

## **Zydus Lifesciences announces successful clinical development of Pembrolizumab biosimilar FYB206, marking a milestone toward USFDA filing**

- *Zydus has in-licensed FYB206, a proposed biosimilar to immuno-oncology therapy Keytruda®<sup>1</sup> (pembrolizumab), exclusively from Formycon AG for the U.S. and Canadian markets*
- *Positive clinical data from the pivotal study underline Formycon's strong position among the leading developers of a pembrolizumab biosimilar*
- *Focus on completing development and preparing the regulatory dossiers*

*Ahmedabad, India, 27 February, 2026*

Zydus Lifesciences Limited, ("Zydus"), an innovation-led life-sciences company with an international presence with subsidiaries/affiliates in India and across the globe, today announced that the pivotal Dahlia pharmacokinetic study (PK study) has successfully met its primary study objective. The randomized, double-blind, multi-centre clinical PK study demonstrated pharmacokinetic equivalence (bioequivalence) of FYB206 (pembrolizumab) with the oncology blockbuster drug Keytruda®. Zydus has in-licensed FYB206, a proposed biosimilar to immuno-oncology therapy Keytruda® (pembrolizumab), exclusively from Formycon AG for the U.S. and Canadian markets.

"The positive clinical data for the FYB206 marks a key milestone in our collaboration with Formycon and reflects our shared commitment to expand access to affordable, life-saving oncology treatments." stated Dr. Sharvil P. Patel, Managing Director of Zydus Lifesciences Limited. "FYB206 represents the absolute cornerstone of our strategic entry into the complex North American immuno-oncology market."

At the beginning of 2025, Formycon and the US Food and Drug Administration (FDA) had agreed on a streamlined clinical strategy that aims to sufficiently demonstrate the therapeutic comparability of FYB206 with the reference drug Keytruda®, based on comprehensive analytical data and data from the Dahlia PK study. Having achieved the primary study objective, Formycon is now focusing on completing all development activities to finalize the documents for regulatory approval. The company is working closely with the regulatory authorities to make FYB206 available as soon as possible after the exclusivity of the reference drug expires.

With the clinical data package effectively complete, this achievement clears the pathway for a near-term Biologics License Application (BLA) filing with the USFDA. This positions Zydus as a potential first-wave filer and a new entrant in the North American immuno-oncology biosimilar market.



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For further information please contact :  
**The Corporate Communications Department**

### **Zydus Lifesciences Limited**

Regd. Office : 'Zydus Corporate Park',  
Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar),  
Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382  
481, Gujarat, India. | Phone : +91-79-71800000,  
+91-79-48040000 | website : [www.zyduslife.com](http://www.zyduslife.com)  
CIN : L24230GJ1995PLC025878

Pembrolizumab is a humanized monoclonal antibody that belongs to the group of immune checkpoint inhibitors and is used to treat a variety of tumors. With its broad range of indications in oncology and global sales<sup>2</sup> of US\$ 31.6 billion in 2025, Keytruda<sup>®</sup> is currently one of the world's best-selling drugs, underscoring the substantial oncology demand and market potential across the world.

#### **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. As of September 30, 2025, the group employs 27,000 people worldwide, including 1,500 scientists engaged in R&D, and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit [www.zyduslife.com](http://www.zyduslife.com) [www.zyduslife.com](http://www.zyduslife.com).

1) Keytruda<sup>®</sup> is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co, Inc, (NYSE: MRK) Rahway, NJ/USA.

2) <https://www.merck.com/news/merck-highlights-progress-advancing-broad-diverse-pipeline/> Merck Announces Fourth-Quarter and Full-Year 2025 Financial Results – Merck.com



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