

Investor News

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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 $\alpha4\beta7$ 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.

⁵ ClinicalTrials.gov. Efficacy, Safety and Immunogenicity of the Proposed Biosimilar Vedolizumab PB016 in Comparison With Entyvio®* (UCESIVE). Available at: Study Details | NCT05771155 | Efficacy, Safety and Immunogenicity of the Proposed Biosimilar Vedolizumab PB016 in Comparison With Entyvio®* | ClinicalTrials.gov [Last accessed: June 2026]

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

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Fresenius (XFRA: FRE, OTCQX: FSNUY) is a global, therapy-focused healthcare company dedicated to saving and improving human lives around the world. Through Fresenius Kabi and Fresenius Helios, the company delivers system-critical, innovative and affordable healthcare across the full continuum of care: Fresenius Kabi is a leading provider of lifesaving medicines, clinical nutrition, and medical technologies for critically and chronically ill patients, reaching around 450 million people each year. Fresenius Helios is Europe's largest private hospital operator, treating around 27 million patients annually.

With more than 178,000 employees and operating in more than 60 countries, Fresenius generated €22.6 billion in revenue in 2025.

For more information, visit www.fresenius.com and follow Fresenius Investor Relations on [LinkedIn](#).

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, the availability of financing and unforeseen impacts of international conflicts. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

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