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Subject: MTSR1: Weekly Competitive Intelligence Newsletter (Apr 30 - May 6, 2024)
Date: Monday, May 6, 2024 at 10:11:21 AM Eastern Daylight Time
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Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: Apr 30 - May 6, 2024

DASHBOARD

KEY TAKEAWAYS OF THE WEEK (Apr 30 - May 6, 2024)

- **Clinical –** Amgen highlighted that an interim look at its anti-obesity drug MariTide had left the company very encouraged, and it planned to rapidly move forward with a final-stage program as well as boost manufacturing capacity for the experimental drug [U.S.]
- **Clinical –** Ventus Therapeutics announced that its partner, Novo Nordisk successfully dosed the first participant in a Phase I clinical study for NNC6022-0001 (undisclosed) [Canada]
- **Regulatory –** Palatin Technologies announced the U.S. FDA completed its 30-day review of the IND application of bremelanotide for the treatment of obesity [U.S.]
- **Commercial –** Novo Nordisk is reducing the U.S. price of WEGOVY (semaglutide) in response to increased competition from rivals and enhanced sales volumes following the resolution of supply issues [U.S.]
- **Commercial –** Novo Nordisk Canada has announced that WEGOVY (semaglutide) injection will be available for Canadians who meet the requirements in the Health Canada approved product monograph on May 6, 2024 [Canada]

DETAILED NEWS

CLINICAL

1 New Trial: A research study to see how well different doses of CagriSema help people with excess body weight lose weight [Global]
Apr 29, 2024

- Novo Nordisk initiated a Phase III trial to investigate efficacy and safety of cagrilintide S.C. in combination with semaglutide S.C. (CagriSema s.c. 1.0 mg/1.0 mg and 1.7 mg/1.7 mg) once-weekly in participants with overweight or obesity
  - **Trial details:** N = 300; Status: Not yet recruiting; Start date: Jun 24, 2024; PCD: Feb 27, 2026; SCD: Apr 10, 2026; Location: U.S., Canada, France, Germany, and the UK
- **Read more:** NCT06388187
- **Implications:** CagriSema's ph2 demonstrated that the combination therapy caused a decrease in bodyweight at week 32 of treatment of 15.6% from baseline. Ph3 trial will provide a deeper insight on efficacy and safety of the drug

2 Amgen touts' new data for obesity drug MariTide, moving rapidly into Phase III work [U.S.]
May 2, 2024

- Amgen highlighted that an interim look at a Phase II trial of its anti-obesity drug MariTide had left the company very encouraged, and it planned to rapidly move forward with a final-stage program as well as boost manufacturing capacity for the experimental drug
- According to Bob Bradway, CEO, Amgen, the company is confident in MariTide's differentiated profile and believe it will address important unmet medical need
  - The company was planning a broad Phase III program in obesity, diabetes, and obesity-related conditions
- MariTide could be given monthly, less frequently than competing drugs. The trials had not had issues with dropouts, suggesting that the tolerability of MariTide (previously known as AMG-133) could be better than the side effects seen with some approved and under-development drugs
- Bradway mentioned that the company was ready, if needed, to deal with the huge demand that Eli Lilly and Novo Nordisk have faced in supplying their own, already approved anti-obesity drugs

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

- **Implications:** Amgen's decision to rapidly advance MariTide into Phase III trials reflects its confidence in the drug's potential and underscores the company's commitment to addressing the unmet medical need in obesity treatment

3 **Elevai Biosciences highlights preclinical data showing potential of in-licensed asset EL-22 (undisclosed) for the treatment of obesity [U.S.]**
May 2, 2024

- Elevai Labs highlighted results from their licensor's 2022 preclinical studies evaluating the treatment effect of its recently in-licensed asset, EL-22 (undisclosed)
  - EL-22 will primarily be commercialized by Elevai Biosciences
- Based on the licensor's 2022 preclinical data, Elevai believes that EL-22 has the potential to treat obesity in combination with GLP-1 receptor agonists by preserving muscle mass while decreasing fat mass
- The Company intends to complete an IND submission in 2025 and to initiate clinical trials in the U.S. to evaluate the myostatin approach in combination with one or more GLP-1 receptor agonists in obesity

- **Read more:** Elevai Biosciences Press Release

- **Implications:** EL-22 could be a drug to be used in combination with GLP-1 RAs to preserve muscle mass, while decreasing fat mass

4 **Trial Update: A study to test how well different doses of BI 3006337 (undisclosed) are tolerated by people with overweight or obesity and with fatty liver disease [U.S.]**
May 1, 2024

- A Phase I trial sponsored by Boehringer Ingelheim titled, *"A study to test how well different doses of BI 3006337 (undisclosed) are tolerated by people with overweight or obesity and with fatty liver disease"* has undergone following changes
  - **PCD and SCD:** Updated from 'Dec 10, 2024' to 'Jan 4, 2025'

- **Read more:** NCT05970640

- **Implications:** N/A

5 **Trial Update: A research study to see if kidney damage in people with chronic kidney disease and type 2 diabetes living with overweight or obesity can be reduced by CagriSema compared to semaglutide, cagrilintide and placebo [U.S.]**
May 1, 2024

- A Phase II trial sponsored by Novo Nordisk titled, *"A research study to see if kidney damage in people with chronic kidney disease and type 2 diabetes living with overweight or obesity can be reduced by cagrisema compared to semaglutide, cagrilintide and placebo"* has undergone following changes
  - **Study Start Date:** Updated from 'Apr 1, 2024' to 'Mar 29, 2024'
  - **Contacts/Locations:** Multiple sites were added and removed from the locations

- **Read more:** NCT06131372

- **Implications:** CagriSema will be tested for CKD within T2D patients that are overweight/obese, like semaglutide with the FLOW study that is expected to present full results soon

6 **Trial Update: Dose-finding study evaluating effect on body composition of enobosarm in patients taking a GLP-1 for chronic weight mgmt [U.S.]**
May 1, 2024

- A Phase II trial sponsored by Veru titled, *"Dose-finding study evaluating effect on body composition of enobosarm in patients taking a GLP-1 for chronic weight mgmt"* has undergone following changes
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Recruiting'
  - **Contacts/Locations:** Updated

- **Read more:** NCT06282458

- **Implications:** N/A

7 **Ventus Therapeutics announces first participant dosed in clinical study with an NLRP3 inhibitor licensed exclusively to Novo Nordisk [Canada]**
May 3, 2024

- Ventus Therapeutics announced that its partner, Novo Nordisk successfully dosed the first participant in a Phase I clinical study for NNC6022-0001 (undisclosed) – an oral NLRP3 inhibitor licensed by Novo Nordisk in Sep 2022
- The Phase 1 study is designed to fully explore the PK, PD, and safety of NNC6022-0001 across a broad range of doses in healthy volunteers

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

- **Implications:** N/A

8 **New Trial: To compare the efficacy and safety of HRS9531 (undisclosed) and placebo in subjects with overweight or obese [China]**
May 2, 2024

- Fujian Shengdi Pharmaceutical initiated a Phase III trial to investigate efficacy and safety of HRS9531 (undisclosed) in overweight or obese participants

- **Trial details:** N = 540; Status: Not yet recruiting; Start date: May 20, 2024; PCD: Jul 30, 2026; SCD: Aug 30, 2025; Location: China

- **Read more:** NCT06396429

- **Implications:** Chinese GLP-1 and GIPR dual agonist moving into Ph3

9 **Trial Update: A study of IBI362 (mazdutide) 9 mg in Chinese adults with obesity [China]**
May 1, 2024

- A Phase III trial sponsored by Innovent Biologics titled, *"A study of IBI362 (mazdutide) 9 mg in Chinese adults with obesity"* has undergone following changes
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Recruiting'
  - **Study Start:** Updated from Dec 31, 2023 to Dec 27, 2023
  - **Eligibility:** Inclusion criteria updated

- **Read more:** NCT06164873

- **Implications:** N/A

10 **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]**
Apr 30, 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
  - **PCD:** Updated from Nov 18, 2025 [Anticipated] to Mar 8, 2026 [Anticipated]
  - **SCD:** Updated from Dec 23, 2025 [Anticipated] to Mar 8, 2026 [Anticipated]

- **Read more:** NCT05202353

- **Implications:** N/A

REGULATORY

11 **Another day, another delay for Novo's Catalent acquisition as FTC imposes 'Second Request' [U.S.]**
May 3, 2024

- On May 2, 2024, Catalent and the Novo Nordisk Foundation received a request for additional information and documentary materials (the "Second Request") from the U.S. Federal Trade Commission (FTC) in connection with the Merger
  - The Second Request was issued under the notification requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR Act)
  - The effect of the Second Request is to extend the waiting period imposed by the HSR Act until 30 days after Catalent and the Novo Nordisk Foundation have substantially complied with the request unless that period is extended voluntarily by the parties or terminated sooner by the FTC
- Catalent and the Novo Nordisk Foundation are in the process of gathering information and documentary materials responsive to the Second Request and intend to continue to cooperate with the FTC to obtain antitrust regulatory clearance for the Merger as expeditiously as possible
- The Merger remains subject to the expiration or termination of the waiting period under the HSR Act, approvals, clearances, and expirations or terminations of any applicable waiting periods under applicable antitrust and foreign investment regimes in certain non-U.S. jurisdictions, as well as other customary closing conditions. Catalent and Novo Holdings expect to close the Merger towards the end of calendar year 2024

- **Read more:** Fierce Pharma, Catalent – 8K Form

- **Implications:** The delay resulting from the 'Second Request' could potentially push back the expected closing of the merger towards the end of calendar year 2024. The FTC's decision to issue a 'Second Request' suggests that regulators are closely scrutinizing the proposed acquisition for potential antitrust concerns

12 **Palatin announces FDA clearance of IND application for the co-administration of bremelanotide with tirzepatide (GLP-1) for the treatment of obesity [U.S.]**
May 2, 2024

- Palatin Technologies announced that the U.S. FDA completed its 30-day review of the IND application of bremelanotide, a melanocortin receptor 4 agonist for the treatment of obesity
- The Company is cleared to begin enrollment in a Phase II clinical study evaluating the safety and efficacy of bremelanotide, co-administered with tirzepatide in obese patients
  - The Phase II clinical study is expected to start mid-calendar year 2024, with topline data results by the end of calendar year 2024

- **Read more:** Palatin Technologies Press Release

- **Implications:** N/A

13 **FTC expands patent listing challenges, targeting more than 300 junk listings for diabetes, weight loss, asthma, and COPD drugs [U.S.]**
Apr 30, 2024

- The FTC expanded its campaign against pharmaceutical manufacturers' improper or inaccurate listing of patents in the U.S. FDA's

Orange Book, disputing junk patent listings for diabetes, weight loss, asthma, and COPD drugs, including Novo Nordisk's OZEMPIC
  - The Commission sent warning letters to 10 companies and notified the U.S. FDA that it disputes the accuracy or relevance of more than 300 Orange Book patent listings across 20 different brand name products
  - These patent listings are currently listed in the U.S. FDA's publication of "*Approved Drug Products with Therapeutic Equivalence Evaluations,"* commonly known as the Orange Book, which lists drug products approved by the U.S. FDA as safe and effective
- To promote competition, the FTC said it is disputing these patent listings as improper or inaccurate
  - Improper Orange Book patent listings can delay cheaper generic alternatives from entering the market, keeping brand name drug prices artificially high
- The warning letters were sent to:
  - AstraZeneca and Novo Nordisk for obesity and type-2 diabetes injectable drugs

- **Read more:** FTC Press Release, Fierce Pharma

- **Implications:** The FTC's latest move against improper Orange Book patent listings targets pharmaceutical giants, highlighting its commitment to combatting inflated drug prices and ensuring access to affordable medications

COMMERCIAL

14 **Fierce competition spurs Novo to reduce U.S. prices of obesity and diabetes drugs [U.S.]**
May 3, 2024

- Novo Nordisk is reducing the U.S. price of WEGOVY (semaglutide) in response to increased competition from rivals and enhanced sales volumes following the resolution of supply issues
- During Q1 2024 Earnings Call, Karsten Munk Knudsen, CFO, Novo Nordisk, shared fresh insights into the pricing dynamics in the U.S. of WEGOVY and diabetes treatment Ozempic (semaglutide)
- OZEMPIC has been used off-label for weight loss, has fast become Novo Nordisk's top-selling product. In Q1 2024 OZEMPIC sales surged 43% in constant currencies to 27.8 Bn Danish krone (€3.7 Bn)
- WEGOVY sales in Q1 2024, leapt 107% in constant currency terms to 9.4 Bn Danish krone (€1.3 Bn)
- The company has been making substantial investments in its manufacturing capacity to accommodate the rapidly increasing demand for the drugs
- There appears to be a marked improvement in the situation since, with Munk Knudsen highlighting that the GLP-1 agonist is now being prescribed to around 25,000 new patients in the U.S. per week vs. 5,000 in Dec 2023
- Bernie Sanders, U.S. Senator mentioned Novo Nordisk must lower the price of OZEMPIC in the U.S. after it was able to do so in Denmark
- Sanders claimed, U.S. citizens are still being charged $969 for the GLP-1 agonist, while it only costs the manufacturer about $5 to make it
- The Danish Medicines Agency (DMA) confirmed that the cost of OZEMPIC had been cut by 34%, although it still remains more expensive than other types of diabetes medication

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

- **Implications:** Novo Nordisk's decision to lower the price of WEGOVY reflects the intensifying competition in the market for obesity and diabetes treatments. This trend is likely to continue in coming years with more competitors approaching the obesity market

15 **Novo Nordisk announces $6 Bn investment in OZEMPIC, WEGOVY amid shortages [U.S.]**
May 3, 2024

- Novo Nordisk is investing $6 Bn to meet the increased demand for these drugs amid shortages of popular drugs for weight loss including OZEMPIC (semaglutide) and WEGOVY (semaglutide)
  - Negelle Morris, Senior Vice President and Head of U.S. cardiometabolic sales at Novo Nordisk, spoke to *Good Morning America* about the topic
  - Although the company is investing money into these products, there will still likely be delays in bringing the in-demand drugs to the market
- According to Negelle Morris, the strategy is to be very mindful and thoughtful about the amount of the lower doses that the company putting into the market and over time the investments that the company is making in manufacturing capabilities will ensure that the company will be able to meet that demand

- **Read more:** RetailWire

- **Implications:** Novo Nordisk continues to invest in semaglutide, regulating the demand via the lower starting doses of semaglutide

16 **Weight loss drug wins 25,000 new U.S. users a week [U.S.]**
May 2, 2024

- Novo Nordisk's WEGOVY (semaglutide) experienced a five-fold increase in the U.S. during the first quarter of the year, surpassing 25,000 weekly sign-ups
  - This demand surge contributed to Novo Nordisk's growth, making it one of Europe's most valuable companies
- Facing scrutiny over high drug prices and emerging competition from Eli Lilly, Novo Nordisk has reduced prices for WEGOVY and OZEMPIC (semaglutide) in the U.S. and anticipates further price decreases, despite expecting a sales growth of up to 27% in 2024
- In the U.S., the cost of these drugs has led to restricted access by health insurance plans, including Medicare. This issue has caught the attention of U.S. lawmakers, prompting an investigation into the pricing disparities between the U.S. and other regions like the UK
- Novo Nordisk has invested in expanding its manufacturing capabilities, which is starting to alleviate supply issues as indicated by

the increase in WEGOVY prescriptions
  - The company remains optimistic about communicating the value of these drugs and their benefits to healthcare systems, including a recent approval for treating heart disease

- **Read more:** BBC

- **Implications:** Semaglutide makes Novo Nordisk one of the most valuable companies of Europe, providing it with sufficient cash for further acquisitions and developments

17 **Walgreens inks deal with Boehringer Ingelheim to advance clinical trials for obesity treatment [U.S.]**
May 2, 2024

- Walgreens signed a deal with Boehringer Ingelheim to use its community pharmacies as clinical trial sites for people living with obesity, overweight and T2D
- Walgreens launched its clinical trials unit back in Jun 2022 as the company's healthcare ambitions continue to grow
  - The company has signed more than 35 clinical trial contract
- Walgreens consumers will have the opportunity to learn about and potentially participate in a Phase III clinical trial within the familiar and accessible environment of Walgreens pharmacies
  - According to the companies the effort aims to improve access and address equitable health representation in clinical trials, especially among Black and Hispanic adults who are more likely to have obesity in the U.S. and have historically been underrepresented
- Boehringer also is partnering with EmVenio Research on the initiative to use mobile research units to extend the reach and bring clinical trial research directly to communities
- Walgreens will use advanced, real-world insights to identify and engage potential study participants as part of the collaboration

- **Read more:** Fierce Healthcare

- **Implications:** The collaboration between Walgreens and Boehringer Ingelheim seeks to address disparities in health representation by targeting Black and Hispanic adults, who are more likely to have obesity in the U.S

18 **WEGOVY, MOUNJARO prices cut as British pharmacies compete for weight-loss patients [UK]**
May 2, 2024

- Online pharmacies and slimming clinics are cutting prices for WEGOVY (semaglutide) and MOUNJARO (tirzepatide) in Britain just months after the weight-loss drugs were launched there, as initial supply shortages ease
- But growing competition between retailers has raised fears that some patients who buy the drugs themselves, rather than relying on the National Health Service (NHS), will miss out on long-term aftercare if they keep switching providers
- Self-paying patients already account for a big chunk of revenues from Novo Nordisk's WEGOVY and rival Eli Lillys' MOUNJARO
- Simple Online Pharmacy in Feb 2024 cut the price of starter doses of MOUNJARO to £159 for a one-month supply from £179
  - It reduced that price further to £149, and marked down the higher MOUNJARO strengths that patients take later

- **Read more:** Reuters

- **Implications:** N/A

19 **Biophytis is deploying its partnership strategy in obesity [U.S.]**
Apr 29, 2024

- Biophytis announced the implementation of a dedicated strategy for its partner search in obesity
  - Biophytis' partnering strategy is based on the search for the best partners selected through precise targeting and an in-depth analysis and understanding of the pharmaceutical landscape to select the right partners and identify mutual benefits
- The company is looking to licence-out BI0101 (20-hydroxyecdysones) to regional or global pharmaceutical companies that will co-develop with us the drug candidate up to marketing authorization in the treatment of obesity and other indications and have the capacity to launch and commercialize it in the main regions
  - BIO101 (20-hydroxyecdysone) is in clinical development (Phase II OBA study in preparation) in obesity, in combination with GLP-1 receptor agonists
- Furthemore, the Company has established a refined and tailored action plan to serve these objectives, which includes close collaboration with local agents to provide expertise and network and a Senior Management's presence in the most attractive business events in pharma
- Biophytis will attend the BIO U.S. conference to be held from Jun 3 to 6, 2024 in San Diego

- **Read more:** Biophytis Press Release

- **Implications:** Biophytis has initiated a phase 2 clinical investigation, integrating BIO101 (20-hydroxyecdysone) with GLP-1 receptor agonists for obesity management. This strategic move, informed by promising preclinical data addressing muscle loss concerns, may present an appealing opportunity for acquisition consideration by industry giants such as Novo and Lilly.

20 **WEGOVY (semaglutide injection) available in Canada [Canada]**
May 2, 2024

- Novo Nordisk Canada has announced that WEGOVY (semaglutide) injection will be available for Canadians who meet the requirements in the Health Canada approved product monograph on May 6, 2024
- Novo Nordisk will work closely with healthcare providers and regulators to continually assess the level of need along with available supply to help ensure that patients who start treatment can remain on treatment

- **Read more:** Novo Nordisk Canada Press Release, WEGOVY – Product Monograph

- **Implications:** Patients who meet the requirements outlined in the Health Canada approved product monograph can now access WEGOVY

MISCELLANEOUS

21 **Here's what 'fair allocation' for GLP-1s and other weight loss drugs could look like [Global]**
Apr 29, 2024

- Due to high demand for GLP-1s and other weight loss drugs has yet to subside, and a new study published in *The New England Journal of Medicine,* aims to establish an ethical framework that can be used to ensure the patients who need these therapies can access them amid shortages
- Several countries, including Belgium and Great Britain, have taken steps to ban or discourage the use of these products for weight loss and instead prioritize their distribution to patients with diabetes
- Neither the federal government in the U.S. nor individual states have made similar moves, though individual health plans and Medicare have restricted use of these products

- **Read more:** Fierce Healthcare

- **Implications:** A tiered approach for fair allocation of GLP-1s and weight loss drugs could challenge current diabetes-focused distribution and highlight broader societal biases against obesity providing equitable access to these drugs

22 **WEGOVY bowel obstruction lawsuit alleges weight-loss injections caused gastroparesis [U.S.]**
May 2, 2024

- After receiving WEGOVY (semaglutide) injection, a Kentucky woman suffered from bowel obstructions and gastroparesis
  - On Apr 26, 2024, Angela Hall filed a complaint against Novo Nordisk in the U.S. District Court for the Eastern District of Kentucky, indicating that the drug maker failed to adequately warn about the risk that WEGOVY may cause bowel obstructions and stomach paralysis, resulting in severe injuries and permanent health problems
- According to the lawsuit, Hall was prescribed Wegovy injections in May 2023 for weight loss. However, by Dec 2023, she was admitted to an emergency room due to symptoms of severe abdominal pain, nausea and vomiting
  - Eventually, the lawsuit indicates Hall was hospitalized on multiple occasions due to small bowel obstruction and gastroparesis. Each time she was hospitalized for multiple days. However, the lawsuit notes that even after Hall was released from the hospital, she continues to need follow-up care due to her injuries

- **Read more:** AboutLawsuits

- **Implications:** N/A

23 **LifeMD becomes the first virtual primary care provider to elevate GLP-1 patient care with real-time, at-home monitoring of blood pressure and body composition [U.S.]**
May 2, 2024

- LifeMD and Withings Health Solutions announced a new strategic partnership designed to revolutionize weight management patient care by providing LifeMD's GLP-1 weight-loss patients with Withings advanced in-home health monitoring devices, including the Body Pro 2 scale and the BPM Connect Pro blood pressure monitor
- With these devices, LifeMD is setting a new standard in virtual care by providing clinicians with near real-time and actionable patient data that can drive compliance, enhance clinical decision-making, encourage preventive healthcare and, most importantly, improve long-term outcomes
- LifeMD's GLP-1 weight-loss program is uniquely positioned to support patients on their weight-loss journey and make healthy living accessible by providing online consultations with licensed clinicians, prescriptions for weight management medications and orders for full-service laboratory testing
- By leveraging the detailed health data from Withings' in-home health monitoring devices, LifeMD aims to gain deeper insight into the effectiveness of GLP-1 treatments and their impact on overall health
- This partnership also lays the groundwork for pioneering real-world evidence studies

- **Read more:** LifeMD Press Release

- **Implications:** The partnership between LifeMD and Withings lays the groundwork for pioneering real-world evidence studies aimed at evaluating the effectiveness of GLP-1 treatments and their impact on overall health

24 **Lilly MOUNJARO, ZEPBOUND supply issues persist amid strong growth [U.S.]**
May 1, 2024

- During Eli Lilly's Q1 2024 Earnings Call, the company reported healthy annualized growth of MOUNJARO (tirzepatide) in T2D and a strong launch for ZEPBOUND (tirzepatide) in obesity, but the emerging story was Eli Lilly's ongoing effort to increase manufacturing supply
- According to an analysis by Wolfe Research's Tim Anderson, alongside brisk sales and payer concerns, matching supply to demand has been a key story for both Eli Lilly and direct competitor Novo Nordisk in the metabolic therapy arena
  - In Q1 2024, MOUNJARO posted revenues of more than $1.8 Bn, growing 218% YoY, and yet still missed consensus estimates
  - Meanwhile in Q1 2024, ZEPBOUND yielded $517 Mn with the company estimating 67% access in the U.S. commercial insurance plans, but Eli Lilly mentioned about the struggle to meet demand for the two tirzepatide brands and pledged increasing supply via several ongoing efforts

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

- **Implications:** Eli Lilly's first-quarter sales growth was hampered by supply constraints for diabetes and obesity drugs, but the company signaled optimism with plans for a significant increase in production capacity in the near future

25 **Elevai Labs acquires exclusive license to two myostatin muscle loss prevention assets with plan to develop in combination with GLP-1 obesity treatments [U.S.]**
May 1, 2024

- Elevai Labs entered into an exclusive licensing agreement with MOA Life Plus to develop and commercialize two novel assets for the treatment of obesity and muscle loss prevention
  - The licensed assets include EL-22, a clinical stage engineered probiotic expressing myostatin, and EL-32, a preclinical engineered probiotic expressing dual myostatin & activin-A
- Elevai intends to evaluate EL-22 for efficacy and safety in combination with popular weight-loss therapeutics currently on the market, with the goal of decreasing fat mass while preventing the muscle wasting that commonly occurs with weight-loss drugs
- Based on preclinical data, Elevai believes that the assets it has licensed have the potential to significantly improve the standard of care for the treatment of obesity in combination with GLP-1 by preserving muscle mass while decreasing fat mass
  - The Company plans to make an IND submission in 2025 and to initiate clinical trials in the U.S. to evaluate the probiotic approach of EL-22 and EL-32 in combination with one or more GLP-1 receptor agonists in obesity

- **Read more:** Elevai Labs Press Release

- **Implications:** Elevai Labs' acquisition of exclusive licenses for myostatin muscle loss prevention assets, alongside their planned integration with GLP-1 obesity treatments, reflects their plan to tap into the expanding anti-obesity market while addressing the challenge of muscle loss commonly associated with GLP1 weight-loss drugs

26 **One dose of Novo Nordisk's WEGOVY back in supply, FDA website shows [U.S.]**
Apr 29, 2024

- The U.S. FDA website for drug shortages showed one dose of Novo Nordisk's weight-loss drug WEGOVY is available after being in short supply, while three other doses remained in limited availability due to increased demand

- **Read more:** WHBL

- **Implications:** N/A

27 **Lilly counts on manufacturing scale-up to unstick obesity drug supply [U.S.]**
Apr 29, 2024

- Eli Lilly expects that, by H2 2024, it will be able to manufacture at least 50% more sellable doses of the main ingredient in its GLP-1 medicines ZEPBOUND and MOUNJARO than it could during the same period in 2023
- David Ricks, CEO, Eli Lilly, mentioned during Q1 Earnings Call that, "*The push to bolster the production capacity for the drugs, respectively sold for obesity and diabetes, is the most ambitious expansion plan in our company's history*"

- **Read more:** Biopharma Dive

- **Implications:** Lilly's projected 50% increase in sellable doses of Zepbound and Mounjaro, expected by the second half of the year could help it to mitigate supply shortages and capitalizing on revenue growth opportunities

28 **Real Chemistry introduces Iris: An insights-as-a-service platform delivering timely insights on the obesity market and the growing influence of GLP-1 therapies [U.S.]**
Apr 29, 2024

- Real Chemistry launched IRIS – the only insights-as-a-service platform focused on helping healthcare leaders and other stakeholders act with clarity and confidence when transformative healthcare market events emerge
- Fueled by the analysis of billions of data points using Real Chemistry's proprietary AI, analytics and insights tools, IRIS offers a live dashboard and timely market reports
  - The reports provide a comprehensive, cross-functional analysis and insights into what's happening now in the healthcare market and the forces that could shape what's coming next; including its first detailed view of the fast-moving GLP-1 agonist obesity market

- **Read more:** Businesswire

- **Implications:** Real Chemistry's launch of IRIS, an insights-as-a-service platform focused on the obesity market and the influence of GLP-1 therapies, offers a comprehensive view of transformative healthcare market events, potentially aiding healthcare leaders in navigating evolving landscapes and anticipating future trends with data-driven clarity and confidence

29 **New WHO/Europe report highlights a direct link between COVID-19 and increased obesity in school-aged children [EU]**
May 1, 2024

- A new report from WHO/Europe confirms what has long been suspected: a link between the COVID-19 pandemic and increased rates in obesity among children seven to nine years old
- The study found that during the pandemic:
  - 36% of children increased their time spent watching television, playing online games or using social media during the weekdays, and 34% increased their recreational screen time on weekends
  - 28% of children experienced a decrease in time spent in outdoor activities during weekdays, and 23% experienced a decrease on weekends
  - Families reported an increase in consuming home-cooked meals (30%), eating together as a family (29%), buying food in bulk (28%) and cooking meals together with children (26%);
  - 42% of children reported a decline in happiness and well-being
  - One in five children reported feeling sad more frequently

- One in four children also reported feeling lonely more frequently

- **Read more:** WHO Europe Press Release

- **Implications:** Childhood obesity has emerged as a growing concern exacerbated by the COVID-19 pandemic. Efforts aimed at combating obesity within this demographic can play a pivotal role in addressing this pressing public health challenge

30 **HK inno.N licenses in GLP-1 analog from Chinese biotech [South Korea]**
May 2, 2024

- HK inno.N, a Korean pharmaceutical company, entered into the rapidly growing global obesity treatment market through a partnership with Sciwind Biosciences, a Chinese biotech firm
- This collaboration is centered around the development and commercialization of Sciwind Biosciences' once-weekly, injectable GLP-1 receptor agonist, XW003 (ecnoglutide), in Korea
  - Ecnoglutide is in Phase III clinical trials in China for T2D and obesity
  - Earlier phase studies in China and Australia confirmed its efficacy in reducing blood sugar and body weight while maintaining a strong safety and tolerance profile
- Under the agreement, HK inno.N will make an upfront payment to Sciwind Biosciences, along with milestone payments and royalties based on sales post-launch. However, the company did not disclose the size of the contract, citing contractual reasons
- The deal grants HK inno.N exclusive rights to develop and commercialize ecnoglutide within Korea

- **Read more:** Korea Biomedical Review

- **Implications:** Future data releases will offer more insight into how ecnoglutide compares with rival treatments. Sciwind has wrapped up enrollment for two additional phase 3 trials: one assessing ecnoglutide against dulaglutide, marketed by Lilly as Trulicity, for type 2 diabetes, and another investigating its efficacy in individuals with overweight or obesity. Outcomes from both trials are anticipated in the second part of the year.

KEY UPCOMING EVENTS

BTIG Obesity Health Forum:

- **Altimmune:** May 8, 2024 (Altimmune Investor update)

GLP-1-Based Therapeutics Summit:

- **Altimmune:** May 15, 2024 (Altimmune Investor update)
- **Veru:** May 16, 2024 (Veru Investor update)

Thank you,
Ben

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