Lymphoma Therapy Now Approved for Australian Patients with Diffuse Large B-cell Lymphoma

MINJUVI® (tafasitamab) provisionally approved by Therapeutic Goods Administration[1]

Recent five-year follow-up data from Phase 2 L-MIND investigation showed patients treated with MINJUVI had prolonged, durable responses[2]

Singapore, 28 June 2023: Independent biopharmaceutical company Specialised Therapeutics (ST) is pleased to announce that a new therapy to treat the most common type of non-Hodgkin lymphoma in adults – diffuse large B-cell lymphoma – is now approved for use in Australia.

The Therapeutic Goods Administration (TGA) has provisionally approved MINJUVI® (tafasitamab) ***"in combination with lenalidomide followed by MINJUVI monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT)".***[1]

Australian lymphoma specialist and current chair of the Australasian Lymphoma Alliance, Professor Chan Cheah, said the MINJUVI approval was a great step forward for patients who had been diagnosed with DLBCL and relapsed, as the MINJUVI regimen provides an opportunity for longer-term disease management.

"I think it is great news for patients," Professor Cheah said. "We do have chemotherapy options and we cure about two-thirds of patients using that approach. Unfortunately, a substantial proportion of patients either don't respond to chemotherapy, or the disease comes back after chemotherapy, and they need better treatments."

MINJUVI, a CD19-targeting immunotherapy that works by attaching to a protein

on the surface of B-cell lymphoma cells, stimulating an immune response against the lymphoma, is also approved in the United States [as Monjuvi® (tafasitamab-cxix)], Great Britain, Canada, Europe and other countries.

Professor Cheah added: “Access to novel immune therapies like MINJUVI is really important for Australian patients. Apart from CAR-T cell therapies – and these are only applicable to a certain proportion of patients with DLBCL – there have been no novel therapies for relapsed DLBCL approved in Australia. MINJUVI has a favourable side effect profile and (combined with lenalidomide) has demonstrated a high response rate in patients with relapsed disease. We now need to see it listed on the Pharmaceutical Benefits Scheme.”

MINJUVI has been approved via a provisional regulatory pathway, with the TGA participating in the Modified Project Orbis initiative to accelerate availability to Australian patients. The approval was based on data from the Phase 2 L-MIND study, an open label, multi-center single arm study which evaluated its safety and efficacy in combination with lenalidomide as a treatment for patients with relapsed or refractory DLBCL who were not eligible for ASCT.[1,3]

Continued approval for this indication depends on verification and description of clinical benefit in the confirmatory Phase 3 frontMIND study which has completed enrollment.[4]

Recently, five-year follow up data were presented which showed that MINJUVI plus lenalidomide followed by MINJUVI monotherapy provided prolonged, durable responses in adult patients with relapsed or refractory DLBCL. The overall response rate (ORR) was 57.5% with a complete response (CR) observed in 41.2% of patients, and a partial response (PR) in 16.2% of patients. The median overall survival was 33.5 months and median progression-free survival (PFS) was 11.6 months.[2] The most common adverse reactions with MINJUVI are infections (73%), neutropenia (51%), asthenia (40%), anaemia (36%), diarrhoea (36%), thrombocytopenia (31%), cough (26%), oedema peripheral (24%), pyrexia (24%), decreased appetite (22%). The most common serious adverse reactions were infection (26%) including pneumonia (7%), and febrile neutropenia (6%).[1]

ST Chief Executive Officer Mr. Carlo Montagner said securing TGA approval was a key regulatory milestone for the company, noting that the therapy was

synergistic with the company's mission to provide therapies that addressed unmet needs in rare patient populations.

"We are delighted to successfully register MINJUVI for Australian patients and look forward to working with the lymphoma community to ensure it is available at the earliest opportunity," he said.

ST markets MINJUVI under an exclusive distribution arrangement with international partner Incyte (NASDAQ: INCY).

Ends.

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout Southeast Asia, as well as in Australia and New Zealand. ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stbiopharma.com

About Diffuse Large B-cell Lymphoma (DLBCL)

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide[5], characterised by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs. It is an aggressive disease with about 40% of patients not responding to initial therapy or relapsing thereafter[5], leading to a high medical need for new, effective therapies[6], especially for patients who are not eligible for an autologous stem cell transplant in this setting.

About L-MIND

The L-MIND trial was a single arm, open-label Phase 2 study (NCT02399085) investigating the combination of tafasitamab and lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma who had at least one, but no more than three, prior lines of therapy, including an anti-CD20 targeting therapy (e.g., rituximab), who were not eligible for high-dose chemotherapy or refused subsequent autologous stem cell transplant. The study's primary endpoint was overall response rate. Secondary outcome measures included duration of response, progression-free survival and overall survival. In May 2019, the study reached its primary completion. For more information about L-MIND, visit https://clinicaltrials.gov/ct2/show/NCT02399085.

About MINJUVI® (tafasitamab-cxix)

Tafasitamab is a humanized Fc-modified CD19 targeting immunotherapy. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which is intended to lead to a significant potentiation of Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP), thus aiming to improve a key mechanism of tumor cell killing.

MINJUVI known as Monjuvi® (tafasitamab-cxix) in the United States is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved underaccelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional marketing authorization in combination with lenalidomide, followed by Minjuvi monotherapy, for the

treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

Monjuvi® and Minjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in Europe and Canada.

XmAb® is a trademark of Xencor, Inc.

References:

1. Minjuvi® (tafasitamab). Product Information, Australia.
2. Minjuvi® (tafasitamab). Oral Abstract # CT022 Five-year follow-up of Phase 2 L-MIND study announced at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, Florida.
3. Salles, G. et al. (2020) 'Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-mind): A multicentre, prospective, single-arm, phase 2 study', The Lancet Oncology, 21(7), pp. 978–988. doi:10.1016/s1470-2045(20)30225-4.
4. gov/study/NCT04824092?term=frontMIND&intr=tafasitamab&rank=1
5. Sarkozy C, et al. Management of relapsed/refractory DLBCL. Best Practice Research & Clinical Haematology. 2018 31:209–16. doi.org/10.1016/j.beha.2018.07.014.
6. Skrabek P, et al. Emerging therapies for the treatment of relapsed or refractory diffuse large B cell lymphoma. Current Oncology. 2019 26(4): 253–265. doi.org/10.3747/co.26.5421.