Fresenius

Investor News

Nick Stone
Senior Vice President
Investor Relations

Fresenius SE & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
T +49 6172 608-2485
nick.stone@fresenius.com
www.fresenius.com

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Fresenius Announces FDA and EMA Acceptance for Review of Vedolizumab Biosimilar Candidate

Fresenius Kabi, an operating company of Fresenius, announced today that the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have accepted for review the Biologics License Application (BLA) and the Marketing Authorisation Application (MAA), respectively, for PB016, a proposed vedolizumab biosimilar candidate to the reference product Entyvio®* (vedolizumab) lyophilized vial for intravenous (IV) administration.

The applications were submitted by Polpharma Biologics S.A.[1], with Fresenius Kabi holding exclusive commercialization rights globally, excluding the Middle East and North Africa, pending regulatory approvals.

"FDA and EMA acceptances for review of IV vedolizumab biosimilar marks important milestones in the development program and underscores our commitment to improving patient access to high-quality, affordable biologic medicines," said Dr. Sang-Jin Pak, President Biopharma at Fresenius Kabi. "With IV vedolizumab, we are advancing our autoimmune biosimilars portfolio and taking another step toward providing additional treatment options for patients living with chronic inflammatory diseases."

PB016, in-licensed from Polpharma Biologics S.A.[1], is a proposed biosimilar to IV vedolizumab, an integrin receptor antagonist indicated for the treatment of adults with moderately to severely active ulcerative colitis and Crohn's disease.

Inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, affects approximately 2.4 million patients in the US and 2.5-3 million patients in Europe and continues to rise every year. [2,3] It is a chronic, progressive condition with no definitive cure and can have a significant, long-term impact on patients' quality of life. Once primarily associated with highly industrialized countries, IBD incidence continues to rise globally alongside increasing industrialization. In this context, biosimilars have the potential to expand access to effective biologic therapies.

The submissions for the intravenous presentation are supported by a comprehensive development program evaluating the proposed biosimilar's similarity to the reference product, consistent with regulatory requirements for biosimilar approval.

Biopharma is a core pillar of Fresenius' #FutureFresenius strategy. The company is building a vertically integrated, end-to-end biopharma business, covering the entire value chain - from research and development to manufacturing and global commercialization. By combining strong technical capabilities, global production expertise, and a balanced commercial footprint, Fresenius is well positioned to expand access to high quality, affordable biologic therapies. The FDA and EMA review acceptances represent the latest progression in Biopharma's growth strategy and strengthens its global biosimilars position.

About vedolizumab

Vedolizumab (PB016) is a monoclonal antibody that selectively targets the α4β7 integrin, reducing gastrointestinal inflammation by inhibiting the migration of lymphocytes into the gut.[4]

It is used in the treatment of adults with moderately to severely active ulcerative colitis and Crohn's disease, chronic inflammatory diseases that can significantly impact patients' quality of life.

Vedolizumab is administered by intravenous infusion.

PB016 is being developed and manufactured by Polpharma Biologics S.A., and Fresenius Kabi has exclusive commercialization rights globally, excluding the Middle East and North Africa, pending regulatory approval.

The biosimilar development program for vedolizumab is designed to demonstrate high similarity to the reference product through comprehensive analytical, non-clinical, and clinical studies, in line with regulatory requirements for biosimilar approval. PB016 has been studied in a Phase 1 trial with healthy volunteers and a Phase 3 trial with ulcerative colitis patients (NCT05771155).[5]

About Fresenius Kabi

Fresenius Kabi, an operating company of the Fresenius Group, is a global healthcare company providing integrated medicines, technologies, and services for critically and chronically ill patients. With more than 41,000 employees and present in over 100 countries, the company's broad portfolio enables access to high quality care across emergency medicine, surgery, oncology, intensive care, and at home – reaching 450 million patients each year.

Through complementary business areas, Fresenius Kabi offers highly complex biopharmaceuticals for cancer, autoimmune and endocrine diseases; leading enteral, parenteral and homecare solutions within clinical nutrition; cutting-edge medical technology including infusion pumps, cell and gene therapy devices, disposables, and world-leading blood collection systems; and intravenous generic drugs and fluids that advance essential patient care worldwide.

For more information, please visit www.fresenius-kabi.com.

References

[1] Fresenius Announces Licensing Agreement with Polpharma Biologics to Commercialize a Proposed Vedolizumab Biosimilar (2025). Available at: Fresenius Announces Licensing Agreement with Polpharma Biologics to Commercialize a Proposed Vedolizumab Biosimilar [last accessed: June 2026]

[2] Lewis J.D., Parlett L.E., Jonsson Funk M.L, et al. (2023) Incidence, Prevalence, and Racial and Ethnic Distribution of Inflammatory Bowel Disease in the United States. Gastroenterology, 165: 1197–1205.

[3] Kumar A., Yassin N., Marley A. et al. (2024) Crossing barriers: the burden of inflammatory bowel disease across Western Europe. Therapeutic advances in Gastroenterology, 16, 1-16.

[4] Wyant T., Fedyk E., Abhyankar B. (2016) An Overview of the Mechanism of Action of the Monoclonal Antibody Vedolizumab. Journal of Crohn's and Colitis, 10(12), 1437–44.

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* Entyvio® is a registered trademark of Millennium Pharmaceuticals, Inc., a Takeda company.

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