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Singapore's Specialised Therapeutics makes new additions to oncology portfolio in APAC region

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Anticipates submitting axatilimab and retifanlimab for local regulatory and reimbursement approval in 2025

Singapore-based biopharmaceutical company Specialised Therapeutics (ST) has expanded its existing supply and distribution agreement with Incyte Biosciences International Sàrl, the Swiss-based affiliate of Incyte, to launch and distribute two additional medicines from its oncology portfolio in Australia, New Zealand and Singapore, with an option to add further countries in the Asia-Pacific (APAC) region.

The expanded agreement will see new therapies axatilimab (registered as Niktimvo in the United States) and retifanlimab (registered as Zynyz in the US and European Union) added to the current partnered portfolio of Minjuvi (tafasitamab) and Pemazyre (pemigatinib).

Under the terms of the expanded agreement, Incyte will be responsible for the development, manufacture and supply of both axatilimab and retifanlimab to the region, while ST will have responsibility for regulatory, distribution and local marketing and medical affairs related activities.

ST anticipates submitting axatilimab and retifanlimab for local regulatory and reimbursement approval in 2025.

Axatilimab is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody. It was approved by the US Food and Drug Administration (FDA) in August 2024 as a treatment for adults and children with chronic graft-versus-host disease (GVHD) who have received at least two prior treatments (systemic therapy) and require additional treatment. Chronic GVHD usually occurs 3 months after a transplant - typically haematopoietic stem cell or bone marrow transplantation, but occasionally also solid organ transplants - where the donor cells (graft) attack the graft recipient's cells (host). Chronic GVHD can affect all organs, but commonly impacts the skin, mouth, eyes, lungs, stomach, bowel, and liver.The Phase II clinical trial for axatilimab involved 79 patients from 13 countries, including Australia and Singapore.