Survey reveals 8 in 10 Americans with ulcerative colitis struggle to find a public restroom during emergencies

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Results from Lilly's "Urgent Conversations" survey reinforce the work by the Crohn's & Colitis Foundation of America, including the "We Can't Wait" mobile bathroom finder app

INDIANAPOLIS, Oct. 16, 2024 /PRNewswire/ -- Results from the national "Urgent Conversations" survey, announced today by Eli Lilly and Company (NYSE: LLY), found that over half (60%) of the general population struggle to find a public restroom, a challenge that is even more pronounced (84%) for people with ulcerative colitis (UC).[1] This survey, of 1,800 U.S. adults, including 200 people with moderately to severely active UC, assessed the availability and accessibility of public restrooms.

UC is a chronic, inflammatory disease that affects the colon and rectum of the gastrointestinal tract and is associated with increased stool frequency, rectal bleeding and bowel urgency. Bowel urgency, the sudden and immediate need to have a bowel movement, is one of the most difficult symptoms for many people with UC.

"People living with UC not only experience a significant need for access to public restrooms, they may also be altering their daily routines in order to leave their homes, as demonstrated by these results," said Richard E. Moses, D.O., J.D., associate vice president global and U.S. medical affairs, immunology and gastroenterology indication lead, Lilly. "Acknowledging and shedding light on these life challenges motivates us at Lilly to support individuals experiencing bowel urgency-related emergencies and recognize the importance of urgency symptoms when developing advanced biologics."

Results from this survey found:

- **People with UC need a public restroom significantly more often and finding an available restroom can be challenging.** In this survey, 63% of respondents with UC vs. 38% of the general population noted they had to use the restroom frequently or every time they leave the house. The vast majority of respondents said it takes longer than 5 minutes to find a clean restroom (81% of people with UC and 73% of the general population).
- **Nearly all respondents (86%) said the lack of public restrooms is a problem, with 43% of all respondents describing this as a "big problem" or "very big problem."** Even in areas most densely populated with public restrooms, roughly one-half of the general population noted there were too few public restrooms available.
- **People with UC are at least three times (42% to 13%) more likely to have a restroom emergency compared to people without UC,** with more than three-quarters of respondents with UC (77%) noting they had an accident as an adult.
- **Notably, restroom emergencies and close calls are not unique to people with UC**. More than one-third (39%) of the general population responded they had a restroom emergency that required finding a restroom immediately as an adult and nearly all the general population (89%) said they experienced a close call where they had found a restroom "just in time."
- **People with UC limit social outings due to the lack of public restrooms.** Approximately two-thirds of respondents with UC have limited social outings or going to public places they have never been in case they need to use a restroom (61% and 60%, respectively). More than two-thirds (79%) of respondents with UC said they make sure they know where the nearest public restroom is and have their toiletries before leaving the house.

"These results reinforce what I hear from my patients with UC. Instead of double-checking they've turned off the stove prior to leaving their homes, people with UC are mapping out the nearest restrooms and packing emergency toiletries," said Marla Dubinsky, M.D., chief, division of pediatric gastroenterology and nutrition, co-director, Susan and Leonard Feinstein IBD Clinical Center, Mount Sinai Kravis Children's Hospital, Icahn School of Medicine, Mount Sinai New York. "Many are staying home to avoid the potential for a bowel-urgency related accident in public."

With public restroom access being a main concern for people with UC, the Crohn's & Colitis Foundation has launched a community-based, non-legislative effort to improve restroom access: The Open Restroom Movement. As part of this movement, the Foundation has created a mobile app called "We Can't Wait" that locates publicly accessible restrooms and identifies sympathetic establishments in the event of bowel urgency.

"For people with UC, the minutes it takes to find a public restroom are consequential. This problem also extends to people who are not living with UC. In fact, 39% of the general population surveyed had experienced an accident as an adult and that number nearly doubled for respondents with UC," said Michael Osso, president and chief executive officer, Crohn's & Colitis Foundation. "These results show that access to clean and readily available restrooms is not just a convenience, but a basic human need worth greater attention and advocacy."

Lilly is dedicated to improving the lives of people with gastroenterological diseases. In October 2023, the U.S. Food and Drug Administration approved Omvoh® (mirikizumab-mrkz) as a first-in-class treatment for adults with moderately to severely active UC. Omvoh is also approved in the European Union and Japan.

This approval was based on the Phase 3 LUCENT trials, which were the first and only to use the patient-centric, Urgency Numeric Rating Scale (NRS)

of 0-10, which evaluates the severity of bowel urgency. Over 950 adults with moderate to severe UC were treated with Omvoh. During the induction study, people took Omvoh for 12 weeks. Then, some people who achieved clinical response continued to take Omvoh in the maintenance study for 40 more weeks, for a total of 52 weeks or 1 year of continuous treatment with Omvoh. At 12 weeks, 65% of people taking Omvoh had improved UC symptoms and 24% of people taking Omvoh achieved clinical remission. Among people who saw improvement at week 12, 51% achieved clinical remission at 1 year. Among people who achieved clinical remission at Week 12, 66% maintained remission at 1 year of continuous treatment. At one year, ~4 out of 10 people on Omvoh reported improvement* in bowel urgency, with some seeing improvement as early as 12 weeks. In Omvoh studies, clinical remission means healing within the colon, as well as no bloody stools and fewer bowel movements.

*Bowel urgency was assessed on a scale of 0 (no urgency) to 10 (worst possible urgency). Improvement was defined as a weekly average score of 0 or 1.

About the "Urgent Conversations" Survey
Urgent Conversations is an online, quantitative survey conducted by Adelphi on behalf of Lilly in January 2024 and obtained responses from 1,800 adults. Respondents included 200 people who had been diagnosed with moderately to severely active UC, who were treated by a gastroenterologist and experienced bowel urgency in the past year, and 1,600 people not diagnosed with UC who have used a public restroom in the past month. People with UC were questioned specifically on bowel urgency, while the general population was only asked about "bathroom emergencies." Learn more about the survey here.

INDICATION AND SAFETY SUMMARY
Omvoh® (ahm-VOH) is a medicine used to treat adults with moderately to severely active ulcerative colitis.

It is not known if Omvoh is safe and effective in children under 18 years of age.

Warnings – Omvoh can cause serious side effects including:
Serious allergic reactions: Omvoh may cause serious allergic reactions that may need to be treated in a hospital and may be life-threatening. Do not use Omvoh if you have had a serious allergic reaction to mirikizumab-mrkz or any of the ingredients in Omvoh. See the Medication Guide that comes with Omvoh for a list of ingredients. Stop using Omvoh and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:

- fainting, dizziness, feeling lightheaded
- swelling of your face, eyelids, lips, mouth, tongue, throat, or trouble swallowing
- trouble breathing, throat tightening, or wheezing
- chest tightness
- fast heartbeat or pounding in your chest
- severe itching, hives, or redness all over your body
- sweating

Infections: Omvoh may lower the ability of your immune system to fight infections and may increase your risk of infections. If you have an infection, your healthcare provider should not start treatment with Omvoh until your infection is gone. Before starting treatment with Omvoh, your healthcare provider should test you for tuberculosis (TB). If you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Omvoh. Your healthcare provider should watch you closely for signs and symptoms of TB while you are being treated with Omvoh and after treatment.

Before starting Omvoh, tell your healthcare provider if you think you have an infection or have symptoms of an infection, such as:

- fever, sweating, or chills
- muscle aches and pain
- cough or shortness of breath
- blood in your mucus (phlegm)
- flu-like symptoms
- headache
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- weight loss
- nausea or vomiting
- pain during urination

After starting Omvoh, tell your healthcare provider right away if you have any symptoms of an infection.

Liver Problems: Omvoh may cause liver problems. Your healthcare provider will do blood tests to check your liver enzyme and bilirubin levels before treatment, for at least 24 weeks during treatment, and possibly after treatment with Omvoh. Your healthcare provider may hold or stop treatment if needed. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including:

- unexplained rash
- nausea
- vomiting
- stomach-area (abdominal) pain
- feeling tired
- loss of appetite
- yellowing of the skin or the whites of your eyes

- dark urine

Common side effects
The most common side effects of Omvoh include:

- upper respiratory infections
- joint pain
- injection site reaction
- headache
- rash
- herpes viral infections

These are not all the possible side effects of Omvoh.

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

Before you use Omvoh, review these questions with your doctor:

- Are you being treated for an infection?
- Do you have an infection that does not go away or keeps coming back?
- Do you have TB or have you been in close contact with someone with TB?
- Do you have any possible symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, or pain during urination?

Tell your doctor about all your medical conditions, including if:

- You have a history of serious allergic reaction to Omvoh, any infections or liver problems.
- You need any vaccines or have had one recently. Medicines that interact with the immune system may increase your risk of getting an infection after receiving live vaccines. You should avoid receiving live vaccines right before, during or right after treatment with Omvoh. Tell your healthcare provider that you are taking Omvoh before receiving a vaccine.
- You are pregnant, or plan to become pregnant. It is not known if Omvoh will harm your unborn baby. There will be a pregnancy registry to collect information about women who are exposed to Omvoh during pregnancy. If you become pregnant while taking Omvoh, you are encouraged to report your pregnancy to Eli Lilly and Company at 1-800-545-5979.
- You are breastfeeding or plan to breastfeed. It is not known if Omvoh passes into your breastmilk.
- You take prescription or over-the-counter medicines, vitamins, and herbal supplements.

How to take
Use Omvoh exactly as your healthcare provider tells you to. Omvoh is intended for use under the guidance and supervision of your doctor. If your doctor decides that you or a caregiver may give your injections at home, you should receive training on the correct way to prepare and inject Omvoh. **Read the detailed Instructions for Use that come with the Omvoh devices for information about how to use Omvoh the correct way.**

Learn more
Omvoh is a prescription medicine. During induction, Omvoh is available as a single dose vial for intravenous infusion containing 300 mg/15 mL that is administered in a healthcare facility. During maintenance, Omvoh is available as a one-time use prefilled pen or syringe with 100 mg/mL for subcutaneous injections. For more information, call 1-800-545-5979 or go to Omvoh.lilly.com.

This summary provides basic information about Omvoh 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 doctor. Be sure to talk to your doctor or other healthcare provider about Omvoh and how to take it. Your doctor is the best person to help you decide if Omvoh is right for you.

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About Omvoh®
Omvoh (mirikizumab-mrkz) is an interleukin-23p19 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults. Omvoh selectively targets the p19 subunit of IL-23 and inhibits the IL-23 pathway. Inflammation due to over-activation of the IL-23 pathway plays a critical role in the pathogenesis of UC. Treatment with Omvoh starts with 300-mg IV infusions, once a week every four weeks for a total of three infusions, and transitions to two, 100-mg subcutaneous self-injections every four weeks during maintenance treatment.

About the LUCENT Clinical Trial Program
Omvoh was studied in two, Phase 3 clinical trials which evaluated the efficacy and safety of Omvoh in adults with moderately to severely active ulcerative colitis (UC) and included patients who had never tried a biologic (biologic-naïve) and harder-to-treat patients who had previously taken a biologic that failed. The induction UC-1 and maintenance UC-2 studies were randomized, double-blind, and placebo-controlled and included those who had inadequate response, loss of response, or failed to tolerate any of the following: corticosteroids, immunomodulators (6-mercaptopurine and azathioprine), biologic therapy (TNF blocker, vedolizumab) or Janus kinase inhibitors (JAKi, tofacitinib). Additionally, 41% of patients in UC-1 had failed at least one biologic and 3% had failed a JAKi and 57% were biologic and JAKi-naïve.

About Crohn's & Colitis Foundation
The Crohn's & Colitis Foundation (C&CF) is the leading nonprofit organization focused on both research and patient support for inflammatory bowel disease (IBD), with the mission of curing Crohn's disease and ulcerative colitis and improving the quality of life for the millions of Americans living with IBD. The Foundation's work is dramatically accelerating the research process, while also providing extensive educational and support resources for patients and their families, medical professionals, and the public.

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 tens of millions of 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. P-LLY

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Omvoh as a treatment for people with moderately to severely active ulcerative colitis and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, or that Omvoh will receive additional regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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.

[1]Data on File. Lilly USA, LLC. DOF-MR-US-0044.

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