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Subject: MTSR1: Weekly Competitive Intelligence Newsletter (Apr 2-8, 2024)
Date: Monday, April 8, 2024 at 1:40:37 PM Eastern Daylight Time
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Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: Apr 2-8, 2024

DASHBOARD

KEY TAKEAWAYS OF THE WEEK (Apr 2 - 8, 2024)

- **Clinical –** Eli Lilly initiated a Phase I trial to evaluate the safety and tolerability of tirzepatide and LY3841136 (undisclosed) in overweight and obese participants [U.S.]
- **Regulatory –** Hanmi Pharmaceutical submitted an investigational new drug application to the U.S. FDA for HM15275 (undisclosed) [U.S.]
- **Commercial –** The U.S. FDA extended estimated shortage duration for MOUNJARO (tirzepatide) in its 15-mg, 12.5-mg, 10-mg and 7.5-mg dose strengths [U.S.]

DETAILED NEWS

CLINICAL

1 New Trial: A study of LY3841136 (undisclosed) in overweight and obese participants [U.S.]
Apr 4, 2024

- Eli Lilly initiated a Phase I trial to evaluate the safety and tolerability of tirzepatide and LY3841136 (undisclosed) in overweight and obese participants
  - **Trial details:** N = 80; Status: Not yet recruiting; Start date: Apr 3, 2024; PCD and SCD: Mar 7, 2025; Location: U.S.
  - **Arms: Experimental:** LY3841136 + Tirzepatide, **Placebo Comparator:** Placebo + Tirzepatide
  - **Primary Outcome Measures:** Number of participants with one or more treatment emergent adverse event(s) (TEAEs) and serious adverse event(s) (SAEs) considered by the investigator to be related to study drug administration [Time Frame: Baseline up to 42 weeks]
- **Read more:** NCT06345066
- **Implications:** N/A

2 Trial Update: A study of RGT001-075 (undisclosed) in adult patients with obesity [U.S.]
Apr 4, 2024

- A Phase I trial sponsored by Regor Pharmaceuticals titled, *"A study of RGT001-075 (undisclosed) in adult patients with obesity"* has undergone following changes
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Recruiting'
  - **SSD:** Mar 8, 2024
  - **Contacts/Locations:** Multiple sites were added
- **Read more:** NCT06277934
- **Implications:** N/A

3 Trial Update: A study to test whether survodutide helps people living with obesity or overweight and with a confirmed or presumed liver disease called non-alcoholic steatohepatitis (NASH) to reduce liver fat and to lose weight [U.S.]
Apr 3, 2024

- A Phase III trial sponsored by Boehringer Ingelheim titled, "*A study to test whether survodutide helps people living with obesity or overweight and with a confirmed or presumed liver disease called non-alcoholic steatohepatitis (NASH) to reduce liver fat and to lose weight"* has undergone following changes
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Recruiting'

- **SSD:** Updated from Mar 20, 2024 to Mar 13, 2024
- **Contacts/Locations:** New site added

- **Read more:** NCT06309992

- **Implications:** N/A

4 **Trial Update: A study of LY3841136 (undisclosed) in healthy and overweight participants [U.S.]**
Apr 1, 2024

- A Phase I trial sponsored by Eli Lilly titled, *"A study of LY3841136 (undisclosed) in healthy and overweight participants"* has undergone following changes
  - **Overall Status:** Updated from 'Active, not recruiting' to 'Completed'
  - **PCD and SCD:** Updated from Jan 25, 2024 [Anticipated] to Jan 25, 2024 [Actual]
  - **Enrollment:** Updated from 160 [Anticipated] to 148 [Actual]

- **Read more:** NCT05295940

- **Implications:** N/A

5 **Weight loss jabs like OZEMPIC have been linked to twenty deaths in Britain including person in their 30s - as experts issue new warning [UK]**
Apr 5, 2024

- MailOnline revealed that weight loss drugs like OZEMPIC (semaglutide) and WEGOVY (semaglutide) have been linked to 20 deaths in Britain. One of the victims was in their 30s
- None of the fatalities, which have all occurred since 2019, are proven to have been caused directly by the game-changing weight loss injections
- However, health chiefs tasked with policing the safety of medicines used in the UK, including the jabs, say reports of side effects indicate 'a suspicion' they may have been to blame
  - Experts warned the patients against buying semaglutide

- **Read more:** MailOnline

- **Implications:** The linkage of 20 deaths in Britain to weight loss injections like OZEMPIC and WEGOVY, including a case involving someone in their 30s, prompts caution. While direct causality isn't established, the associations have led to increased regulatory attention and a call for more stringent safety evaluations.

6 **Trial Update: Study to evaluate the safety and effectiveness of SAXENDA (liraglutide) for weight management in routine clinical practice in Taiwan [Taiwan]**
Apr 1, 2024

- An observational trial sponsored by Novo Nordisk titled, *"Study to evaluate the safety and effectiveness of SAXENDA (liraglutide) for weight management in routine clinical practice in Taiwan"* has undergone following changes
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Enrolling by invitation'
  - **SSD:** Updated from Feb 22, 2024 to Feb 23, 2024

- **Read more:** NCT06283641

- **Implications:** N/A

7 **New Trial: A study to evaluate the safety, tolerability, and pharmacokinetics of PB-119 (undisclosed) injection in Chinese obese subjects [Undisclosed]**
Apr 5, 2024

- PegBio initiated a Phase I/II trial to evaluate the safety, tolerability, and PK of PB-119 (undisclosed) injection in Chinese obese subjects
  - **Trial details:** N = 32; Status: Not yet recruiting; Start date: May 30, 2024; PCD and SCD: Apr 29, 2025; Location: Undisclosed
  - **Arms: Experimental:** PB-119, **Placebo Comparator:** Placebo
  - **Primary Outcome** Measures: Incidence of Treatment-Emergent Adverse Events [Time Frame: From the first dosing (Day 1) of study drug until completion of the post treatment follow-up visit (24 week)]

- **Read more:** NCT06350812

- **Implications:** PegBio has commenced a Phase I/II study to assess the safety, tolerability, and pharmacokinetics of the PB-119 injection in obese individuals in China.

REGULATORY

8 **Hanmi Pharmaceutical submits IND to U.S. FDA for obesity drug HM15275 (undisclosed) Phase I trial [U.S.]**
Apr 1, 2024

- On Mar 29, 2024, Hanmi Pharmaceutical submitted an investigational new drug (IND) application to the U.S. FDA for HM15275, next-generation GLP-1/GIP/GCG triple-agonist to initiate a Phase I clinical trial targeting obesity
- The trial will assess the safety, tolerability, PK, and PD of HM15275 in both healthy adults and those with obesity
- The company aims to commercialize HM15275 by 2030
- In Jun 2024, the company is scheduled to present findings from various studies of HM15275 at the upcoming 2024 American Diabetes Association Meeting in the U.S. in Jun 2024

- **Read more:** Korea Biomedical Review, Hanmi Pharmaceutical Press Release *(Translated from Korean)*

- **Implications:** The upcoming Phase I trial aims to explore its safety and efficacy in treating obesity, with commercialization targeted by 2030.

9 **Search warrant executed on Sydney residence in relation to substandard compounded semaglutide [Australia]**
Apr 5, 2024

- On Mar 27, 2024, Therapeutic Good Administration (TGA) officers executed a search warrant on a Sydney residence linked to an individual suspected of being involved in the manufacture and sale of compounded semaglutide
- In the execution of this warrant, several items were seized from the residence. These will be subject to further analysis and examination by the TGA
- The warrant and seizure were part of an ongoing investigation into the alleged unlawful manufacture, supply, and export of therapeutic goods, including prescription-only medicines. This included medical professionals in Australia and overseas being sent faxes promoting the medicines
- The TGA is also aware that several patients have suffered adverse events from the medication after it had been sent to them via the post
  - Given the potential health harms of these products, the TGA also published a related safety alert on the substandard semaglutide vials

- **Read more:** TGA Press Release

- **Implications:** The TGA raid on a Sydney home for illegal production and sale of semaglutide underscores the crackdown on unauthorized pharmaceutical activities highlights the critical need for regulatory vigilance to protect public health.

10 **Drugmaker seeks approval for China's first biosimilar OZEMPIC [China]**
Apr 1, 2024

- Hangzhou Jiuyuan Gene Engineering developed a biosimilar version of Novo Nordisk's OZEMPIC (semaglutide) and has applied for approval to sell it in China. While the semaglutide product is targeted to T2D, a similar article written by Forbes reports that Jiuyuan Gene says in the future it plans to continue its research and development of semaglutide and carry out clinical development for other uses, like weight loss while actively working overseas to create international markets
- Hangzhou Jiuyuan Gene Engineering, which is majority owned by China's Huadong Medicine posted on its official social media account that it was seeking approval to sell the drug, which it calls JIYOUTAI (semaglutide), to control blood sugar in patients with T2D
  - Cheaper copies of OZEMPIC could dampen demand for WEGOVY
- Novo Nordisk plans to launch in China in 2024 with a focus on patients paying out of their own pockets
  - Approval for JIYOUTAI would make the injectable drug China's first locally developed biosimilar semaglutide drug
- According to a clinical trials registry, Jiuyuan Genecompleted a late-stage clinical trial in China last year comparing its semaglutide injection with OZEMPIC in 476 patients
- According to Novo Nordisk's annual report 2023, company's patents in China on OZEMPIC and related drug WEGOVY (semaglutide) are set to expire in 2026

- **Read more:** SRN News, Forbes

- **Implications:** Hangzhou Jiuyuan Gene Engineering's bid to get approval for JIYOUTAI, a biosimilar of OZEMPIC, could mark a pivotal shift in China's pharmaceutical landscape by offering a more affordable treatment option for Type 2 Diabetes and potentially weight loss. This move not only challenges Novo Nordisk's market share in China but also signals Jiuyuan's ambitions to compete globally, especially as OZEMPIC's patents expire in 2026. The approval of JIYOUTAI would introduce significant competition, potentially affecting pricing and accessibility of semaglutide-based treatments in China and beyond.

COMMERCIAL

11 **ZEPBOUND patients have a solution for obesity drug shortage: Release the vials [Global]**
Apr 3, 2024

- According to David Ricks, CEO, Eli Lilly, ZEPBOUND (tirzepatide) isn't in short supply because there's a lack of medicine but rather the pre-filled pens that patients use to inject the right dose of the drug. Making that device requires some of the most complex production systems on the plane
- However, there's another way to administer the drug: Lilly could ditch the pen and sell ZEPBOUND in vials
  - That would require patients to fill a syringe on their own but ease the drugmaker's production woes
  - Eli Lilly is turning to vials outside the U.S., and increasingly popular versions of the drug is being packaged in a similar manner

- **Read more:** Medwatch

- **Implications:** This solution represents a practical approach to overcoming manufacturing and supply challenges, ensuring that patients have continued access to vital treatments while possibly influencing future pharmaceutical distribution strategies. However, implementation of difficult to use vials over easy to use autoinjectors could dilute the Zepbound experience for patients

12 **Eli Lilly's popular diabetes drug MOUNJARO to face continued supply squeeze through April, FDA says [U.S.]**
Apr 2, 2024

- The U.S. FDA extended its estimated shortage duration for MOUNJARO (tirzepatide) in its 15-mg, 12.5-mg, 10-mg and 7.5-mg dose strengths to reflect "limited availability" through the end of Apr 2024. The shortage for several strengths was previously expected to persist through Mar 2023
  - Two lower dose strengths, 5 mg and 2.5 mg are listed as available on the U.S. FDA's shortage database
  - However, even those are currently marked as unavailable on Amazon Pharmacy
  - The U.S. FDA attributed the supply squeeze to demand increases

- To address the issue, the drugmaker is moving with purpose and urgency to ensure our innovations are available to those who need them

- **Read more:** Fierce Pharma, FDA Drug Shortages

- **Implications:** Despite Eli Lilly's efforts to keep up with production, shortages in supply underscore the challenge of meeting the high demand for this treatment, reflecting the complexities of pharmaceutical supply chains. The limited availability of higher doses might push demand towards lower doses, further straining supply. This situation risks disrupting patient adherence, emphasizing the need for effective solutions to ensure continuous access to essential medications.

13 **Costco begins offering OZEMPIC prescriptions to some members [U.S.]**
Apr 2, 2024

- The warehouse retailer is now offering its U.S. members access to prescriptions for GLP-1 weight loss drugs through its low-cost health care partner Sesame
- Costco first partnered with Sesame, a direct-to-consumer health care marketplace that connects medical providers nationwide with consumers, when it began offering its members online health checkups for as low as $29
- But about two months after that announcement, Costco and Sesame noticed that customers were inquiring about weight-loss help and began working on a new program to address that interest, said Sesame co-founder and CEO David Goldhill
- The fruit of their labor, a renewable three-month program, officially launched on Tuesday and includes a video consultation with a weight loss doctor or specialist, a GLP-1 or weight loss prescription, if appropriate, and ongoing support through unlimited messaging and guidance with a health care provider
- Sesame says it has an available supply of injectable semaglutide, including OZEMPIC (semaglutide) and WEGOVY (semaglutide), as well as oral weight-loss medications
  - The company advertises that patients could lose 5% of their body weight in just three months, 10% in six months and 15% in a year
- The cost of medication is not included in the $179 three-month plan, and Sesame warned on its website that without insurance, GLP-1s can cost between $950 and $1,600 per month

- **Read more:** CNN

- **Implications:** Costco's new service, offering OZEMPIC prescriptions through Sesame, addresses the growing demand for accessible weight loss treatments. This move signifies a trend towards integrating retail with healthcare to enhance access to specialized care.

14 **Lack of medicare coverage for GLP-1 drugs tied to lower prescription rates: Study [U.S.]**
Apr 2, 2024

- According to a study from the University of Pennsylvania and healthcare data firm Truveta Research, Medicare policy prohibiting the coverage of GLP-1 receptor agonists for obesity may be driving lower prescription and initiation rates of these therapies in adults aged 65 to 69 years
  - This study found nearly 414,000 adults between 60 to 69 years of age who were overweight or obese but without type 2 diabetes and were eligible for GLP-1 RA treatment
  - However, of these seniors, fewer than 1%--or just over 1,200 were prescribed these anti-obesity medications
- According to the study, prescription rates were even lower among Medicare-aged patients
  - In the subgroup of patients aged 65 to 69 years, only 0.24% of eligible patients were prescribed GLP-1 treatments, compared to 0.37%in counterparts who were 60 to 64 years old
  - Medicare-aged patients also saw a lower rate of dispensing, with 15.2% filling their prescriptions within 60 days, as opposed to 22.7% in the younger age group
- These findings suggest that Medicare-aged adults face unique gaps in access, occurring at both the medication prescribing and filling stages and this effect could likely be driven by a lack of coverage

- **Read more:** Biospace

- **Implications:** The lack of access to obesity treatments for Medicare beneficiaries highlights the need for policy changes to improve treatment availability and address healthcare equity, especially in preventive care and chronic disease management for older adults.

15 **An update on weight loss drug coverage from FEHB plans [U.S.]**
Apr 1, 2024

- In early 2023, the U.S. Office of Personnel Management (OPM) issued a letter to FEHB carriers related to the prevention and treatment of obesity. Besides guidance on screening and prevention, OPM specified that carriers must cover at least one GLP-1 weight-loss drug
- Additionally, carriers must annually evaluate their coverage as new drugs receive the U.S. FDA approval to meet the OPM mandate of non-discriminatory access to safe and clinically appropriate drug therapy for individuals with chronic conditions
- For federal employees and annuitants, this means there will be a wide range of cost and coverage options for weight-loss drugs from FEHB plans

- **Read more:** FedSmith

- **Implications:** The OPM's mandate for FEHB plans to cover GLP-1 weight-loss drugs enhances obesity treatment coverage for federal employees and retirees, ensuring access to essential medications and reflecting a commitment to comprehensive healthcare benefits.

16 **Biocon leads India's push into anti-obesity drugs as patents lapse [India]**
Apr 8, 2024

- Biocon is pivoting to anti-obesity therapies as patents for the blockbuster medications start to expire, unleashing a wave of generic supply for the market that's expected to touch $100 Bn by 2030
- Biocon has 15 peptide formulations are under development, of which one or two drugs will seek regulatory approval in 2024
- Weight loss drugs have already produced record profit for innovative pharmaceutical companies from Novo Nordisk to Eli Lilly. The gold rush is set to spread to generic makers like India's biggest players when patents expire in the coming years on OZEMPIC and WEGOVY, allowing cheaper copies of the medication to flood the market and plug supply gaps
- Peter Bains, Group CEO, Biocon, mentioned in an interview that, "*Biocon is building capability to take advantage of what could be a very, very strategic peptide opportunity with GLPs at the center*"

- **Read more:** Business Standard

- **Implications:** This move positions Biocon to meet growing demand with more affordable generic options, leveraging the expiry of key patents to carve a significant niche in the global obesity treatment landscape.

MISCELLANEOUS

17 **Novo Nordisk triumphs in UK probe of 'hyperbolic' WEGOVY claims [UK]**
Apr 3, 2024

- Novo Nordisk has emerged unscathed from a probe into claims it ran an "orchestrated PR campaign" to shape the obesity debate in the UK
- The U.K. drug promotion watchdog carried out the investigation in response to media reports about Novo Nordisk's links to experts but found no evidence of wrongdoing
- The Observer newspaper ran a series of articles with titles such as "'Orchestrated PR campaign', the UK Prescription Medicines Code of Practice Authority (PMCPA) treated the articles as a complaint, because its director saw them as potential evidence that Novo Nordisk may have breached the code
  - That led to an investigation into whether the company breached various parts of the UK code, including a clause reserved for severe failings that bring discredit upon, or reduce confidence in, the pharmaceutical industry
- Novo successfully defended itself against all the claims
  - The PMCPA panel found no evidence that Novo Nordisk was responsible for the strong statements about WEGOVY by people that the company had engaged to provide services

- **Read more:** Fierce Pharma

- **Implications:** This verdict supports Novo Nordisk's promotional practices, affirming its commitment to ethical standards in the pharmaceutical industry.

18 **Novo says OZEMPIC starter kits still not available in Germany in Q2 [Germany]**
Apr 3, 2024

- Novo Nordisk has warned that starter kits of OZEMPIC (semaglutide) will still not be available in Germany during Q2 2024, as shortages in Europe due to the drug's slimming effect drag out
  - In a statement by the company posted on the website of German healthcare regulator BfArM, Novo Nordisk urged physicians to only issue prescriptions for patients already on the therapy
- The company also reiterated that doctors should only prescribe OZEMPIC for its approved use in diabetes, saying that there were sufficient supplies of WEGOVY (semaglutide) which the obesity drug that is based on the same active ingredient
- Novo Nordisk warned that intermittent OZEMPIC shortages are expected throughout 2024
- In its German statement posted on BfArM's website, Novo said the OZEMPIC 0.25 mg starter strength will still not be available in Germany during the second quarter, with the 0.5 mg intermediate dose only available in limited volumes

- **Read more:** Saltwire

- **Implications:** Clients in Germany using OZEMPIC may face difficulties in accessing the medication due to shortages into Q2 2024. It's important to discuss treatment options with their healthcare providers, especially if patients are new to OZEMPIC, given the focus on existing patients. Preparing for possible continued shortages throughout 2024 will be key in managing their diabetes treatment.

19 **Australians accessing OZEMPIC despite lack of weight loss approval [Australia]**
Apr 4, 2024

- Use of OZEMPIC (semaglutide) for weight loss in Australia is considered "off label". This is when a doctor prescribes a medicine for a purpose outside of what is approved
- OZEMPIC is only approved to be used for the treatment of diabetes in Australia, but its off-label prescribing for weight loss is driving shortages which the TGA thinks will last until 2025
- To manage these shortages, Australian doctors and pharmacies are being asked not to start new patients on OZEMPIC and to prioritise it for patients with T2D who are already stabilised on this medicine

- **Read more:** Mirage News, The University of Sydney News

- **Implications:** Similar to Germany, Australia is facing shortages and HCPs are asked to prioritize T2D patients over off-label usage of OZEMPIC. Australia needs to prepare for continuous shortages.

20

Novo Nordisk's principal scientist outlines global trend on diabetes and obesity
Apr 4, 2024

- The Ministry of Health and Welfare, in collaboration with the Korea Health Industry Development Institute and Novo Nordisk, hosted the "Novo Nordisk Partnering Day- Korea 2024"
- Tomas Landh, Senior Principal Scientist, Novo Nordisk, shared the company's strategic approach toward combating diabetes and obesity, highlighting the challenges and innovations in the field
- Landh mentioned, Novo Nordisk have some 85 opportunities across different business development stages ongoing right now in obesity and the company has got large inbound opportunities in obesity
- Landh stressed that anti-obesity medications cannot succeed alone, and it would require a combination of things, including lifestyle management

- **Read more:** Korea Biomedical Review

- **Implications:** There is a need for comprehensive solutions beyond medication when tackling obesity and diabetes. Novo Nordisk Highlighted their involvement in obesity-related development opportunities including integrated lifestyle management as part of the treatment. This approach marks a significant step towards addressing the global health challenges of diabetes and obesity with multifaceted strategies.

21 **Antitrust watchdog FTC probes Novo Nordisk Korea over needle supply cessation [South Korea]**
Apr 4, 2024

- The Fair Trade Commission (FTC) is reportedly looking into Novo Nordisk Korea over allegations of monopolistic practices related to the cessation of its needle supply, NovoFine Plus pen needle
- NovoFine Plus pen needles are ultra-fine needles designed for injecting medication, renowned for causing minimal pain during injection, making them highly preferred by diabetes patients and caregivers of children patients
- Joongang Ilbo reported the FTC believed that Novo Nordisk ceased the domestic sales of NovoFine Plus for business management reasons which is to boost the sales of OZEMPIC, which includes NovoFine Plus needles as part of the medication package, even though there was no substitute in Korea
- The FTC is set to convene a deliberation soon to determine the appropriate measures and extent of sanctions against Novo Nordisk for its conduct

- **Read more:** Korea Biomedical Review

- **Implications:** The lack of alternative needle options in Korea has raised concerns, and the FTC is considering sanctions against Novo Nordisk, emphasizing the significance of fair market practices and patient access to necessary medical supplies.

22 **Aurisco launches manufacturing facility for GLP-1 peptides [China]**
Apr 3, 2024

- Aurisco Pharmaceutical announced the completion of its investment in cGMP peptide manufacturing capacity at the company's site in Yangzhou, China inspected by the U.S. FDA
- In addition to its current fermentation and synthetic capabilities, the new advanced manufacturing and purification workshops introduce multi-metric ton capacity to produce Aurisco's generic GLP-1 peptides
- The new, cutting-edge facilities are set to commence operations mid-2024 with the commercial scale validation of recombinant semaglutide

- **Read more:** Chem Expert

- **Implications:** Set to start operations mid-2024, this facility, inspected by the U.S. FDA, signifies a boost in the global supply of GLP-1 treatments, potentially making them more accessible and affordable.

23 **New research shows BMI fails as a measure of childhood obesity, leading to flawed policy**
Apr 4, 2024

- A new research has found BMI completely fails as an accurate measure of obesity in children, calling into question the foundation for all past and present government child obesity policies
- For nearly a generation, weight-to-height ratio charts and BMI for age and sex have been used to diagnose children with obesity, but they have now been proven to be an inaccurate measure since they don't distinguish fat mass from muscle mas
- This is because muscle weighs more than fat, changing the results

- **Read more:** Leisure Opportunities

- **Implications:** It is essential to reevaluate the accuracy of BMI measurements for childhood obesity. This calls for revisions in government policies and diagnostic approaches.

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!
Kind regards,
Diksha

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