Specialised Therapeutics Expands Partnership with Incyte to Include Two Additional Therapies for Hard-to-Treat Conditions

Singapore 11 June 2025: Independent biopharmaceutical company Specialised Therapeutics (ST) is pleased to announce the expansion of its existing supply and distribution agreement with Incyte Biosciences International Sàrl, the Swiss-based affiliate of Incyte (NASDAQ:INCY), 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 region. The expanded agreement will see new therapies axatilimab (registered as Niktimvo® in the United States) and retifanlimab (registered as Zynyz® in the U.S. 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 Chief Executive Officer, Mr Carlo Montagner, welcomed the expansion of the partnership agreement with Incyte, a leading global biopharmaceutical company, and the opportunity to bring these important medicines to eligible patients in the local region.

“Specialised Therapeutics has partnered with Incyte since 2021 and we are delighted to be extending this successful partnership,” he said. “As part of our initial agreement, our teams have worked collaboratively to commercialise Minjuvi, which has been approved for use in Australia, and Pemazyre, which has

been approved in Australia and Singapore, and we look forward to expanding the portfolio to help more patients with rare and hard-to-treat conditions."

"The addition of axatilimab and retifanlimab to the partnership agreement with Incyte recognises our strong track record of working with local stakeholders to bring innovative medicines to patients where unmet medical needs persist, despite the availability of existing treatments," said Mr Montagner. "Our focus will be on seeking regulatory and reimbursement approval for all four medicines in the region, to ensure equitable access to these treatments are available for patients as soon as practicable."

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

Incyte CEO, Mr Hervé Hoppenot said the expanded partnership agreement reflected the synergies between the two companies, with a shared goal of improving outcomes for patients with unmet medical needs.

"We are pleased to extend our partnership with ST to include axatilimab and retifanlimab," he said. "ST has already demonstrated its ability to navigate complex regional regulatory pathways for Minjuvi and Pemazyre, and we look forward to continuing our work together to make these new therapies available for the oncology community in the Asia-Pacific region."

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.[1] 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").[2] Chronic GVHD can affect all organs, but commonly impacts the skin, mouth, eyes, lungs, stomach, bowel, and liver.[2,3] The Phase II clinical trial for axatilimab involved 79 patients from 13 countries, including Australia and Singapore.[4]

Retifanlimab is an intravenous immune checkpoint (PD-1) inhibitor that has been

approved in the US in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) and as a single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression or intolerance to platinum-based chemotherapy.[5] Retifanlimab is also approved in the US[6] and Europe[7] for the treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). MCC is a rare and aggressive type of skin cancer, that is often difficult to diagnose due to the lack of specific features to distinguish it from other common skin cancers.[8] Australia has the highest incidence of MCC in the world.[9] The pivotal Phase II clinical trial of retifanlimab in MCC enrolled 101 chemotherapy-naïve patients from 12 countries, including Australia.[10] In addition to MCC, retifanlimab, in combination with chemotherapy, is currently being investigated as a potential therapeutic option in other hard-to-treat cancers, including metastatic non-small cell lung cancer (NSCLC).

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About Specialised Therapeutics

Founded in 2007, Specialised Therapeutics is the region's largest independent specialty pharmaceutical company, providing new therapies and technologies to patients in Australia, New Zealand and across Southeast Asia. Headquartered in Singapore, ST partners with global pharmaceutical, biotech and diagnostic companies to bring novel healthcare opportunities to patients who are impacted by a range of diseases. ST has built a strong track record of success, navigating complex regulatory, reimbursement and commercialisation environments in its diverse regions. The ST mission is to provide specialty therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, CNS, neurology, endocrinology, ophthalmology

and supportive care, although it is not confined to these areas. ST is a member of the World Orphan Drug Alliance (WODA).

Additional information can be found at www.stbiopharma.com

About axatilimab (Niktimvo®)

Axatilimab-csfr (registered as Niktimvo® in the United States) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the US for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and paediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialise axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialisation license agreement for axatilimab in chronic GVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD – a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids (NCT06585774) are underway. Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

About retifanlimab (Zynyz®)

Retifanlimab-dlwr (registered as Zynyz® in the United States and European Union) is a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), indicated in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) and as

a single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression or intolerance to platinum-based chemotherapy in the U.S.

Zynyz is also indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in the US. This indication is approved under accelerated approval based on tumour response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Zynyz is marketed by Incyte in the US. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a registered trademark of Incyte.

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