Lilly Increases Manufacturing Investment to $9 Billion at Newest Indiana Site to Boost API Production for Tirzepatide and Pipeline Medicines

May 24, 2024

Largest investment in active pharmaceutical ingredient manufacturing of synthetic medicines in U.S. history

Since 2020, the company has committed more than $18 billion to build, upgrade and acquire facilities in the U.S. and Europe

INDIANAPOLIS, May 24, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it has more than doubled its investment in its Lebanon, Indiana, manufacturing site with a new $5.3 billion commitment, increasing the company's total investment in this site from $3.7 billion to $9 billion. This expansion will enhance Lilly's capacity to manufacture active pharmaceutical ingredients (API) for Zepbound® (tirzepatide) injection and Mounjaro® (tirzepatide) injection so that more adults with chronic diseases like obesity and type 2 diabetes may benefit from these important treatments.

Since 2020, Lilly has committed more than $16 billion to develop new manufacturing sites in the U.S. and Europe. New locations outside Indiana include Research Triangle Park and Concord, North Carolina; Limerick, Ireland; and Alzey, Germany. Separately, the company has invested an additional $1.2 billion to update existing manufacturing facilities in Indianapolis and recently acquired an injectable manufacturing facility in Pleasant Prairie, Wisconsin, from Nexus Pharmaceuticals. Together, these manufacturing investments total more than $18 billion.

"Today's announcement tops the largest manufacturing investment in our company's history and, we believe, represents the single largest investment in synthetic medicine API manufacturing in U.S. history," said David A. Ricks, Lilly's chair and CEO. "This multi-site campus will make our latest medicines, including Zepbound and Mounjaro, support pipeline growth and leverage the latest technology and automation for maximum efficiency, safety and quality control. Importantly, we are investing in our home state of Indiana, creating high-wage, advanced manufacturing, engineering and science jobs for hundreds of current and future Hoosier families."

Lilly embarked on a significant manufacturing expansion in 2020, driven by the research results for tirzepatide. The company made this strategic investment decision at risk so that upon the approval of Mounjaro (2022) and Zepbound (2023), it could make these medicines available to adults living with type 2 diabetes and obesity, respectively. Since then, the strong demand for these medicines – the only approved treatments activating two incretin hormone receptors, GIP and GLP-1 – underscores the urgent unmet need for treatments in both type 2 diabetes and obesity.

As part of this additional investment in the Lebanon site, located within Indiana's LEAP Research and Innovation District, Lilly expects to add 200 full-time jobs for highly skilled workers such as engineers, scientists, operating personnel and lab technicians, resulting in an estimated 900 full-time employees when the facility is fully operational. Additionally, there will be more than 5,000 construction jobs during the site's development.

"Lilly continues to play a transformational role in shaping Indiana's opportunity economy, and I couldn't be more proud about their pole position leadership in developing the LEAP Research and Innovation District in Lebanon, Indiana. Lilly has long been driving global innovation and economic growth that will be felt for decades here at home," said Indiana Governor Eric J. Holcomb. "As an international company, headquartered in Indiana, Lilly had a world of options to consider before making this investment, and choosing Indiana once again reinforces the incredible environment we've cultivated and the talented workforce we have to carry Lilly's success forward. I can't wait to see the incredible benefits this investment leads to for patients around the world, knowing they were made in Indiana."

To support Lilly's expansion project, the state will partner on infrastructure solutions – road improvements, water, electric and other utilities – as well as workforce development commitments and certain economic incentives tied to the company's achievement of investment and employment goals. The state's workforce development support includes the contribution of land, pending approval, for the construction of a learning and training center that will be part of the larger LEAP industrial development, along with a commitment to work with Lilly to raise capital for its completion. The new training center aligns with Lilly's previously announced financial support for scholarship and training programs with Purdue University and Ivy Tech Community College, and the BioCrossroads-led training center at 16 Tech – part of Indiana's recent Tech Hub designation.

"Lilly's commitment to meeting the demand for our life-changing medicines goes beyond buildings and extends to improving education opportunities and upskilling a global workforce of the future," said Edgardo Hernandez, executive vice president and president, Lilly Manufacturing Operations. "Academia is a critical partner to both industry and government as we work together to advance innovation in our state and communities around the globe."

Since breaking ground at its Lebanon manufacturing site in 2023, Lilly has transformed a significant portion of the nearly 600 acres within the complex into an active construction site. The company expects to begin making medicines in Lebanon toward the end of 2026 – with operations scaling up through 2028.

INDICATION AND SAFETY SUMMARY WITH WARNINGS FOR MOUNJARO®

Mounjaro® (mown-JAHR-OH) is an injectable medicine for adults with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose).

- It is not known if Mounjaro can be used in people who have had inflammation of the pancreas (pancreatitis). Mounjaro is not for use in people with type 1 diabetes. It is not known if Mounjaro is safe and effective for use in children under 18 years of age.

Eli Lilly & Co.
Exhibit 2092
BPI Labs v. Eli Lilly
IPR2025-01346
Ex. 2092-001

Warnings - Mounjaro may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

- Do not use Mounjaro if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Mounjaro if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Mounjaro if you are allergic to it or any of the ingredients in Mounjaro.

Mounjaro may cause serious side effects, including:

Inflammation of the pancreas (pancreatitis). Stop using Mounjaro and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Mounjaro with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, or mood changes, hunger, weakness and feeling jittery.

Serious allergic reactions. Stop using Mounjaro and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, and very rapid heartbeat.

Kidney problems (kidney failure). In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Mounjaro. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

Changes in vision. Tell your healthcare provider if you have changes in vision during treatment with Mounjaro.

Gallbladder problems. Gallbladder problems have happened in some people who use Mounjaro. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), and clay-colored stools.

Common side effects
The most common side effects of Mounjaro include nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion, and stomach (abdominal) pain. These are not all the possible side effects of Mounjaro. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

Tell your healthcare provider if you have any side effects. **You can report side effects at 1-800-FDA-1088 or** www.fda.gov/medwatch**.**

Before using Mounjaro

- **Your healthcare provider should show you how to use Mounjaro before you use it for the first time.**
- **Talk to your healthcare provider about low blood sugar and how to manage it.**
- **If you take birth control pills by mouth, talk to your healthcare provider before you use Mounjaro. Birth control pills may not work as well while using Mounjaro.** Your healthcare provider may recommend another type of birth control for 4 weeks after you start Mounjaro and for 4 weeks after each increase in your dose of Mounjaro.

Review these questions with your healthcare provider:

- ❑ Do you have other medical conditions, including problems with your pancreas or kidneys, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- ❑ Do you take other diabetes medicines, such as insulin or sulfonylureas?
- ❑ Do you have a history of diabetic retinopathy?
- ❑ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? It is not known if Mounjaro will harm your unborn baby or pass into your breast milk.
- ❑ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?

How to take

- Read the **Instructions for Use** that come with Mounjaro.
- Use Mounjaro exactly as your healthcare provider says.
- Mounjaro is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **Use Mounjaro 1 time each week, at any time of the day.**
- **Do not** mix insulin and Mounjaro together in the same injection.
- You may give an injection of Mounjaro and insulin in the same body area (such as your stomach area), but not right next to each other.
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- If you take too much Mounjaro, call your healthcare provider or seek medical advice promptly.

Learn more
Mounjaro is a prescription medicine. For more information, call 1-833-807-MJRO (833-807-6576) or go to **www.mounjaro.lilly.com.**

This summary provides basic information about Mounjaro but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Mounjaro and how to take it. Your healthcare provider is the best person to help you decide if Mounjaro is right for you.

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INDICATION AND SAFETY SUMMARY WITH WARNINGS FOR ZEPBOUND®
Zepbound® (ZEHP-bownd) is an injectable prescription medicine that may help adults with obesity, or with excess weight (overweight) who also have weight-related medical problems, lose weight and keep it off. It should be used with a reduced-calorie diet and increased physical activity.

- Zepbound contains tirzepatide and should not be used with other tirzepatide-containing products or any GLP-1 receptor agonist medicines. It is not known if Zepbound is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products. It is not known if Zepbound can be used in people who have had pancreatitis. It is not known if Zepbound is safe and effective for use in children under 18 years of age.

Warnings - Zepbound may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

- Do not use Zepbound if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Zepbound if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Zepbound if you have had a serious allergic reaction to tirzepatide or any of the ingredients in Zepbound.

Zepbound may cause serious side effects, including:

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Zepbound. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

Kidney problems (kidney failure). Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration.

Gallbladder problems. Gallbladder problems have happened in some people who use Zepbound. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), or clay-colored stools.

Inflammation of the pancreas (pancreatitis). Stop using Zepbound and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.

Serious allergic reactions. Stop using Zepbound and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, or very rapid heartbeat.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Zepbound with medicines that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, mood changes, hunger, weakness or feeling jittery.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Zepbound.

Depression or thoughts of suicide. You should pay attention to changes in your mood, behaviors, feelings or thoughts. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.

Common side effects
The most common side effects of Zepbound include nausea, diarrhea, vomiting, constipation, stomach (abdominal) pain, indigestion, injection site reactions, feeling tired, allergic reactions, belching, hair loss, and heartburn. These are not all the possible side effects of Zepbound. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

Tell your healthcare provider if you have any side effects. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch**.

Before using Zepbound

- **Your healthcare provider should show you how to use Zepbound before you use it for the first time.**
- **Tell your healthcare provider if you are taking medicines to treat diabetes including insulin or sulfonylureas which could increase your risk of low blood sugar. Talk to your healthcare provider about low blood sugar levels and how to manage them.**
- **If you take birth control pills by mouth, talk to your healthcare provider before you use Zepbound. Birth control pills may not work as well while using Zepbound.** Your healthcare provider may recommend another type of birth control for 4 weeks after you start Zepbound and for 4 weeks after each increase in your dose of Zepbound.

Review these questions with your healthcare provider:

❑ Do you have other medical conditions, including problems with your pancreas or kidneys, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
❑ Do you take diabetes medicines, such as insulin or sulfonylureas?
❑ Do you have a history of diabetic retinopathy?
❑ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?
❑ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? Zepbound may harm your unborn baby. Tell your healthcare provider if you become pregnant while using Zepbound. It is not known if Zepbound passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using Zepbound.

- Pregnancy Exposure Registry: There will be a pregnancy exposure registry for women who have taken Zepbound during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may contact Lilly at 1-800-LillyRx (1-800-545-5979).

How to take

- Read the **Instructions for Use** that come with Zepbound.
- Use Zepbound exactly as your healthcare provider says.
- Zepbound is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **Use Zepbound 1 time each week, at any time of the day.**
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- If you take too much Zepbound, call your healthcare provider, seek medical advice promptly, or contact a Poison Center expert right away at 1-800-222-1222.

Learn more
Zepbound is a prescription medicine. For more information, call 1-800-LillyRx (1-800-545-5979) or go to www.zepbound.lilly.com**.**

This summary provides basic information about Zepbound but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Zepbound and how to take it. Your healthcare provider is the best person to help you decide if Zepbound is right for you.

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About Lilly

Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram and LinkedIn. C-LLY

Forward Looking Statement
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about planned capital investments in new manufacturing capacity and related initiatives and reflects Lilly's current beliefs and expectations. However, as with any such undertaking, there are substantial risks and uncertainties in the manufacturing process, development and commercialization of pharmaceutical products any of which could impact the overall commercial success of our products, and as related to cost, completion timing, expected capacity, personnel, and other factors which could impact expected benefits of the capacity expansion and related initiatives. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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