20 AM Eastern Daylight Time
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Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: May 14 - May 20, 2024

# COMPETITIVE INTELLIGENCE NEWSLETTER

DASHBOARD

## KEY TAKEAWAYS OF THE WEEK (May 14 - 20, 2024)

- **Clinical –** According to two studies presented at the European Congress on Obesity in Italy, Novo Nordisk's WEGOVY (semaglutide) can maintain meaningful weight loss for up to four years and improve cardiovascular health regardless of the amount of weight lost [Italy]
- **Regulatory –** Eli Lilly entered into a settlement agreement requiring defendant Totality Medispa to make a monetary payment and prohibiting Totality from engaging in certain conduct, following a series of lawsuits Eli Lilly filed in Sep 2023 and Oct 2023 [U.S.]
- **Commercial –** Jiangsu Hengrui Pharmaceuticals announced that Hercules USA will receive exclusive rights from Jiangsu Hengrui Pharmaceuticals to develop, manufacture and commercialize its GLP-1 product portfolio worldwide, except for Greater China [Global]

## DETAILED NEWS

### CLINICAL

**1 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]**
*May 14, 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 following changes
  - **Enrollment:** Updated from 600 [Anticipated] to 725 [Actual]
- **Read more:** NCT06066515
- **Implications:** N/A

**2 Trial Update: A first-in-human study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of HM15211 [U.S.]**
*May 20, 2024*

- A Phase I trial sponsored by Hanmi Pharmaceutical titled, *"A first-in-human study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of HM15211"* has undergone following changes
  - **Overall Status:** Updated from 'Recruiting' to 'Completed'
  - **PCD and SCD:** Updated from Oct 2018 [Anticipated] to Sep 14, 2018 [Actual]
  - **Enrollment:** Updated from 40 [Anticipated] to 41 [Actual]
  - **Outcome Measures:** Updated from Number of participants with adverse events [ Time Frame: 1 month ] to Number of Participants With Adverse Events [ Time Frame: 1 month ]
  - **Contacts/Locations:** Sites were removed and added to location
- **Read more:** NCT03374241
- **Implications:** N/A

**3 Dosing begins in Lexaria's comprehensive GLP-1 animal study [U.S.]**
*May 17, 2024*

- Lexaria Bioscience announced that dosing has begun in the 12-week animal study WEIGHT-A24-1 to model diabetes treatment and weight loss effects of DehydraTECH-processed glucagon-like peptide 1 (GLP-1) drugs and DehydraTECH-processed

cannabidiol (CBD), alone and in combination in diabetic preconditioned rats
- Each arm of the study will be dosed for a 12-week period following an acclimation period
- One arm of this 12-arm study will, for the first time, evaluate DehydraTECH-processed pure semaglutide and compare it to re-formulated RYBELSUS (semaglutide) processed with DehydraTECH, containing Novo Nordisk's SNAC (salcaprozate sodium) technology
- Another arm will, also for the first time, evaluate DehydraTECH-processed liraglutide
- Animals in each of the first eight study arms are being dosed with the following:
  - One pure liraglutide DehydraTECH composition
  - One pure semaglutide DehydraTECH composition
  - Two reformulated Ryblesus DehydraTECH compositions
  - Four different DehydraTECH-CBD compositions
- Based on the results of the initial eight study arms, study arms nine and 10 will each utilize the best-performing DehydraTECH-CBD composition with the DehydraTECH-liraglutide composition, and separately, the best performing DehydraTECH-semaglutide composition
  - Study arms 11 and 12 are placebo and positive control arms
- Upon completion of the study, brain tissue will be analysed to help determine whether DehydraTECH processing results in higher brain absorption than non-DehydraTECH arms, as Lexaria has evidenced numerous times in previous similar animal studies
  - The study will also include a comprehensive battery of liver and kidney function testing and blood chemistry analyses

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

- **Implications:** Lexaria believes that DehydraTECH could be able to help in processing of GLP-1 drugs so that they can enable greater penetration of GLP1s into brain tissue. In turn, this could also potentially allow for lower dosing and a concomitant reduction in adverse side effects of GLP1s

**4** **Biophytis announces the design of its Phase II OBA clinical study in obesity [U.S.]**
*May 14, 2024*

- Biophytis announced the design of its Phase II OBA clinical study in obesity with BIO101 (20-hydroxyecdysone)
  - BIO101 (20-hydroxyecdysone) will be evaluated in obese patients treated with GLP-1 RAs, together with hypocaloric dieting
- The OBA Phase II study will test the efficacy and safety of BIO101 in patients with obesity and overweight with secondary comorbidities, who are starting treatment with GLP-1 RAs for weight loss
- The OBA Phase II study is a double-blind, randomized, placebo-controlled clinical study in which 164 patients are planned to be enrolled with obesity (BMI ≥30) or overweight (BMI ≥27 with one or more sequalae e.g. diabetes, hypertension) at the start of treatment with GLP-1 RAs in combination with hypocaloric diet. Double-blind treatment with 350 mg BID of BIO101 will be given for 21 weeks
  - The primary efficacy endpoint is muscle strength as measured by knee extension, and important secondary outcomes include 6 Minute Walking Distance and other performance tests, muscle strength normalized to lean body mass, appendicular lean mass and fat mass, biomarkers, and various Patient-Reported Outcomes
- Biophytis is preparing for filing an Investigational New Drug to start the OBA Phase II study in the U.S. in the coming weeks
- The OBA Phase II clinical study is expected to start mid-2024, upon regulatory approvals, with first patients expected to be treated in H2 2024 and the results of the safety and efficacy of BIO101 drug candidate are expected to be available in 2025

- **Read more:** Biospace

- **Implications:** Successfully obtaining regulatory approvals for the Phase 2 study and achieving favorable early results can enhance Biophytis' credibility and put the company ahead in the race to preserve muscle loss by being an “add-on” therapy to GLP-1s

**5** **Trial Update: A study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of K-757 (undisclosed) and K-833 (undisclosed) in overweight/obese patients with type 2 diabetes [U.S.]**
*May 14, 2024*

- A Phase I trial sponsored by Kallyope titled, *“A study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of K-757 (undisclosed) and K-833 (undisclosed) in overweight/obese patients with type 2 diabetes”* has undergone following changes
  - **Overall Status:** Updated from ‘Recruiting’ to ‘Active, not recruiting’

- **Read more:** NCT06305351

- **Implications:** N/A

**6** **Trial Update: Research study looking at how well semaglutide tablets taken once daily work in people who have a body weight above the healthy range (OASIS 4) [U.S., Canada, Germany, Poland]**
*May 14, 2024*

- A Phase III trial sponsored by Novo Nordisk titled, *“Research study looking at how well semaglutide tablets taken once daily work in people who have a body weight above the healthy range (OASIS 4)”* has undergone following changes
  - **Overall Status:** Updated from ‘Active, not recruiting’ to ‘Completed’
  - **SCD:** Updated from May 7, 2024 [Anticipated] to May 7, 2024 [Actual]
  - **Enrollment:** Updated from 281 [Anticipated] to 307 [Actual]

- **Read more:** NCT05564117

- **Implications:** N/A

**7** **Dual-action drug spurs twice the weight loss in mice as GLP-1 agonist alone [Denmark]**
*May 17, 2024*

- Novo Nordisk working on a novel drug, GLP-1 MK-801 and currently published a study in the *Nature* which reports mice lose twice as much weight as mice treated with GLP-1 only
- Researchers have shown that a novel, bimodal, drug that affects neuroplasticity causes twice the amount of weight loss in obese mice than a GLP-1 agonist alone
- The drug, MK-801, integrates N-methyl-D-aspartate (NMDA) antagonism with glucagon-like peptide-1 (GLP-1) agonism
  - The drug's developers believe that, in humans, it could possibly achieve the same efficacy of current therapeutics with a lower dosage, reducing side effects
- Drugs based on the intestinal hormone GLP-1 effectively target the part of the brain that controls appetite. The NMDA receptor, meanwhile, is a glutamate-activated cation channel
- Genome-wide association studies suggest that glutamatergic neurotransmission and NMDA receptor-mediated synaptic plasticity are important for body weight homeostasis

- **Read more:** Inside Precision Medicine

- **Implications:** While this is preclinical data, the demonstrated superior efficacy over existing GLP-1 agonists is highly compelling. The next critical step is to observe how this drug performs in clinical trials and whether it can replicate these promising results in humans

**8** **Novo Nordisk's WEGOVY sustains weight loss for four years in two studies [Italy]**
*May 14, 2024*

- According to two studies presented at the European Congress on Obesity in Italy, Novo Nordisk's WEGOVY (semaglutide) can maintain meaningful weight loss for up to four years and improve cardiovascular health regardless of the amount of weight lost
- The first study was published in the journal *Nature Medicine,* followed patients in Novo Nordisk's SELECT cardiovascular outcomes study for more than 200 weeks and found that patients treated with WEGOVY were able to sustain their initial weight loss over that period of time
  - Patients in the WEGOVY group showed consistent weight loss through 65 weeks, after which they were able to sustain their body weight for four years with no rebound
  - On average, participants dropped 10.2% of their body weight vs. 1.5% in placebo counterparts
- The treatment difference of 8.7% was strongly statistically significant in favour of WEGOVY
- In addition to weight loss, the long-term readout showed that 52% of the WEGOVY-treated participants transitioned to a lower body mass index (BMI) category after two years, vs. only 16% in the placebo group
  - After treatment with WEGOVY, 12% achieved healthy BMI
- The second study presented at the European Congress on Obesity also drew from the SELECT trial and looked at the relationship between weight change and cardiovascular outcomes
  - Results showed that WEGOVY treatment improved cardiovascular outcomes, regardless of the patients' starting weight and the amount of body weight they lost
  - These findings indicate that even people with mild obesity, or those who are only able to lose a modest amount of body weight, may still derive clinical benefit from WEGOVY
- In terms of safety, the proportion of participants in the SELECT trial with SAEs was lower in those treated with WEGOVY vs. the placebo group—33% vs. 36%—which was mainly driven by differences in cardiac disorders

- **Read more:** Biospace

- **Implications:** Britain's public health service's decision to limit coverage of the medicine to two years was "because of questionable long-term effectiveness" which could now be amended after release of this data. While the drug can help users lose weight initially and maintain the weight loss for up to four years with weekly injections, it is unclear how long these effects last after stopping the medication

**9** **Roche reports positive Phase I results for its dual GLP-1/GIP receptor agonist CT-388 in people with obesity [Switzerland]**
*May 16, 2024*

- Roche announced positive results from the Phase I clinical trial of CT-388, a dual GLP-1/GIP receptor agonist being developed for the treatment of obesity and type 2 diabetes
- The study found that a once-weekly SC injection of CT-388 over 24 weeks resulted in significant weight loss in healthy adults with obesity vs. placebo
  - The weight loss achieved with CT-388 was clinically meaningful, with a mean placebo-adjusted weight loss of 18.8% (p-value < 0.001)
  - At week 24, 100% of CT-388 treated participants achieved a weight loss of >5%, 85% achieved >10%, 70% achieved >15%, and 45% achieved >20%
  - The treatment was well tolerated, with mild to moderate gastrointestinal-related AEs being the most common, consistent with the incretin class of medicines that CT-388 belongs to
  - All participants with a pre-diabetes status at baseline became normoglycemic after 24 weeks of CT-388 treatment, whereas glycemic status of participants treated with placebo remained largely unchanged during this period
- An additional cohort from the ongoing placebo-controlled Phase I trial of CT-388 will evaluate obese patients (BMI>30 kg/m2) with type 2 diabetes over a 12-week treatment duration
  - Roche expects data from this additional cohort in H2 2024

- **Read more:** Roche Press Release

- **Implications:** Novo's next-gen obesity bet CagriSema has shown 17.1% average weight loss in a 20-week phase 1 obesity trial,

compared to 9.8% for Wegovy so weight loss of 18.8% from CT-388 at 24 weeks seems promising. Carmot's attempt to differentiate its candidates from the competition is based on "biased signaling" that is designed to minimize recruitment of ß-arrestin. The approach is intended to achieve greater weight loss and glycemic control plus a more favorable tolerability profile. These results are focused on CT-388's use as a monotherapy, but Roche's pipeline already has the antibody RO7204239 which could be potentially explored in combination with the drugs

**10** **Allurion announces three scientific presentations at the European Congress on obesity, including study on lean mass preservation for sustainable, healthy weight loss [EU]**
*May 15, 2024*

- Allurion Technologies announced three scientific presentations at the 31st European Congress on Obesity (ECO) held in Venice, Italy, on 12-15 May, 2024
- Presentations included data from a study of 712 patients treated with the Allurion Program, which is anchored by the Allurion Balloon and enhanced by the Virtual Care Suite featuring Allurion's proprietary behavior change program –
  - This study was conducted at six obesity centers in six countries, and the data showed patients achieved total body weight loss (TBWL) of 14.1% on average at 4 months, 70% of which came from fat mass and only 30% of which came from lean body mass
- Presentations at ECO also include data on the positive impact of a behavior change coaching skills course developed by Allurion and the positive impact of GLP-1s on the Allurion Program
- **Read more:** Morning Star
- **Implications:** The Allurion Program's approach to preserving lean mass while promoting significant fat loss distinguishes it from other weight loss programs, potentially enhancing its position in the weight loss market.

**11** **Trial Update: A study on how CagriSema affects levels of atorvastatin and warfarin in the blood of participants with excess body weight [Canada]**
*May 14, 2024*

- A Phase I trial sponsored by Novo Nordisk titled, *"A study on how CagriSema affects levels of atorvastatin and warfarin in the blood of participants with excess body weight"* has undergone following changes
  - **Outcome Measures:** Multiple additions made to secondary outcome measures
- **Read more:** NCT06289504
- **Implications:** N/A

**12** **New Trial: A Phase Ib study to evaluate the safety of XEN-101 [Undisclosed]**
*May 16, 2024*

- Xeno Biosciences initiated a Phase I trial to evaluate the effects of XEN-101 (undisclosed) on safety, tolerability, and pharmacodynamics in subjects with obesity
  - **Trial details:** N = 32; Status: Not yet recruiting; Start date: June 2024; PCD and SCD: September 2024; Location: Undisclosed
- **Read more:** NCT06417697
- **Implications:** Xeno plans to position this drug as a daily oral pill which could be an alternative for gastric bypass

**13** **Trial Update: A study in people with obesity to test the effects of BI 456906 (survodutide) compared with semaglutide on glucagon receptor activity in the liver [Undisclosed]**
*May 14, 2024*

- A Phase I trial sponsored by Boehringer Ingelheim titled, *"A study in people with obesity to test the effects of BI 456906 (survodutide) compared with semaglutide on glucagon receptor activity in the liver"* has undergone following changes
  - **SSD:** Updated from Jun 10, 2024 to Jun 28, 2024
  - **PCD and SCD:** Updated from Mar 8, 2026 [Anticipated] to Mar 30, 2026 [Anticipated]
- **Read more:** NCT05202353
- **Implications:** N/A

## REGULATORY

**14** **FDA discloses paragraph IV patent certifications for OZEMPIC [U.S.]**
*May 17, 2024*

- The U.S. FDA reported Paragraph IV was filed for new dosage/forms of:
  - Novo Nordisk OZEMPIC (semaglutide) injection 2 mg/3 mL; 1 ANDA filed on 4/11/2024
  - ANDA filings for 2mg/1.5 mL and 4mg/3 mL and 8mg/3 mL all previously disclosed
  - A Paragraph IV certification is an assertion by an ANDA filer that a patent listed in the Orange Book either is invalid or unenforceable or will not be infringed by a proposed generic product; the U.S. FDA did not name the filing company
- **Read more:** U.S. FDA - Paragraph IV Patent Certifications
- **Implications:** The disclosure of these certifications indicates ongoing efforts to introduce generic versions of Semaglutide, potentially leading to lower-cost alternatives upon patent expiration or successful litigation.

**15** **Lilly update on MOUNJARO and ZEPBOUND (tirzepatide) compounding litigation [U.S.]**
*May 14, 2024*

- Eli Lilly entered into a settlement agreement requiring defendant Totality Medispa to make a monetary payment and prohibiting

Totality from engaging in certain conduct, following a series of lawsuits Eli Lilly filed in Sep 2023 and Oct 2023

- Eli Lilly's settlement will stop Totality Medispa from misleading consumers into believing that this med spa is selling MOUNJARO (tirzepatide) or ZEPBOUND (tirzepatide) approved by the U.S. FDA, that its compounded products have been the subject of clinical tests, or that its compounded medicines have been proven safe and effective to achieve certain clinical results
- Eli Lilly is the only lawful supplier of the U.S. FDA approved tirzepatide medicines in the U.S., the company does not sell or provide tirzepatide active pharmaceutical ingredient (API) to any compounding pharmacies
- The settlement agreement requires Totality Medispa to make a monetary payment and to take several corrective actions. Totality must:
  - Only obtain and distribute compounded tirzepatide products that are produced in compliance with U.S. federal law
  - Report to the U.S. FDA any adverse events that patients experience after using Totality's compounded tirzepatide
  - Display on its website and all advertisements that "Compounded versions of tirzepatide are not FDA-approved, and neither the U.S. FDA nor any global regulatory agency has reviewed these products for safety, quality, or efficacy"
  - Not make any statements suggesting its products are genuine, FDA-approved Lilly products
- No longer use Eli Lilly branding in the promotion of any of its products

- **Read more:** Eli Lilly Press Release

- **Implications:** Mounjaro settlement dictates that Totality MediSpa cannot promote its unauthorized Mounjaro or Zepbound versions as genuine Lilly medication. Meanwhile, all but one of Lilly's Mounjaro and Zepbound dose strengths are expected to be in "limited availability" through the second quarter, according to the FDA's shortage database.

## COMMERCIAL

**16** **Jiangsu Hengrui Pharmaceuticals out-licenses GLP-1 portfolio outside Greater China to Hercules in exchange for 19.9% stake [Global]**
*May 16, 2024*

- Jiangsu Hengrui Pharmaceuticals announced that Hercules USA will receive exclusive rights from Jiangsu Hengrui Pharmaceuticals to develop, manufacture and commercialize its GLP-1 product portfolio worldwide, except for Greater China
  - The newly created company, currently referred to as "Hercules CM NewCo," is backed by Bain Capital Life Sciences, RTW Investments, Atlas Venture, and Lyra Capital, and was incorporated in May 2024
  - As part of the consideration for the external licensing transaction, Hengrui will receive 19.9% of the equity of Hercules and receive licensing fees for the GLP-1 product portfolio
- The GLP-1 product portfolio are a group of drugs for diabetes, obesity and other metabolic diseases, including
  - HRS-7535 is a small molecule GLP-1 receptor agonist
  - HRS9531 is a peptide GLP -1/GIP dual receptor agonist injectable and oral products
  - HRS-4729 is the next generation incretin product
- Upfront payment of $100 Mn and near-term milestone payments of $10 Mn upon completion of technology transfer
- Based on the clinical development progress of HRS-7535 and the first U.S. FDA approval for marketing, Hercules will pay Hengrui a cumulative clinical development and regulatory milestone payment of no more than $200 Mn
- Based on the actual annual net sales of the GLP-1 product portfolio in the licensed regions, Hercules will pay Hengrui a cumulative sales milestone payment of no more than $5.725 Bn

- **Read more:** Jiangsu Hengrui Pharmaceuticals Press Release (Translated from Chinese) – Link to PDF not available, Biopharma Dive

- **Implications:** Hercules is the latest example of the significant investment pouring into what's become one of the most competitive areas in pharmaceutical research. Hercules' most advanced drug, HRS-7535, is an oral "incretin" in Phase 2 testing in people with Type 2 diabetes and obesity

## MISCELLANEOUS

**17** **In Novo pricing probe, Sanders cranks up the heat with dire warning on projected GLP-1 spending [U.S.]**
*May 16, 2024*

- After recently placing a spotlight on Novo Nordisk's "outrageous" U.S. pricing for GLP-1 drugs, Senator Bernie Sanders is doubling down on his cost fighting crusade
- This time, the senator is flagging budgetary concerns related to the GLP-1 class of diabetes and obesity medicines
- In a new report, the Senate Health, Education, Labor and Pensions Committee claims high GLP-1 drug prices, coupled with high uptake, could "bankrupt entire health care system" in the U.S.
- In a statement, the senator said the "*Unjustifiably high prices of these weight loss drugs could also cause a massive spike in prescription drug spending that could lead to an historic increase in premiums for Medicare and everyone who has health insurance"*
- A Novo Nordisk spokesperson said, "*The company is reviewing the report and will continue to cooperate with Sanders' pricing"* investigation

- **Read more:** Fierce Pharma

- **Implications:** Pricing pressure continues to mount on Novo to reduce cost on Ozempic and Wegovy

**18** **Dandelion Health launches GLP-1 data library to advance precision medicine [U.S.]**
*May 14, 2024*

- Dandelion Health launched its GLP-1 data library, the first truly multimodal real-world clinical dataset built specifically to surface insights and opportunities related to the GLP-1 receptor agonist drug class

- Gathered from Dandelion's consortium of non-academic medical center health system partners, the GLP-1 data library reflects the full longitudinal patient records for millions of patients — 200,000 of whom are on various GLP-1 agonist
- Life sciences and other research organizations can use the GLP-1 data library for a range of use cases, including:
  - Evaluating the quality of weight loss through biomarkers found in body scans
  - Comparing the efficacy of treatments head-to-head across a range of different real-world measures
  - Demonstrating GLP-1's therapeutic effects beyond current uses, including secondary benefits derived from exploratory use or demonstrated with additional data modalities
  - Quantifying any side effects associated with GLP-1 use
  - Developing precision-medicine tools to identify patients with uncontrolled symptoms or to match patients to the right treatment plans
- Dandelion is already working with a number of AI developers and researchers on unique proofs of concept using its GLP-1 data library
- Dandelion will publish these findings in a scientific preprint in Q2 2024

- **Read more:** Dandelion Health Press Release

- **Implications:** Establishing the first multimodal real-world GLP-1 data library positions Dandelion Health as a leader in health data analytics, enhancing its brand reputation and market presence

**19** **Bernie Sanders urges OZEMPIC maker Novo Nordisk to be fair over 'outrageously expensive' U.S. drug prices [U.S.]**
*May 13, 2024*

- Bernie Sanders has urged Novo Nordisk, and forced the company to slash prices on popular weight loss and diabetes treatments OZEMPIC (semaglutide) and WEGOVY (semaglutide), taking his fight to lower "outrageously high" drug prices in the United States to the company's doorstep as its profits soar amid ongoing struggles to meet booming appetite for the revolutionary drugs
- In a column published in Danish newspaper Politiken *(subscription only)* on May 13, 2024, Senator Sanders, called on the Danish public to put pressure on the country's largest business to cut prices for OZEMPIC and WEGOVY in the U.S. and other parts of the world
- According to Sanders, OZEMPIC and WEGOVY are potential game changers for people around the world but they cannot benefit the millions of people who can't afford them

- **Read more:** Forbes

- **Implications:** High cost of GLP1s continue to remain a concern as it drives spending for the population eligible for this drug

**20** **A Russian company has developed a generic version of Eli Lilly's tirzepatide [Russia]**
*May 13, 2024*

- The Russian company Promomed has initiated the first phase of a clinical trial for the first Russian generic of tirzepatide for obesity and diabetes developed by Eli Lilly
- The study, which will involve 173 volunteers, will examine the safety, tolerability, and immunogenicity of WRYC12201 (tirzepatide) from Promomed. The experiment will take place in Moscow at the Bessalar private clinic

- **Read more:** GxP News

- **Implications:** Data from ph1 trial for this generic tirzepatide would be interesting to observe

**21** **Denmark faces WEGOVY shortage due to rising demand, medicines agency says [Denmark]**
*May 13, 2024*

- On May 13, 2024, the Danish medicines agency warned of a supply shortage for two separate doses of Novo Nordisk's hugely popular weight loss drug WEGOVY (semaglutide) due to increasing demand
- The Danish medicines agency said in a statement that there will be a shortage of Novo Nordisk's WEGOVY Flextouch 1 mg pen from late May to mid-Jun 2024 and there will also be a shortage of 0.5 mg WEGOVY Flextouch pen between mid-Jun and mid-Jul 2024

- **Read more:** KFGO, The Print

- **Implications:** Novo Nordisk does not expect a shortage of its Wegovy weight-loss drug in Denmark despite warning by the Danish Medicines Agency of strained supply of two separate doses in the coming weeks

**22** **Fire at key Novo Nordisk construction site extinguished [Denmark]**
*May 16, 2024*

- Novo Nordisk announced a fire had been extinguished at a construction site in Kalundborg, Denmark, where the company is investing heavily to boost the production capacity of its popular weight-loss drug WEGOVY (semaglutide) and OZEMPIC (semaglutide) for diabetes
- Novo Nordisk is investing around $6 Bn to expand the Kalundborg site to help boost capacity and meet soaring demand for WEGOVY and OZEMPIC

- **Read more:** SWI

- **Implications:** N/A

**23** **MOUNJARO going back to normal supply from June: Lilly/Mitsubishi [Japan]**
*May 16, 2024*

- Eli Lilly and its distribution partner Mitsubishi Tanabe announced that normal shipments will resume for all dosage forms of Eli

Lilly's GIP/GLP-1 receptor agonist MOUNJARO (tirzepatide) in Japan, beginning early next month
- Shipment restrictions will be lifted for all dose versions of the drug (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg) from Jun 4, 2024, as the companies now believe they can ensure stable supplies
- The decision factors into the impact of the removal of MOUNJARO's 14-day prescription limit in Apr 2024. Japan places such prescription limit on most new medicines in their first year on the market
- GLP-1 agents have been hit by a class-wide supply shortage, but Eli Lilly has also lifted shipment controls for TRULICITY (dulaglutide), another Eli Lilly drug in the class, with normal supplies started from Apr 22, 2024

- **Read more:** Pharma Japan *(Subscription required)*
- **Implications**: The lifting of the 14-day prescription limit, coupled with restored supply, positions Mounjaro favorably in terms of regulatory compliance and market penetration in Japan, potentially leading to faster adoption and broader market acceptance

**KEY UPCOMING EVENTS**

**UBS Obesity Therapeutics Day:**
- **Altimmune:** May 23, 2024 (Altimmune Investor update)

Thank you!
Kind regards
Diksha

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