

## **Zydus and Formycon enter into an Exclusive Partnership for the Licensing and Supply of Biosimilar to Keytruda® (Pembrolizumab), in US and Canada**

*Ahmedabad, India and Planegg-Martinsried, Germany, December 9, 2025*

Zydus Lifesciences Limited (including its subsidiaries and affiliates), an innovation-led life-sciences company, with an international presence, today announced that its wholly owned subsidiary, Zydus Lifesciences Global FZE, United Arab Emirates has entered into a strategic partnership with Formycon AG for the exclusive licensing and supply of checkpoint inhibitor FYB206, a biosimilar of Keytruda®<sup>1</sup> (Pembrolizumab) in the USA and Canada market.

Under the terms of this agreement, Formycon AG will develop, register, manufacture and supply the product, while Zydus Lifesciences Global FZE, United Arab Emirates will be responsible for the commercialization of FYB206 in the defined territories. The BLA application is expected to be submitted to the USFDA in the near future and is aimed at making immunotherapy affordable and accessible to patients in need.

Commenting on this strategic partnership, Managing Director of Zydus Lifesciences Limited, Dr. Sharvil P. Patel stated, “We are happy to collaborate with Formycon to develop and commercialize a biosimilar of Keytruda® across US and Canada. This venture marks Zydus’ entry into the North American biosimilar market, debuting with an immunotherapy product. This collaboration also complements Zydus’ recent proposed acquisition of Agenus Inc.’s California, USA based manufacturing facilities, which we plan to integrate and leverage for manufacturing in the future. By combining our expertise and resources, we aim to drive significant organizational growth and deliver maximum value to patients through expanded access to affordable oncology care.”

Dr. Stefan Glombitza, CEO of Formycon, stated, “FYB206, a biosimilar of Keytruda®, demonstrates Formycon’s advanced expertise in developing biosimilar medicines for highly regulated countries. Partnering with Zydus, an organization recognized for its regulatory proficiency and commercial presence, enables us to deliver this important therapeutic option to the patients. This collaboration strengthens our collective commitment to expanding access to medicines.”

### **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



**PRESS  
RELEASE**

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 : L24230GJ1995PLCQ25878

lives. The group aspires to transform lives through path-breaking discoveries. For more details visit [www.zyduslife.com](http://www.zyduslife.com)

#### **About Formycon**

Formycon AG (FSE: FYB) is a leading, independent developer of high-quality biosimilars, follow-on products of biopharmaceutical medicines. The company focuses on therapies in ophthalmology, immunology, immuno-oncology and other key disease areas, covering almost the entire value chain from technical development through clinical trials to approval by the regulatory authorities. For commercialization of its biosimilars, Formycon relies on strong, well-trusted and long-term partnerships worldwide. With FYB201/ranibizumab and FYB202/ustekinumab, Formycon already has two biosimilars on the market. Another biosimilar, FYB203/aflibercept, has been approved by the FDA, EMA, and MHRA. Four pipeline candidates – including FYB208/dupilumab – are currently in development. With its biosimilars, Formycon is making an important contribution to providing as many patients as possible with access to highly effective and affordable medicines.

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

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



**PRESS  
RELEASE**

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