

News Release

European Patient Survey finds Crohn's Disease Patients Living with Perianal Fistulas Experience a More Significant Negative Impact on Their Quality of Life than Crohn's Disease Patients without Perianal Fistulas

- *The self-selective patient survey is one of the largest and most comprehensive surveys of its kind to explore the impact of perianal fistulas in Crohn's disease on quality of life, with 820 respondents from 33 countries^{1,2,3,4,5,6}*
- *Findings of the survey are being presented at the virtual Congress of the European Crohn's and Colitis Organisation (ECCO) taking place on 2nd – 3rd and 8th – 10th July, 2021¹*

Zurich, SWITZERLAND and Brussels, BELGIUM, July 9, 2021 – The [European Federation of Crohn's and Ulcerative Colitis Associations](#) (“EFCCA”) in collaboration with Takeda Pharmaceutical Company Limited (“Takeda”) today announced results from one of the largest of its kind self-reported patient surveys, exploring the health-related and overall real-world impact of perianal fistulas on the quality of life of people with Crohn's disease (CD), compared to the impact of CD without perianal fistulas.^{1,2,3,4,5,6}

The survey found that CD patients living with perianal fistulas reported a more significant impact on their overall quality of life and an increase in certain symptoms, such as anal pain and perianal leaking, when compared to CD patients without perianal fistulas.¹ CD patients living with perianal fistulas also reported feeling more unhygienic, uncomfortable, and guilty about their condition toward family and friends than CD patients without perianal fistulas.¹

Perianal fistulas are a severe and disabling complication of Crohn's disease,⁷ a chronic inflammatory disease that mainly affects the gastrointestinal tract and is associated with a substantial burden on the health-related quality of life of patients.^{8,9} In adult patients with CD, the cumulative incidence of perianal fistulas is estimated to be 15%, 21-23% and 26-28% over five, 10 and 20 years, respectively.^{10,11,12} Despite this, there have been few studies assessing the patient perspective of living with the condition.¹

To understand the burden across many aspects of life, the survey explored topics across many areas. The findings show that as well as impacting work and social life, perianal fistulas had a greater negative impact on CD patients' ability to do sports, work and employment, dating and sexual life.¹ 37.4% of

CD patients with perianal fistulas stated that they were often unable to play sports, compared to 25.7% of CD patients without perianal fistulas.¹ When asked about sexual activity, 26.4% of CD patients with perianal fistulas avoided having sex, 6.9% have ended relationships and 5.5% have avoided dating because of their painful condition.¹ Almost double the number of CD patients with perianal fistulas compared to CD patients without perianal fistulas (14.3% vs. 8.0%) admitted they have had to change profession because of their condition.¹ On top of this, the survey revealed that CD patients with perianal fistulas found it more difficult to talk about their condition with others, impacting their relationships.¹

“We are proud to have embarked on this research to find out the impact of perianal fistulas on quality of life from patients’ perspective,” commented Luisa Avedano, Chief Executive Officer of EFCCA. “The results support what we have long suspected: that the added burden of perianal fistulas significantly impacts the lives of people with Crohn’s disease. The results will help us work to empower Crohn’s disease patients living with perianal fistulas and ultimately help to improve their lives.”

“We conducted this survey in order to obtain this greater understanding of the burden of living with perianal fistulas in addition to Crohn’s disease,” said Dana Agam, Patient Advocacy and Services Lead, GI Franchise Takeda Europe and Canada. “The findings of this survey may be useful in helping to tailor comprehensive care strategies to better support patients with this painful and disabling complication.”

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About the International Patient Survey

There were 820 respondents to the anonymous, self-selective survey,¹ making it one of the most comprehensive surveys on the patient perspective on life with perianal fistulas in Crohn’s disease to date.^{1,2,3,4,5,6} To ensure the results would provide valuable insights, the questionnaire was developed in cooperation with both medical and patient representatives.¹ It consisted of 46 questions and assessed multiple aspects of living with CD, including topics such as impact on close relationships and social life, and impact on professional life.² The survey itself which invited CD patients, with or without perianal fistulas to participate and self-select their diagnosis, was available through the EFCCA website from 15th July to 31st December 2019.¹ Responses were received from 33 countries around the world, including countries in Europe, Colombia, Israel, Mexico, United States, Greenland, Dominican Republic and Guadeloupe.² It was made available in English, French, German, Greek, Hebrew, Italian, Polish, Portuguese, Romanian, Spanish and Slovenian.²

The survey was commissioned and developed by EFCCA. Takeda provided editorial support in the development and distribution of the survey and analysis of data, and funded medical writing of the

publication of results. The full survey findings are being presented at the virtual Congress of the European Crohn's and Colitis Organisation (ECCO) taking place on 2nd – 3rd and 8th – 10th July, 2021.¹

About Perianal Fistulas in CD

CD is a chronic inflammatory disease of the digestive system.¹³ People living with CD may experience perianal fistulas, which can cause intense pain, swelling, infection, and anal discharge.^{7,14} In adult patients with CD, the cumulative incidence of perianal fistulas is estimated to be 15%, 21-23% and 26-28% over five, 10 and 20 years, respectively.^{10,11,12} Perianal fistulas in CD are abnormal tracts with an internal opening in the anal canal or rectum and an external opening in the skin near the anus.^{15,16} They may develop from inflamed or infected anal glands and/or penetration of fissures or ulcers in the rectum or anal canal.^{15,16}

European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA)

The European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) is an umbrella organization representing 45 national Crohn's disease and ulcerative colitis (collectively known as inflammatory bowel disease or IBD) patient associations. We are an organization of people united in our commitment to improve the lives of the over 10 million people living with IBD worldwide (3.4 million in Europe alone) and to give them a louder voice and more visibility. Our areas of intervention are networking, awareness raising, advocacy, empowerment, and solidarity. Our mission is to improve the lives of people with Crohn's disease and ulcerative colitis. Our vision and ultimate goal are to find a cure for IBD.

Takeda in Gastroenterology

We believe that gastrointestinal (GI) and liver diseases are not just life-disrupting conditions, but diseases that can impact a patient's quality of life.^{17,18} Beyond a fundamental need for effective treatment options, we understand that improving patients' lives also depends on their needs being recognized. With nearly 30 years of experience in gastroenterology, Takeda has made significant strides in addressing GI patient needs with treatments for inflammatory bowel disease (IBD), acid-related diseases, short bowel syndrome (SBS), and motility disorders. We are making significant strides toward closing the gap on new areas of unmet needs for patients who have celiac disease, eosinophilic esophagitis, alpha-1 antitrypsin-associated liver disease, and acute pancreatitis, among others. Together with researchers, patient groups and more, we are working to advance scientific research and clinical medicine in GI.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE: 4502/NYSE: TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-

transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in healthcare in approximately 80 countries. For more information, visit <https://www.takeda.com/>.

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