



## **New Lilly Study Reveals Underappreciation of Bowel Urgency as a Symptom of Ulcerative Colitis and Highlights Communication Gap Between Healthcare Providers and Patients**

December 9, 2021

- Findings from the CONFIDE Study show bowel urgency was the second most commonly reported symptom experienced by people with moderately-to-severely active ulcerative colitis, but many patients don't feel comfortable reporting it to healthcare providers**
- More than 60 percent of those patients who don't feel comfortable reporting bowel urgency to their healthcare providers cite embarrassment as the top reason**
- Findings will be presented at the Advances in Inflammatory Bowel Diseases (AIBD) conference, taking place in Orlando and virtually December 9-11, 2021, with additional CONFIDE results presented at future congresses in 2022**

INDIANAPOLIS, Dec. 9, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced results from the CONFIDE Study (Communicating Needs and Features of IBD Experiences) that show bowel urgency – defined as the sudden or immediate need for a bowel movement – is the second most commonly reported symptom suffered by study respondents living with moderately-to-severely active ulcerative colitis (UC), regardless of whether or not they were receiving an advanced therapy (biologic or novel oral therapy). In this study, only one in four healthcare providers perceived bowel urgency as one of the top three most reported symptoms by their patients.

The CONFIDE Study examines the experience of those living with moderately-to-severely active UC and Crohn's disease and aims to advance the understanding of the burden, barriers and care experience of individuals with inflammatory bowel disease (IBD) and how they communicate with their healthcare providers. These U.S.-specific data were collected from a cross-sectional survey of healthcare professionals and adults with moderately-to-severely active UC and Crohn's disease in the U.S., Europe and Japan.

"Bowel urgency is a disruptive, often underreported symptom of ulcerative colitis and can be embarrassing and difficult for many people to talk about," said David T. Rubin, M.D., professor of medicine, chief, Section of Gastroenterology, Hepatology and Nutrition, University of Chicago Medicine and scientific advisor to the CONFIDE Study. "It is essential for those who care for people with inflammatory bowel disease to create an environment where they can have an open and trusting conversation about bowel urgency, especially considering this symptom is significantly associated with many patients' perceived disease severity."

In the CONFIDE Study, respondents living with moderately-to-severely active UC were asked which symptoms they experienced in the last month, as well as symptoms they had ever experienced, respectively. Diarrhea (experienced over the last month: 62.5%; have ever experienced: 74.0%), bowel urgency (experienced over the last month: 47.0%; have ever experienced: 61.5%) and increased stool frequency (experienced over the last month: 38.5%; have ever experienced: 57.5%) were reported as the top three symptoms suffered among respondents.

When asked to rank the top three symptoms they felt were most reported by their patients, three out of four healthcare providers (76.0%) did not identify bowel urgency, noting instead that the top three symptoms reported to them included diarrhea (73.5%), blood in stool (69.0%) and increased stool frequency (37.5%).

Of the respondents living with moderately-to-severely active UC who experienced bowel urgency, only two out of five (38.2%) felt completely comfortable reporting bowel urgency to their healthcare provider. For those who were not comfortable discussing bowel urgency with their healthcare provider, more than 60 percent reported that the top reason for not doing so was they were embarrassed to talk about it.

"The first findings from the CONFIDE Study shed light on an important conversation that may not be happening between healthcare providers and people living with ulcerative colitis. Many patients still feel embarrassed or struggle to explain symptoms like bowel urgency, a common experience that can take a toll on a person's day-to-day life," said Melodie Narain-Blackwell, founder, Color of Crohn's and Chronic Illness.

Notably, when respondents with moderately-to-severely active UC were asked about their perceived disease severity, bowel urgency was significantly associated with those who considered their disease activity to be severe (62.9%) when compared with those that reported mild-to-moderately active disease (42.9%). Among the overall patient population surveyed, three-quarters (76.5%) of people were receiving advanced therapies (biologic or novel oral therapy), however; bowel urgency was still being currently experienced by almost one-half (46.4%) of respondents.

"One of the most important aspects of accurate diagnosis and treatment is to ensure that patients feel completely comfortable talking about their symptoms with their provider," said Cem Kayhan, M.D., gastroenterology indications medical leader at Lilly. "These initial results from the CONFIDE Study help advance our understanding of the real-world experience of those living with and treating moderately-to-severely active ulcerative colitis, including those who are receiving advanced therapies and still experiencing bowel urgency. We look forward to sharing additional insights from the CONFIDE Study in the near future."

### **About The CONFIDE Study**

- The CONFIDE Study is a global, cross-sectional survey of healthcare professionals and people with moderately-to-severely active UC or Crohn's disease in the U.S., Europe and Japan. The study looks at the experience and impact of symptoms

and aims to provide further understanding of the burden, barriers and care experience of those living with these diseases. The global CONFIDE Study includes more than 1,600 adults living with UC or Crohn's disease and more than 800 healthcare providers from the U.S., Europe and Japan. This specific U.S. disclosure included a total of 200 healthcare provider respondents and 200 adults living with ulcerative colitis.

#### **About the CONFIDE Scientific Advisory Panel\***

- The CONFIDE study was conducted by Adelphi Real World on behalf of Eli Lilly and Company, with expert guidance provided by some of the leading voices in UC research today, including (in alphabetical order):
  - Marla Dubinsky, Co-Director, Susan and Leonard Feinstein Inflammatory Bowel Disease Clinical Center, U.S.
  - Toshifumi Hibi, Professor, Kitasato University, Kitasato Institute Hospital, Japan
  - Remo Panaccione, Professor of Medicine, University of Calgary Cumming School of Medicine, Canada
  - David T. Rubin, Professor of Medicine, Chief, Section of Gastroenterology, Hepatology and Nutrition, University of Chicago Medicine, U.S.
  - Stefan Schreiber, Director of Internal Medicine, University Hospital Schleswig-Holstein, Germany
  - Simon Travis, Professor of Clinical Gastroenterology, Nuffield Department of Medicine, University of Oxford, U.K.

#### **About Ulcerative Colitis**

Ulcerative colitis is a chronic inflammatory bowel disease that affects the colon. UC occurs when the immune system sends white blood cells into the lining of the intestines, where they produce chronic inflammation and ulcerations. There is an unmet need for additional treatment options for UC that provide meaningful symptom relief, including bowel urgency, and deliver sustained clinical remission.

#### **About Eli Lilly and Company**

Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [lilly.com](http://lilly.com) and [lilly.com/newsroom](http://lilly.com/newsroom). P-LLY

\*Members of the scientific advisory board serve as consultants and have received honoraria from Eli Lilly and Company.

#### **Lilly 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 the treatment of patients with ulcerative colitis and/or Crohn's disease and reflects Lilly's current beliefs and expectations. However, as with any disease treatment, there are substantial risks and uncertainties. Among other things, there can be no guarantee that future study results would be consistent with the study results reported. 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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