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Zydus unveils first publicly announced acceptance by USFDA of KeytrudaÂ® biosimilar application

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FYB206 was developed without a comparative Phase III efficacy trial, following a development pathway agreed upon with the USFDA in early 2025



Ahmedabad-based Zydus Lifesciences, an innovation-led global life-sciences company, and Formycon AG, an independent developer of biosimilars, have 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® (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.

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 $31.7 billion. In the first half of 2026, combined sales of Keytruda® and Keytruda Qlex™ totaled $16.4 billion. 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.