Shilpa Biologicals and SPIMACO Bio sign strategic license agreement for PD-1 Biosimilar for MENA market

September 16, 2026 | News

Shilpa Biologicals to serve as exclusive development, technology transfer and manufacturing partner with SPIMACO Bio

Shilpa Biologicals, an India-based integrated biologics development and manufacturing organisation, has announced an exclusive Middle East and North Africa (MENA) strategic licensing and commercialisation agreement with SPIMACO Bio of Saudi Arabia for portfolio of PD-1 inhibitor biosimilars across the Middle East and North Africa (MENA).

Under the agreement, Shilpa Biologicals retains ownership of the intellectual property and serves as exclusive developer and manufacturer — earning upfront, development, and commercial milestone payments and product-supply revenue — while SPIMACO Bio leads commercialisation, regulatory execution, and market access across the region.

PD-1 inhibitors are among the most important advances in modern oncology — a class of immunotherapy that helps the body's own immune system recognise and attack cancer cells across a broad range of tumour types.

By combining Shilpa Biologicals' end-to-end development and manufacturing capabilities with SPIMACO Bio's regional reach, the partnership aims to make these life-changing therapies more accessible and affordable for patients across MENA, where the cancer burden continues to rise.

The collaboration is structured around a phased technology transfer programme that will establish local manufacturing of the biosimilars in Saudi Arabia. This will strengthen regional supply security, build high-value biomanufacturing capability within the Kingdom, and support the localization objectives of Saudi Vision 2030 — reinforcing both companies' commitment to a resilient and increasingly self-sufficient regional healthcare ecosystem.

The global PD-1/PD-L1 inhibitor market is valued at approximately $74 billion in 2026 and is projected to reach $142 billion by 2031, a compound annual growth rate of about 13.9% (Mordor Intelligence, 2026). Within the Middle East oncology drugs market is estimated at $3.4 billion and forecast to grow at roughly 7.7% annually through 2031 (Cognitive Market Research, 2025). This opportunity is expected to widen further as leading originator PD-1 therapies approach loss of market exclusivity, accelerating demand for high-quality, more affordable biosimilar alternatives.