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ASIA EDITION

Australian oncology drug Paxalisib receives rights to develop and commercialize in China

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Kazia enters a licensing agreement with Simcere to provide rights to Paxalisib

Sydney-based Kazia Therapeutics Limited, an oncology-focused drug development company announced that it has entered into a licensing agreement with Simcere Pharmaceutical Group Ltd (Simcere) to develop and commercialize Kazia's investigational new drug, paxalisib, in Greater China.

Simcere will assume responsibility for the development, registration, and commercialization of paxalisib in Greater China - a territory that includes Mainland China, Hong Kong, Macau, and Taiwan. Kazia retains rights to the development and commercialisation of paxalisib in all other territories and will continue to drive forward the GBM AGILE pivotal study as planned, including in China.

Under the terms of the agreement, Kazia will receive an upfront payment of US$ 11 million (~AU$ 14.2 million), comprising US$ 7 million in cash and a US$ 4 million equity investment, priced at a 20% premium to recent trading. Kazia will also receive contingent milestone payments of up to US$ 281 million (~AU$ 362 million) for glioblastoma, with further milestones payable for indications beyond glioblastoma. Simcere will additionally pay Kazia mid-teen percentage royalties on commercial sales. Transaction proceeds will be applied directly to the further development of paxalisib.

Simcere is one of China's leading pharmaceutical companies, with over 40 marketed products and an extensive development pipeline. Simcere's primary areas of strategic focus are oncology, central nervous system disease, and autoimmune disease. Simcere to bring first-class capabilities in clinical development, regulatory affairs, and commercialization to paxalisib.

Paxalisib is currently the subject of six additional studies in other forms of brain cancer beyond glioblastoma. Paxalisib is a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is disordered in the vast majority of patients with glioblastoma, the most common and most aggressive form of primary brain cancer. In a phase II study in patients with newly diagnosed glioblastoma with unmethylated MGMT promotor status, paxalisib has shown highly encouraging signals of clinical efficacy.