

Zydus and Formycon: FYB206 Becomes First Publicly Announced Keytruda® Biosimilar Accepted for Review by USFDA

- *The US Food and Drug Administration (USFDA) has accepted the Biologics License Application (BLA) for FYB206 for review. To the best of the companies' knowledge, this is the first publicly announced acceptance by the USFDA of a filing for a proposed biosimilar to Keytruda®.*
- *FYB206 was developed without a comparative Phase III efficacy trial, following a development pathway agreed upon with the USFDA in early 2025.*
- *Zydus holds exclusive commercialization rights for the United States and Canada and brings extensive commercial experience in the North American market for this product.*

Ahmedabad, India and Planegg-Martinsried, Germany, 13 October 2026

Zydus Lifesciences Limited (Zydus), an innovation-led global life-sciences company, and Formycon AG (Formycon), an independent developer of biosimilars, today jointly announced that the US Food and Drug Administration (USFDA) has accepted for review the Biologics License Application (“BLA”) for FYB206, a proposed biosimilar to Keytruda®¹ (pembrolizumab). To the best of the companies' knowledge, this is the first publicly announced acceptance by the USFDA of an application for a Keytruda® biosimilar. The BLA was submitted in the third quarter of 2026. Under the Biosimilar User Fee Amendments (BsUFA), the USFDA aims to complete its review within twelve months of submission, comprising up to 60 days for the filing review and 10 months for the substantive review. Based on this timeline, a decision could be expected in the third quarter of 2027. The regulatory dossier for FYB206 has also been submitted to Health Canada.

Dr. Sharvil P. Patel, Managing Director of Zydus Lifesciences Limited, said: “Acceptance of the application marks a significant step toward expanding access to affordable pembrolizumab therapy in the U.S. and Canada. As demand for high-quality, accessible oncology treatments continues to rise, FYB206 has the potential to improve patient access and outcomes while strengthening our oncology biosimilars portfolio. Leveraging the biologics expertise of Formycon and our established oncology platform in North America, we remain focused on delivering meaningful value to patients.”

Dr. Stefan Glombitza, CEO of Formycon AG, said: “With the FDA’s acceptance of the FYB206 application for review, we are among the very first companies to advance a biosimilar to the world’s best-selling biologic medicine to this stage. We developed FYB206 on a path agreed with the FDA, without conducting a comparative Phase III efficacy trial. This enabled us to accelerate the program and



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substantially reduce development investment while maintaining the rigorous scientific standards required for biosimilar approval. With Zydus, we have a partner with strong commercial capabilities and a clear oncology strategy in the US and Canada. Together, we aim to make this important cancer therapy accessible to more patients.”

Pembrolizumab is an immune checkpoint inhibitor that binds to and blocks the PD-1 receptor and is used to treat numerous types of cancer. In 2025, worldwide sales of Keytruda®, including the subcutaneous formulation Keytruda Qlex™, reached USD 31.7 billion.² In the first half of 2026, combined sales of Keytruda® and Keytruda Qlex™ totaled USD 16.40 billion.³ Keytruda® therefore remains the world’s best-selling biologic medicine. In February 2025, Formycon agreed with the USFDA that FYB206 does not require a comparative Phase III efficacy trial.

In December 2025, Formycon and Zydus had entered into an exclusive licensing and supply agreement for FYB206 in the United States and Canada. Formycon is responsible for completing development, preparing and filing the regulatory dossiers, and supplying the product. With the USFDA’s acceptance of the BLA for review, Formycon has reached a regulatory milestone under the agreement that entitles it to a milestone payment from Zydus. Zydus will commercialize FYB206 in both markets, subject to regulatory approval and resolution of any intellectual property issues. Formycon holds the global rights to FYB206 and will participate in the gross profits of its commercialization partners.

1) Keytruda® is a registered trademark and Keytruda Qlex™ is a trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ/USA.

2) Merck & Co., Inc.: Annual Report on Form 10-K for the fiscal year 2025.

3) Merck & Co., Inc.: Second-Quarter 2026 Financial Results, August 4, 2026:

<https://www.merck.com/news/merck-highlights-key-regulatory-and-clinical-milestones-across-broad-diverse-pipeline/>

About Zydus Lifesciences Limited:

Zydus Lifesciences Limited is an innovation-led life-sciences company with leadership positions across pharmaceuticals and consumer wellness, supported by an emerging MedTech franchise and a global footprint across the United States, India and other international markets. The group employs 30,000 people worldwide, including 1,500 scientists engaged in research and development. Zydus is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that improve lives. Further information is available at www.zyduslife.com.

About Formycon:

Formycon AG is a listed, independent developer of biosimilars based in Martinsried, one of the leading life science locations in Europe, just outside Munich, Germany. Its 200 employees from 27 countries cover the entire development chain, from laboratory analysis through manufacturing and clinical testing



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to the documents for approval. Three Formycon biosimilars are approved in ophthalmology and immunology and are marketed worldwide through commercialization partners. Four further candidates are in development, among them biosimilars to two of the best-selling biologic medicines in the world. With its products, Formycon makes highly effective therapies affordable for more people.

Formycon AG is listed in the Prime Standard of the Frankfurt Stock Exchange: FYB / ISIN: DE000A1EWVY8 / WKN: A1EWVY. Further information can be found at: www.formycon.com

About Biosimilars:

Biosimilars are successor products to biologic medicines. They are not copies; each one is developed from the ground up and must demonstrate to the health authorities that it has no clinically meaningful differences from the reference product in terms of safety and efficacy. According to the IQVIA Institute, 118 biologic medicines with sales of USD 232 billion will lose their exclusivity in the U.S. alone by 2034, and for only twelve of them is a biosimilar in development. In Europe, biosimilars have saved EUR 75 billion and made more than seven billion days of treatment possible.

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Disclaimer:

FYB206 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

Certain statements contained in this release may constitute "forward-looking statements" that involve a number of risks and uncertainties. Forward-looking statements can generally be identified by the use of the words "may," "likely," "will," "should," "plan," "expect," "anticipate," "estimate," "believe," "intend," "project," or "aim," or the negative of these words or other variations of these words or comparable terminology. Forward-looking statements are based on assumptions, forecasts, estimates, projections, opinions or plans that, by their nature, are subject to significant risks and uncertainties and contingencies that are subject to change.

Zydus and Formycon do not and will not give any assurance that any forward-looking statement will be achieved or prove to be accurate. Actual future business, financial condition, results of operations and prospects may differ materially from those projected or anticipated in the forward-looking statements. Subject to applicable legal requirements, neither Zydus, Formycon nor any other person intends to update, review or revise any forward-looking statements in this release to reflect actual events or developments, whether as a result of new information becoming available, new developments occurring in the future or otherwise, nor does it undertake any such obligation.



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