Subject: MTSR1: Weekly Competitive Intelligence Newsletter (Apr 9-15, 2024)
Date: Monday, April 15, 2024 at 7:55:48 AM Eastern Daylight Time
From: Benjamin Kumpfmueller <bkumpfmueller@sai-med.com>
To: Metsera <metsera@populationhp.com>
CC: Diksha Matta <dmatta@sai-med.com>, Diane Suchon <DSuchon@sai-med.com>, Nidhi Srivastava <nidhis@theratraq.com>, Ailen Thomas <AilenT@theratraq.com>
Attachments: image003.png

Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: Apr 9-15, 2024

DASHBOARD

KEY TAKEAWAYS OF THE WEEK (Apr 9 - 15, 2024)

- **Clinical –** Biophytis is launching a new clinical development program named OBA, with BIO101 (20-hydroxyecdysone) as a potential treatment for obesity in combination with GLP-1 receptor agonists [Global]
- **Regulatory –** PRAC has determined there is no causal association between GLP-1 receptor agonists for weight loss or obesity and suicidal and self-injurious thoughts and actions [EU]
- **Commercial –** German liberal party FDP, is in favour of reimbursing weight-loss injections - Novo Nordisk's WEGOVY (semaglutide) or Eli Lilly's MOUNJARO (tirzepatide) [Germany]

DETAILED NEWS

CLINICAL

1 **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) [Global]**
Apr 11, 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 the following changes
  - **PCD:** Updated from Mar 19, 2024 [Anticipated] to Mar 25, 2024 [Actual]

- **Read more:** NCT05564117

- **Implications:** The OASIS 4 trial of oral semaglutide for obesity treatment has reached its primary completion date, moving it closer to market approval, contingent on favorable efficacy and safety data.

2 **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 [Global]**
Apr 9, 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 the following changes
  - **Overall Status:** Updated from 'Not yet recruiting' to 'Recruiting'
  - **Contacts/Locations:** Multiple sites were added

- **Read more:** NCT06131372

- **Implications:** This research likely draws on previous findings from the FLOW study, which explored semaglutide's benefits on CKD, aiming to broaden the drug's approved uses.

3 **Biophytis launches OBA Phase II clinical study in obesity with BIO101 (20-hydroxyecdysone) [Global]**
Apr 8, 2024

- Biophytis announced that it is launching a new clinical development program named OBA, with BIO101 (20-hydroxyecdysone) as a potential treatment for obesity in combination with GLP-1 receptor agonists
  - BIO101 is the first oral daily MAS receptor activator and has demonstrated metabolic effects on muscle and fat tissues in preclinical studies in obesity
- 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
    - BIO101 will be evaluated in obese patients treated with GLP-1 RAs, and following hypocaloric dieting
- The company expects the first efficacy results to be available in 2025
    - Further information on the OBA program and the clinical study is expected to be provided through the coming weeks

- **Read more:** Biophytis Press Release

- **Implications:** N/A

4 **Trial Update: VK2735 for weight management Phase II (VENTURE) [U.S.]**
Apr 12, 2024

- A Phase II trial sponsored by Viking Therapeutics titled, "*VK2735 for weight management Phase II (VENTURE)"* has undergone following changes
    - **Overall Status:** Updated from 'Recruiting' to 'Active, not recruiting'
    - **PCD:** Updated from Mar 2024 [Anticipated] to Feb 27, 2024 [Actual]
    - **Enrollment:** Updated from 125 [Anticipated] to 176 [Actual]
    - **Contacts/Locations:** Multiple sites were removed

- **Read more:** NCT06068946

- **Implications:** N/A

5 **Lipocine announces positive LPCN 2401 clinical results showing improved body composition in participants with obesity [U.S.]**
Apr 11, 2024

- Lipocine announced results from a Phase II clinical trial of LPCN 2401 (undisclosed)
    - Results showed improvement in body composition through decreased fat mass (FM) and increased lean mass (LM) or fat free mass (FFM) in patients with BMI ≥ 30 (obese) or BMI ≥ 27 with at least one weight-related comorbidity
- Among treatments B and C, 27 participants were randomized and completed the baseline and at least one post-baseline DEXA. At baseline, mean BMI was 36.0 kg/m2 and mean age was 52.4 yrs. LPCN 2401 intervention resulted in significant FM lost and LM gained vs. placebo, a significant improvement was noted as early as Week 20
    - A significant reduction in AF (fat in the area roughly between the pelvis and ribs) and a significant increase in BMC were observed in treatment B, the LPCN 2401 intervention arm
    - The intervention was observed to be weight neutral, with fat lost offset by lean mass gained
    - An overall improvement in body composition is evidenced by substantial decrease in the fat mass to lean mass ratio
- LPCN 2401 resulted in numerically greater fat mass loss than Treatment A (monotherapy). Numerical trends towards improvement in blood pressure and HbA1c with LPCN 2401 support the benefit of Treatment B relative to both placebo and Treatment A
- LPCN 2401 was well-tolerated with the frequency and severity of observed treatment-emergent AEs vs. placebo
    - No GI or muscle spasm adverse events were reported by participants receiving LPCN 2401
- The Week 36 LPCN 2401 results support its potential for improved body composition in chronic weight management with incretin mimetics

- **Read more:** Lipocine Press Release

- **Implications:** LPCN 2401's mechanism, which includes not only fat reduction but also muscle mass enhancement is shifting the focus from weight loss alone to overall health improvement. As an adjunct therapy to GLP-1/GIP agonists, LPCN 2401 may improve muscle mass, quality, and functionality while maintaining weight loss and amplifying fat loss.

6 **Semaglutide beneficial in HFpEF patients with diabetes [U.S.]**
Apr 6, 2024

- Weekly injections of the semaglutide relieves symptoms in patients with heart failure with preserved ejection fraction (HFpEF), obesity, and diabetes much like it does in similar patients without diabetes, according to results of a pivotal trial likely to expand the drug's approved indications
- The new trial, called STEP-HFpEF DM, like the previous STEP-HFpEF trial, also associated semaglutide with a lower risk for serious AEs
    - In STEP-HFpEF DM, 616 adult patients with a BMI > 30 and HFpEF, defined as left ventricular ejection fraction of ≥ 45%, were randomly assigned to semaglutide or placebo administered over a 16-week dose-escalation phase. It was followed by 36 weeks on the assigned therapy, which in the experimental arm was semaglutide in a target dose of 2.4 mg weekly
    - At the end of the study with follow-up for approximately 95% of patients in both arms, there was a highly significant advantage for QOL
    - A reduction in body weight, the other co-primary endpoint, was also seen in both groups but was significantly greater in those randomly assigned to semaglutide
    - Several secondary endpoints were consistent with a clinical advantage for semaglutide
    - Overall, there were only seven heart failure events over the course of follow-up in the semaglutide group vs. 18 in the placebo group

- **Read more:** MedScape, ACC, STEP-HFpEF DM NEJM Publication, STEP-HFpEF and STEP-HFpEF DM pooled analysis

- **Implications:** STEP-HFpEF DM shows similar results to previous STPEP-HFpEF trial in obese non-diabetic patients. Results could drive usage of semaglutide in HFpEF patients to improve QoL.

7 **GLP-1s like OZEMPIC, WEGOVY don't substantially increase thyroid cancer risk, study suggests [EU]**
Apr 9, 2024

- According to a study published in *The British Medical Journal,* popular diabetes and weight loss GLP-1 medications were not found

to cause a substantial increase in the risk of developing thyroid cancer
- The researchers looked at health data for 145,410 patients living in Denmark, Sweden and Norway who were prescribed GLP-1 medications like OZEMPIC (semaglutide), WEGOVY (semaglutide), RYBELSUS (semaglutide), SAXENDA (liraglutide) and VICTOZA (liraglutide) and another 291,667 patients who were treated with DPP4 inhibitors, another type of diabetes drug
- The researchers concluded that GLP1 receptor agonist use was not associated with a substantially increased risk of thyroid cancer over a mean follow-up of 3.9 years
  - In the main analysis comparing GLP1 receptor agonists with DPP4 inhibitors, the upper limit of the confidence interval was consistent with no more than a 31% increase in relative risk

- **Read more:** Forbes

- **Implications:** No increased risk for thyroid cancer with semaglutide, building more confidence for this treatment.

8 **Trial Update: A trial assessing safety, tolerability, pharmacokinetics and pharmacodynamics of ZP7570 (dapiglutide) [Germany]**
Apr 9, 2024

- A Phase I trial sponsored by Zealand Pharma titled, "*A trial assessing safety, tolerability, pharmacokinetics and pharmacodynamics of ZP7570 (dapiglutide)"* has undergone following changes
  - **PCD and SCD:** Updated from Jul 4, 2024 [Anticipated] to Nov 15, 2024 [Anticipated]
  - **Study Description:** Updated
  - **Interventional Study Model:** Updated
  - **Enrollment:** Updated from 54 [Anticipated] to 84 [Anticipated]

- **Read more:** NCT06000891

- **Implications:** N/A

9 **Trial Update: A research study looking at the safety of multiple doses of ZP8396 (petrelintide) and how it works in the body of healthy participants [Germany]**
Apr 8, 2024

- A Phase I trial sponsored by Zealand Pharma titled, "*A research study looking at the safety of multiple doses of ZP8396 (petrelintide) and how it works in the body of healthy participants"* has undergone following changes
  - **Overall Status:** Updated from 'Recruiting' to 'Active, not recruiting'
  - **Enrollment:** Updated from 68 [Anticipated] to 68 [Actual]
  - **Contacts/Locations:** Multiples sites were removed and added

- **Read more:** NCT05613387

- **Implications:** N/A

10 **New Trial: A study to evaluate AMG 133 (maridebart cafraglutide) in Chinese participants with obesity or overweight [Undisclosed]**
Apr 8, 2024

- Amgen initiated a Phase I trial to evaluate the pharmacokinetics, safety, and tolerability of AMG 133 (maridebart cafraglutide) administered subcutaneously in Chinese subjects with obesity or overweight
  - **Trial details:** N = 20; Status: Not yet recruiting; Start date: Apr 24, 2024; PCD and SCD: Sep 3, 2024; Location: Undisclosed

- **Read more:** NCT06352892

- **Implications:** N/A

11 **New Trial: A study to test how well different doses of BI 3034701 (undisclosed) are tolerated by healthy men and people with overweight or obesity [Undisclosed]**
Apr 8, 2024

- Boehringer Ingelheim initiated a Phase I trial to evaluate safety, tolerability and pharmacokinetics of single SC doses of BI 3034701 (undisclosed) in healthy male volunteers (Part A) and of multiple rising SC doses in otherwise healthy male and female volunteers with obesity/overweight (Part B)
  - **Trial details:** N = 124; Status: Not yet recruiting; Start date: May 15, 2024; PCD and SCD: Jul 14, 2025; Location: Undisclosed

- **Read more:** NCT06352437

- **Implications:** N/A

12 **New Trial: A study in people with overweight or obesity to test how BI 1820237 (undisclosed), BI 456906 (survodutide), or a combination of both affects brain activity [Undisclosed]**
Apr 8, 2024

- Boehringer Ingelheim initiated a Phase I trial to evaluate the effects of a SC dose of BI 1820237 (undisclosed) and BI 456906 (survodutide), and combination thereof on functional MRI measurements in otherwise healthy male and female individuals with obesity/overweight (Single-blind, Cross-over Design)
  - **Trial details:** N = 24; Status: Not yet recruiting; Start date: Apr 15, 2024; PCD and SCD: Dec 9, 2024; Location: Undisclosed

- **Read more:** NCT06352424

- **Implications:** N/A

REGULATORY

13 **EMA safety committee (PRAC) finds no causal association between GLP-1 drugs and suicidal thoughts [EU]**
Apr 12, 2024

- The EMA mentioned in the Meeting highlights from the PRAC Apr 8-11, 2024, that PRAC has determined there is no causal association between GLP-1 receptor agonists for weight loss or obesity and suicidal and self-injurious thoughts and actions
  - According to PRAC draft agenda for the meeting on 8-11, 2024 document which was released on Apr 8, 2024, the EMA was set to review several diabetes and weight-loss treatments in connection with potential increased risk of suicidal ideation and self-harm
- Following the review of the available evidence, the PRAC concluded there is no link between drugs in the GLP-1 receptor agonists class and self-injury
- The safety committee had started reviewing this potential link in Jul 2023, following reports of suicidal thoughts and thoughts of self-injury from people using liraglutide and semaglutide medicines, respectively the active ingredients in Novo Nordisk's weight-loss drug SAXENDA (liraglutide) and WEGOVY (semaglutide), OZEMPIC (semaglutide), and RYBELSUS (semaglutide)
  - PRAC considered the results of a U.S. study published in Jan 2024 for its review, which found there is no higher risk of suicidal ideation with semaglutide compared with non-GLP1 receptor agonist anti-obesity or anti-diabetes medications
  - The EMA also conducted another study based on electronic health records to determine a potential risk of suicide-related and self-injury-related events in people with type 2 diabetes mellitus
- Having reviewed all the available evidence, the PRAC concluded that "no update to the product information is warranted"

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

- **Implications:** Without the need for warnings about potential psychiatric side effects, these drugs can continue to be marketed without additional regulatory hurdles, which might have been imposed had the outcome been different.

14 **Scotland accepts Lilly's MOUNJARO for type 2 diabetes among six other drugs [Scotland]**
Apr 9, 2024

- The Scottish health technology assessment (HTA) body has accepted Eli Lilly's MOUNJARO (tirzepatide) for the treatment of type 2 diabetes
- On Apr 8, 2024, the Scottish Medicines Consortium announced that it has accepted Lilly's MOUNJARO (tirzepatide) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
- However, the SMC was unable to recommend MOUNJARO as monotherapy when metformin is considered inappropriate due to intolerance or contraindications because Lilly's submission related only to its use in addition to other medicinal products for the treatment of diabetes
  - Therefore, the drug is approved for restricted use in addition to other oral anti-diabetic medicines as an option when GLP-1 receptor agonists would be considered

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

- **Implications:** N/A

15 **Daewoong seeks permit for Korea's 1st homegrown SGLT2 diabetes drug ENVLO in Mexico [Mexico]**
Apr 8, 2024

- Daewoong Pharmaceutical applied for product approval for ENVLO (enavogliflozin), diabetes drug to Mexico's Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)
  - COFEPRIS is responsible for regulating a variety of health-related topics in Mexico, including food safety, pharmaceutical drugs, medical devices, organ transplants, and environmental protection
  - The application utilizes clinical data from Korea, allowing the company to forego additional clinical trials in Mexico
- Additionally, ENVLO has shown improvements in cardiovascular risk factors such as weight, blood pressure, and lipid levels, supported by extensive clinical data involving Korean patients
- In pursuit of transforming Envlo into a global blockbuster drug, Daewoong has been actively seeking to enter international markets

- **Read more:** Korea Biomedical Review

- **Implications:** N/A

16 **China starts review of Novo Nordisk's clinical trial application for new weight-loss drug [China]**
Apr 12, 2024

- The National Medical Products Administration has started examining Novo Nordisk's amycretin for clinical trials
- According to a recent Phase I clinical trial study by the company, patients treated with amycretin for 12 weeks lost on average 13.1% of weight, vs. 6% when using semaglutide
  - Novo Nordisk's application for clinical trials of a new generation of drugs in China indicates its preparation to maintain market advantage even after the semaglutide patent expires in 2026
  - Novo Nordisk has been increasing its investments in China

- **Read more:** Yicai Global

- **Implications:** Novo Nordisk intends to conduct clinical trials with amycretin in China, showing its long-term commitment to this market.

17 **Israeli Health Ministry forbids sale of OZEMPIC for weight loss [Israel]**
Apr 10, 2024

- The Israeli Health Ministry instructed pharmacists nationwide to cease selling OZEMPIC (semaglutide) for weight loss, limiting its use to diabetes patients only
  - Those who have begun using OZEMPIC for weight loss are advised to gradually transition to WEGOVY (semaglutide)

- Israelis with obesity received special authorization (form 29C) to use OZEMPIC, though they were not diabetic, leading to a nearly year-long depletion of OZEMPIC stocks and a severe shortage for the diabetic patients

- **Read more:** The Jerusalem Post

- **Implications:** N/A

COMMERCIAL

18 **Ginkgo Bioworks and Novo Nordisk expand alliance to collaborate across R&D value chain [Global]**
Apr 10, 2024

- Ginkgo Bioworks announced the expansion of its strategic partnership with global healthcare leader Novo Nordisk under a framework agreement that initially is contemplated to run over five years
- Novo Nordisk and Ginkgo have created a flexible and scalable new model for their R&D partnership
- Together, the partners aim to improve the manufacturing of Novo Nordisk's medicines for serious chronic diseases, including diabetes and obesity medications
- The companies also plan to collaborate on several early pipeline projects, further technology exploration, and engineering of scalable manufacturing solutions across Novo Nordisk's portfolio

- **Read more:** PR Newswire

- **Implications:** Novo Nordisk is aggressively expanding its portfolio through strategic alliances, collaborations, and acquisitions.

19 **MediaRadar CEO: What the 'enormous' increase in GLP-1 ad spend means [U.S.]**
Apr 8, 2024

- MediaRadar released a report that found ad spending on weight loss and diabetes drugs topped $1 Bn in 2023, up 51% year-over-year
  - Advertising spend around diabetes medications made up the lion's share of that amount, with weight loss drug spending coming in just shy of $300 Mn
- According to Todd Krizelman, CEO, MediaRadar, that the spending figures represent an enormous expansion of advertising around these specific drugs, especially since more and more research indicates their value beyond weight loss
  - Krizelman expects to see an expansion in terms of advertising spend since these GLP-1 drugs are in the early stages of their 14-year runs for patent protection
- The sizable upfront investment to gain the public's attention is also noteworthy since the messaging differs from more of the prescription drug marketing that's focused on doctors rather than consumers

- **Read more:** Medical Marketing and Media

- **Implications:** The focus on direct-to-consumer advertising, rather than solely on healthcare professionals, marks a strategic shift in how pharmaceutical companies are marketing these drugs.

20 **German liberal party favours reimbursement of weight-loss injections – Press [Germany]**
Apr 12, 2024

- On Apr 8, 2024, German liberal party FDP, is in favour of reimbursing weight-loss injections - Novo Nordisk's WEGOVY (semaglutide) or Eli Lilly's MOUNJARO (tirzepatide)
- According to Andrew Ullmann, Member of Parliament, health insurance companies should be able to cover the costs if the effectiveness and safety of the medication is proven and it is prescribed as part of medical treatment and weight-loss injections should not be seen as a lifestyle drug, but as part of a comprehensive approach to treating severe obesity and preventing its complications
  - Tino Sorge, Opposition Member of Parliament, took a similar stance. If a lifestyle preparation also proves to be effective against serious illnesses, reimbursement should be possible, for example, if the weight-loss injection is authorised for cardiovascular diseases
- On Apr 7, 2024, Harald Schneider, German Endocrinologist, mentioned that he is also in favour of statutory coverage of weight-loss injections, at least for the patients with certain risk profiles
- Karl Lauterbach, Health Minister, stated that, *"The Ministry would like to see how sustainable are the results achieved with the weight-loss drug, before deciding whether to reimburse them"*

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

- **Implications:** Reimbursement approval could significantly boost the market for these drugs in Germany, potentially making it a lucrative market for pharmaceutical companies like Novo Nordisk and Eli Lilly. A decision on whether to reimburse the weight-loss injections is unlikely to be made until there is clear evidence of their long-term effectiveness and sustainability, which would be necessary to convince the authorities.

MISCELLANEOUS

21 **Recipharm's new CEO on 'fast and furious' changes, with eyes on GLP-1, biologics manufacturing [Global]**
Apr 12, 2024

- Recipharm doesn't manufacture GLP-1 medications yet, the company is is now considering how it can help ease production issues
- According to Greg Behar, CEO, Recipharm, the company has a "ready-to-roll site" in Wasserburg, Germany, with inspections to be completed in two months, that could be used for GLP-1s
  - Greg Behar, stated that, *"We're pretty confident that this will add really attractive capacity. The site is designed for pre-filled syringes and is anticipated to be online in the third quarter this year"*
  - And in the wake of the Novo-Catalent deal, Recipharm, along with other CDMOs, is weighing its opportunities

- **Read more:** Endpoints News *(Subscription required)*
- **Implications:** N/A

22 **Obesity drugmaker lands first biopharma uplisting onto Nasdaq since last summer [U.S.]**
Apr 12, 2024

- Skye Bioscience is developing a CB1 receptor inhibitor, a similar type of obesity drug as the one Novo Nordisk got in its up to $1.075 Bn acquisition of Inversago Pharma in Aug 2023
- As Novo Nordisk's WEGOVY (semaglutide) and Eli Lilly's ZEPBOUND (tirzepatide) surge in demand, drugmakers are looking at making different types of obesity medications than GLP-1s, which have run into toxicity issues, problems with muscle loss and manufacturing issues
- On Apr 11, 2024, Skye Bioscience made the stock move after raising slightly more than $100 Mn across three private placements from 21 different investors since Aug 2023
  - Skye Bioscience is developing nimacimab, a CB1 receptor inhibitor for obesity and chronic kidney disease
  - The company will pair nimacimab with one of the approved GLP-1 medications in an approximately 200-person Phase II set to start in Q2 2024. Patients will be on the drugs for 26 weeks and then go through 12 weeks of follow-up

- **Read more:** Endpoints News *(Subscription required)*
- **Implications:** Skye Bioscience's strategy to pair nimacimab with approved GLP-1 medications in upcoming clinical trials underscores a trend towards combination therapies.

23 **Eli Lilly loses case against Florida compounding pharmacy [U.S.]**
Apr 11, 2024

- Eli Lilly suffered a loss in its legal campaign against compounded versions of its popular diabetes and weight loss drug tirzepatide
- On April 10, 2024, a Florida federal judge tossed Eli Lilly's lawsuit against a Miami compounding pharmacy, ruling that Eli Lilly can't use state law as a back door to privately enforce the Federal Food, Drug, and Cosmetic Act (FDCA)
  - The decision comes just a couple months after another Florida judge dismissed a separate case Eli Lilly brought against a different compounding pharmacy
- Eli Lilly argued in its recent lawsuit that RxCompoundStore.com is not genuinely compounding versions of its tirzepatide
  - The company accused the pharmacy of simply unlawfully manufacturing prescription drugs without the U.S. FDA approval
- Eli Lilly and Novo Nordisk have brought a string of lawsuits against wellness centers and compounding pharmacies for what they believe is improper marketing of their diabetes and weight loss products

- **Read more:** Endpoints News *(Subscription required)*
- **Implications:** The ruling suggests that pharmaceutical companies might face challenges in controlling the distribution and manufacturing of their patented drugs once they are available in the market. Compounding pharmacies, under certain conditions, can create versions of these drugs, which could potentially bypass the patents held by the original manufacturers.

24 **TRULICITY lawsuit filed over GLP-1 gastroparesis side effects [U.S.]**
Apr 10, 2024

- A woman suffering due to gastroparesis side effects from TRULICITY (dulaglutide) has filed a product liability lawsuit against Eli Lilly, indicating that the drug maker failed to adequately warn consumers and the medical community about the risk that users may be left with painful and debilitating stomach paralysis complications
  - TRULICITY is a member of a class of diabetes and weight loss drugs known as GLP-1 receptor agonists
- On Apr 5, 2024, Allee Smith filed a complaint in the U.S. District Court for the Northern District of Iowa, indicates that she suffers from severe and permanent injuries after using TRULICITY, including persistent vomiting, diarrhoea and extreme abdominal pain, which has resulted in multiple emergency room visits and continues to cause her to experience problems
- Although Eli Lilly has acknowledged that gastrointestinal events are a well-known side effect of Trulicity and other GLP-1 receptor agonists, the lawsuit indicates that the drug maker downplayed the severity and long-lasting nature of these problems, and never disclosed that some users develop a form of stomach paralysis known as gastroparesis, which can interfere with normal digestion, and has no cure

- **Read more:** About Lawsuits
- **Implications:** N/A

25 **The rise of 'OZEMPIC babies' and the uncharted territory of semaglutide in pregnancy [U.S.]**
Apr 10, 2024

- According to a study published in the *JAMA Network,* which used data from four Nordic countries, the U.S. MarketScan Database and the Israeli Maccabi Health Services database, did not find a greater risk of major congenital malformations in infants after periconceptional use of GLP-1 receptor agonists and other second-line antidiabetic medications vs. insulin
  - The authors stressed, although reassuring, confirmation from other studies is needed, and continuous monitoring will provide more precise estimates as data accumulate
- Semaglutide remains a popular subject of clinical trials, but a recent review of clinical trials revealed a dearth of studies focused on GLP-1 receptor agonists in pregnant women
- The Washington Post recently highlighted a growing number of pregnancies in users of GLP-1 receptor agonists like semaglutide
  - The paper notes that some doctors speculate that the weight loss effects of GLP-1 drugs may increase the chances of unexpected pregnancy in some patients by improving hormonal balance and ovulation
  - The drugs could also interfere with the absorption of oral contraceptives in some cases

- **Read more:** Drug Discovery and Development

- **Implications:** The possibility that GLP-1 drugs could interfere with the absorption of oral contraceptives calls for further investigation.

26 **Dallas-based SpotSee launches device to track temperature integrity of insulin and GLP-1 medications [U.S.]**
Apr 10, 2024

- SpotSee launched TempMonitor, a simple and affordable single-use temperature indicator designed for patients who rely on insulin and GLP-1 medications
  - SpotSee's TempMonitor product will be on display at LogiPharma 2024, Apr 16 – 18, 2024 at Centre de Congrès de Lyon in Lyon, France

- **Read more:** Dallas Innovates

- **Implications:** N/A

27 **Harris Poll notes increase in pharma reputation among Americans who know about GLP-1 drugs [U.S.]**
Apr 3, 2024

- According to a Harris Poll, GLP-1 medications are helping to boost the pharma industry's reputation in the U.S.
  - 55% of people who are taking a GLP-1 or know someone who is say they have a positive perception of the pharma industry
  - The number drops to 50% among people who were familiar with GLP-1s (but not taking them or know anyone who is) and dips even further to 40% among those who are unfamiliar with the glucagon-like peptides class
  - The sample size was 2,016 adults in the U.S.
- The new Harris Poll data track with another recent attitudinal study by Pew Research that found among the three-fourths of Americans who had at least heard of OZEMPIC, WEGOVY or other similar drugs, more than half (53%) think the drugs are good options for obesity or weight-related conditions
  - Social media, studies and news reports have fuelled the familiarity of GLP-1 drugs, like the hourlong Oprah Winfrey special in Mar 2024 that addressed obesity bias and stigma alongside generally glowing reports of specific Novo Nordisk and Eli Lilly brands
  - According to JP Morgan, the obesity medicine market is expected to top $100 Bn by 2030

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

- **Implications:** GLP-1 medications, particularly due to their efficacy in managing obesity and weight-related conditions, are helping to improve the public's view of the pharmaceutical sector.

28 **Gerresheimer supplies the top two in weight-loss drugs, CEO says [Germany]**
Apr 12, 2024

- According to Dietmar Siemssen, CEO, Gerresheimer, the company has contracts with the leading players in the weight-loss drugs sector
  - Injectors are used to administer the GLP-1 medications by Novo Nordisk and Eli Lilly, such medications are expected to bring at least 350 Mn euros of annual revenue for Gerresheimer within three years

- **Read more:** The Economic Times

- **Implications:** N/A

29 **Lilly's new plant in Germany a symbol of policy success - Chancellor Olaf Scholz [Germany]**
Apr 8, 2024

- According to Chancellor Olaf Scholz, Eli Lilly's new injectable drug production facility to open in 2027 is an encouraging sign for Germany's pharma strategy
- Construction works in Alzey will start in the summer and manufacturing is expected to start in 2027
- The factory will focus on incretin therapies, such as diabetes and weight-loss drug MOUNJARO (tirzepatide)
  - Other incretin therapy in Eli Lilly's portfolio is TRULICITY (dulaglutide) for diabetes, as well as pipeline prospects such as retatrutide
  - MOUNJARO currently is in limited supply in all countries where it is marketed - including Germany - because of high demand in the U.S., combined with manufacturing issues
- The new plant will create 1,000 more jobs, according to Lilly

- **Read more:** APM Health *(Subscription required)*, The Business Times

- **Implications:** Lilly continues to increase its manufacturing capabilities to meet market demand. Nevertheless, the newly announced factory in Germany will be only up and running in 2027.

30 **Top medicine for weight loss is being developed in Hungary [Hungary]**
Apr 7, 2024

- According to Gábor Orbán, CEO, Gedeon Richter, the company's development success series continues, with an active ingredient against excess weight in the most advanced phase
- According to István Greiner, Research and Development Director, Gedeon Richter, the company is in the more advanced Phase (Phase II) of developing an active substance against obesity
- István Greiner, stated that, *"This anti-obesity substance, which is being developed for the treatment of obesity, will also act on patients via neuropsychiatric pathways (via the brain, to reduce the feeling of hunger)*

- **Read more:** Magyar Nemzet, Hungary Today

- **Implications:** N/A

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

_____

Benjamin Kumpfmüller, PhD, MBA
Director

SAI Med Partners LLC
Barcelona, Spain
Mobile: +34 657243555
bkumpfmueller@sai-med.com

_____