

Ferring Receives Positive Vote from U.S. FDA Advisory Committee for RBX2660

- *Vaccines and Related Biological Products Advisory Committee reviewed data from the biologics license application for RBX2660*
- *RBX2660 is an investigational microbiota-based live biotherapeutic studied for its potential to reduce recurrence of *C. difficile* infection after antibiotic treatment*
- *Recurrent *C. difficile* infection represents a significant burden for patients, caregivers, and the healthcare system*

Saint-Prex, Switzerland and Parsippany, NJ, USA – September 22, 2022 – Ferring Pharmaceuticals today announced that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) of the U.S. Food and Drug Administration (FDA) issued a positive vote for RBX2660, an investigational microbiota-based live biotherapeutic studied for its potential to reduce recurrence of *C. difficile* infection (CDI) after antibiotic treatment.

VRBPAC voted 13 to 4 that the data were adequate to support the effectiveness of RBX2660 to reduce the recurrence of CDI in adults 18 years of age and older following antibiotic treatment for recurrent CDI. The Committee also voted 12 to 4 with 1 abstention that the data were adequate to support the safety of RBX2660 when administered to adults 18 years of age and older following antibiotic treatment for recurrent CDI. The advisory committee provides recommendations to the FDA, which the agency may consider but is not required to follow, when making its decision.

“Patients with recurrent *C. difficile* infection currently have limited treatment options,” said Paul Feuerstadt, MD, FACG, AGAF, Yale University School of Medicine. “The committee’s vote is a step toward potentially addressing the debilitating cycle of recurrence and the suffering faced by these patients.”

The committee reviewed data from the biologics license application (BLA) for RBX2660. The clinical development program for RBX2660 included six studies with a total of 1061 participants, of which 978 were treated with RBX2660.

“Today’s advisory committee vote represents an important milestone in Ferring’s ongoing efforts to address the unmet need for interventions that can reduce the incidence of recurrent *C. difficile* infection, which represents a significant health burden for patients,” said Mirjam Mol-Arts, Executive Vice President, Chief Medical Officer, Ferring Pharmaceuticals.

About *C. difficile* infection

C. difficile infection (CDI) is a serious and potentially deadly disease that impacts people across the globe. The *C. difficile* bacterium causes debilitating symptoms such as severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea, and colitis (an inflammation of the colon).¹ Declared a public health threat by the U.S. Centers for Disease Control and Prevention (CDC) requiring urgent and immediate action, CDI causes an estimated half a million illnesses and tens of thousands of deaths in the U.S. alone each year.^{1,2,3}

C. difficile infection often is the start of a vicious cycle of recurrence, causing a significant burden for patients and the healthcare system.^{4,5} It has been estimated that up to 35% of CDI cases recur after initial diagnosis and people who have had a recurrence are at significantly higher risk of further

infections.^{6,7,8,9} After the first recurrence, it has been estimated that up to 65% of patients may develop a subsequent recurrence.^{8,9}

About RBX2660

RBX2660 is an investigational microbiota-based live biotherapeutic studied for its potential to reduce recurrence of *C. difficile* infection after antibiotic treatment. RBX2660 has been granted Fast Track, Orphan, and Breakthrough Therapy designations from the U.S. Food and Drug Administration (FDA). RBX2660 was developed by Rebiotix, a Ferring company.

About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. Headquartered in Saint-Prex, Switzerland, Ferring is a leader in reproductive medicine and maternal health, and in specialty areas within gastroenterology and urology. Ferring has been developing treatments for mothers and babies for over 50 years and has a portfolio covering treatments from conception to birth. Founded in 1950, privately owned Ferring now employs around 6,000 people worldwide, has its own operating subsidiaries in more than 50 countries, and markets its products in 110 countries.

Learn more at www.ferring.com, or connect with us on [Twitter](#), [Facebook](#), [Instagram](#), [LinkedIn](#) and [YouTube](#).

Ferring is committed to exploring the crucial link between the microbiome and human health, beginning with the threat of recurrent *C. difficile* infection. Ferring is working to develop novel microbiome-based therapeutics to address significant unmet needs and help people live better lives. Connect with us on our dedicated microbiome therapeutics development channels on [Twitter](#) and [LinkedIn](#).

References:

1. Centers for Disease Control and Prevention. What Is *C. Diff*? 17 Dec. 2018. Available at: <https://www.cdc.gov/cdiff/what-is.html>.
2. Centers for Disease Control and Prevention. Biggest Threats and Data, 14 Nov. 2019. Available at: <https://www.cdc.gov/drugresistance/biggest-threats.html>
3. Fitzpatrick F, Barbut F. Breaking the cycle of recurrent *Clostridium difficile*. *Clin Microbiol Infect*. 2012;18(suppl 6):2-4.
4. Centers for Disease Control and Prevention. 24 June 2020. Available at: <https://www.cdc.gov/drugresistance/pdf/threats-report/clostridioides-difficile-508.pdf>.
5. Feuerstadt P, et al. *J Med Econ*. 2020;23(6):603-609.
6. Riddle DJ, Dubberke ER. *Clostridium difficile* infection in the intensive care unit. *Infect Dis Clin North Am*. 2009;23(3):727-743.
7. Nelson WW, et al. Health care resource utilization and costs of recurrent *Clostridioides difficile* infection in the elderly: a real-world claims analysis. *J Manag Care Spec Pharm*. Published online March 11, 2021.
8. Kelly, CP. Can we identify patients at high risk of recurrent *Clostridium difficile* infection? *Clin Microbiol Infect*. 2012; 18 (Suppl. 6): 21–27.
9. Smits WK, et al. *Clostridium difficile* infection. *Nat Rev Dis Primers*. 2016;2:16020. doi: 10.1038/nrdp.2016.20.
10. Leong C, Zelenitsky S. Treatment strategies for recurrent *Clostridium difficile* infection. *Can J Hosp Pharm*. 2013;66(6):361-368.

###

For more information, please contact

Lisa Ellen

Director, Brand Communications

+1-862-286-5696 (direct)

lisa.ellen@ferring.com

Carine Julien

Corporate Communications Manager

+41-76-301-0178

carine.julen@ferring.com