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Zydus partners with Formycon for supply of Biosimilar to KeytrudaÂ® (Pembrolizumab) in US and Canada

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Aimed at making immunotherapy affordable and accessible to patients in need



Zydus Lifesciences has 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® (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 commercialisation 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, “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 recognised 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.”