ASX RELEASE
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KAZIA LICENSES RIGHTS TO PAXALISIB IN GREATER CHINA TO SIMCERE, A LEADING CHINESE PHARMACEUTICAL COMPANY

Sydney, 29 March 2021 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an oncology-focused drug development company, is pleased to announce that it has entered into a licensing agreement with Simcere Pharmaceutical Group Ltd (Simcere, 先声药业) (HKSE: 2096) to develop and commercialise Kazia's investigational new drug, paxalisib, in Greater China.

Key Points

- Simcere will assume responsibility for the development, registration, and commercialisation of paxalisib in Greater China - a territory which 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 to 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. It was incorporated in 1995 and is listed on the Hong Kong Stock Exchange (HKSE: 2096). Simcere's primary areas of strategic focus are in oncology, central nervous system disease, and autoimmune disease.
- Paxalisib is currently the subject of six additional studies in other forms of brain cancer beyond glioblastoma.

Kazia CEO, Dr James Garner, commented, “China is one of the world’s largest pharmaceutical markets, with specific requirements and opportunities for innovative oncology products. We are delighted to partner with Simcere to secure the commercial success of paxalisib in this critical territory. Simcere’s track record of success is unrivalled, and they bring to paxalisib first-class capabilities in clinical development, regulatory affairs, and commercialisation. We look forward to working closely with our new partners to make paxalisib available for Chinese patients as swiftly as possible.”

Dr Renhong Tang, Senior Vice President at Simcere, added, “we are tremendously excited by the potential for paxalisib to make a difference in this very challenging disease. The need for new therapies in brain cancer is significant in China, and we share Kazia’s commitment to bringing forward new treatment options for patients.”

Kazia has been advised in this transaction by Janette Dixon at JustPartnering and by Dragon Financial Partners.

Simcere Pharmaceutical Group

Simcere Pharmaceutical Group is rapidly transitioning to an innovation and R&D-driven pharmaceutical company, with a mission of “providing today’s patients with medicines of the future.” It has established a national key laboratory of translational medicine and innovative pharmaceuticals. Simcere focuses on oncology, central nervous system disease and autoimmune disease therapeutic areas, with a diversified product portfolio and industry-leading capabilities. Its vigorous in-house R&D efforts and extensive R&D collaborations have made it a strategic cooperation partner with world leading pharmaceutical companies and biotechnology companies, in an effort to bring more global life science breakthroughs to China.

For more information, please visit www.simcere.com.

Equity Issuance

Under the terms of the transaction, Simcere will make a US$ 4 million (~AU$ 5.2 million) equity investment in Kazia, priced at a 20% premium to recent trading.

In relation to Kazia’s 2016 purchase of Glioblast Pty Ltd, this transaction satisfies the conditions for Milestone 4 of that agreement and will therefore result in the issuance of escrowed ordinary shares to Glioblast shareholders, under terms previously disclosed by Kazia.

Paxalisib

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. In January 2021, patient recruitment commenced for paxalisib in the GBM AGILE platform study, which is expected to serve as the basis for registration in key territories.

Investor Conference Call

Kazia is pleased to invite investors to attend a conference call to further discuss the partnership with Simcere.

The call will be held on Tuesday 30 March 2021 at 8:00am, Sydney time (AEDT), which is 5:00pm on 29 March in New York (ET) and 2:00pm on 29 March in San Francisco (PT).

Participants will need to **pre-register** for the call via the following link:

https://s1.c-conf.com/diamondpass/10013168-83hs6e.html

Click the 'Register Now' button and follow the prompts to complete pre-registration. You will receive a calendar invite with dial in numbers, passcode and PIN to join the conference call.

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About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib commenced recruitment to GBM AGILE, a pivotal study in glioblastoma, in January 2021. Seven additional studies are active in other forms of brain cancer. Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020.

For more information, please visit www.kaziatherapeutics.com.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.

Q&A

Why has Kazia chosen to partner Greater China rights to paxalisib at this stage?

China has unique regulatory and market access requirements, which require active engagement some time before a commercial launch. Partnering with a first-class Chinese pharmaceutical company at this stage helps to ensure that the launch of paxalisib is not delayed in China, and that it is optimised for commercial success.

Moreover, the proceeds of this transaction will allow Kazia to substantially fund the remaining development of the paxalisib program, and to undertake additional exploratory clinical studies as appropriate. In effect, the paxalisib program has become partially self-sustaining in economic terms.

How does this transaction affect the likelihood of a global (ex-China) partnership for paxalisib?

Kazia retains unfettered rights to all territories outside Greater China and may license all or part of these territories at its absolute discretion.

'Global' licensing deals with large pharmaceutical companies often exclude particular territories, for example in the licensor's home country, and so the exclusion of Greater China rights for paxalisib is highly unlikely to constrain such a transaction.

Kazia will continue to evaluate all options and will seek to put in place additional commercial arrangements at a time and in a manner that ensures the most effective product launch and which optimizes value for Kazia's shareholders.

How do the deal terms of this transaction compare to Kazia's expectations in other territories?

China accounts for 8-10% of the global pharmaceutical market. The remaining ~90% of the commercial rights for paxalisib remain available to Kazia for future transactions. Given that territories such as the United States are typically associated with higher profit margins, and that any transaction for such territories is likely to take place in the context of a more substantial body of clinical data for the asset, Kazia expects to realise proportionally superior value in any such partnership.

How do the terms of this transaction compare to similar licensing deals in China?

The licensing terms in this transaction are highly consistent with previous transactions between multinational companies and Chinese companies in this disease area.

In September 2018, Novocure (St Helier, Jersey) and Zai Lab (Shanghai, China) announced a strategic collaboration and license agreement for Novocure's Tumor Treating Fields (TTF) medical device, marketed as Optune®. Optune was previously approved by FDA for

glioblastoma in 2011. The transaction included a US$ 15 million upfront payment, undisclosed milestones, and a royalty rate from 10% to mid-teens.[1]

In November 2019, Mimivax LLC (Buffalo, NY) and Fosun Pharma Industrial (Shangahi, China) entered into a licensing agreement for Mimivax's SurVaxM product, following completion of a phase II clinical trial in glioblastoma. The transaction included a US$ 10 million upfront payment and up to $138 million in contingent milestones. Any royalties were undisclosed.[2]

What is the size of the Chinese pharmaceutical market?

The pharmaceutical market in the People's Republic of China was estimated to be worth approximately US$ 130 billion in 2018.[3] China accounts for around 8%-10% of total global pharmaceutical expenditure.

How common is glioblastoma in China?

Glioblastoma is not believed to demonstrate substantial ethnic or geographic differences in incidence, and so Chinese patients would be expected to develop glioblastoma at about the same rate as patients in other countries, when matched for age and other factors.

There are estimated to be around 25,000 new cases of glioblastoma in China each year, which is approximately twice the annual number of cases in the United States.

How is glioblastoma treated in China, compared to Western countries?

Patients in China are treated in very similar fashion to those in the US and other Western countries. The Stupp Regimen, comprising surgery, chemoradiotherapy, and up to six months of maintenance treatment with temozolomide, is the standard of care in China, as it is elsewhere around the world.

Temozolomide is widely available as a generic medicine in China. In addition, Avastin® (bevacizumab) was approved in China for recurrent glioblastoma in September 2020.

At what level does Kazia anticipate paxalisib to be priced in China?

Kazia is not able to provide indicative pricing for paxalisib in China at this stage. In general, novel medicines are typically priced lower in China than in the United States.

Which other companies were considered as partners? Why did Kazia decide to partner with Simcere?

Kazia conducted a broad-based process which involved outreach to more than two dozen companies in China. Short-listed candidates were invited to submit proposed deal terms, and the final decision was based on a combination of value, capability, and commitment.

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[1] Novocure press release – 12 September 2018
[2] Mimivax press release – 18 November 2019
[3] DaXue Consulting

Simcere was selected as the partner of choice because of its first-class R&D capabilities, its extensive commercial infrastructure, its track record of success, its entrepreneurial culture, and the shared values between the two companies.

Kazia licensed paxalisib from Genentech in 2016. How do the deal terms of this transaction compare to Kazia's financial commitments to Genentech?

Kazia's potential receipts from Simcere substantially exceed its obligations to Genentech in respect of the licensed territories.

The GBM AGILE study is expected to commence recruitment in China during CY2021. What are the implications of this transaction for paxalisib's inclusion in this study?

Kazia and Simcere expect the GBM AGILE study to proceed as planned in China, and to provide the basis for a product approval. The companies will collaborate closely to consult with the Chinese regulatory agency, the National Medical Products Administration (NMPA), over the coming months.