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BeiGene receives manufacturing approval for biologics facility in China

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The Guangzhou site is expected to be the first paperless biological manufacturing facility in China



BeiGene, Ltd., a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, has announced approval from the China National Medical Products Administration (NMPA) for BeiGene to begin manufacturing commercial supply of its approved anti-PD-1 antibody, tislelizumab, at its state-of-the-art biologics facility in Guangzhou, China.

At over one million square feet (100,000 square meters) and 8,000 liters of biologics capacity approved for commercial supply, this wholly owned facility will immediately begin production of commercial supply of tislelizumab for the China market.

An additional phase of construction currently in progress to bring total capacity to 64,000 liters is expected to be completed by the end of 2022.

BeiGene's Guangzhou manufacturing facility has been designed to operate in compliance with current Good Manufacturing Practice (cGMP) standards adopted by the U.S. Food & Drug Administration (FDA), the China National Medical Products Administration (NMPA), and the European Medicines Agency (EMA).

The Guangzhou site is expected to be the first paperless biological manufacturing facility in China and integrates new technologies such as 3D modeling, digital twin, augmented interfaces, and artificial intelligence to improve quality and efficiency.