

BeiGene inks deal with Novartis to jointly develop oncology drug

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BeiGene, Ltd, a China based commercial-stage biotechnology company focused on developing and commercialising innovative medicines worldwide, has announced a collaboration and license agreement with Novartis Pharma AG to develop, manufacture and commercialise BeiGene's anti-PD-1 antibody tislelizumab in the US, Canada, Mexico, member countries of the European Union, the United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan.

The Companies have agreed to jointly develop tislelizumab in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialisation upon regulatory approvals.

In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and BeiGene has an option to co-detail the product in North America, funded in part by Novartis.

"We are excited to collaborate with Novartis to further explore the potential of tislelizumab in multiple combinations and indications. Novartis is a well-recognised leader in oncology with a unique portfolio of cancer treatments and pipeline agents," said John V Oyler, Co-Founder, CEO, and Chairman, BeiGene. "This important collaboration stands on a strong foundation of tislelizumab's broad global development program, which has delivered two approvals in China, currently spans 15 potentially registration-enabling clinical trials, and has enrolled over 7,700 patients to date, including approximately 2,500 patients in more than 20 countries and regions outside of mainland China."

Under the agreement BeiGene will receive an upfront cash payment of \$650 million from Novartis. BeiGene is eligible to receive up to \$1.3 billion upon the achievement of regulatory milestones, \$250 million upon the achievement of sales milestones, and royalties on future sales of tislelizumab in the licensed territory. Under the terms of the agreement, BeiGene will be responsible for funding ongoing clinical trials of tislelizumab, Novartis has agreed to fund new registration, bridging, or post-marketing studies in its territory, and each party will be responsible for funding clinical trials evaluating tislelizumab in combination with its own or third party products. Each party retains the worldwide right to commercialise its propriety products in combination with tislelizumab.