

Orion and Shilpa Medicare expand partnership to develop Nivolumab Biosimilar for Europe

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Shilpa Medicare has announced that its wholly owned subsidiary, Shilpa Biologicals has entered into a co-development and supply agreement with Orion Corporation, a globally operating Nordic pharmaceutical company, for intravenous (IV) nivolumab biosimilar referencing one of the world's most widely used cancer immunotherapies to widen patient access across Europe.

Nivolumab helped usher in the era of immuno-oncology, transforming the outlook for patients with cancers such as melanoma and lung cancer. As the originator approaches loss of exclusivity in Europe, this partnership aims to put a high-quality, EU-GMP-manufactured nivolumab biosimilar within reach of more patients, reducing healthcare burden. In 2025, Nivolumab recorded sales of approximately \$4.1 billion (Source: IQVIA/IMS) Europe — underscoring the scale of the opportunity.

Under the agreement, Orion will hold the exclusive rights to register, market, distribute and sell the nivolumab biosimilar across Europe. Shilpa Biologicals, headquartered in India, will lead product development and serve as exclusive long-term commercial manufacturer and supplier for Europe. Shilpa will receive development and regulatory milestone payments, and supply revenue over life of partnership.