

Australia approves MINJUVI® (tafasitamab) for treatment of relapsed or refractory follicular lymphoma

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Biopharmaceutical company Specialised Therapeutics (ST), based in Singapore, has announced that Minjuv® (tafasitamab), in combination with rituximab and lenalidomide, has been registered by the Therapeutic Goods Administration (TGA) for the treatment of Australian adults with relapsed or refractory follicular lymphoma (R/R FL) (Grade 1-3a).

The TGA registration establishes Minjuvi as the first and only chemotherapy-free CD19 and CD20 dual-targeted immunotherapy combination regimen to be approved in Australia for this group of patients.

Follicular Lymphoma (FL) is the second most common form of non-Hodgkin Lymphoma (NHL), accounting for 20-30% of all NHL cases. An estimated 1,500 Australians are newly diagnosed with FL each year.

The TGA registration of Minjuvi in combination with rituximab and lenalidomide in R/R FL was based on the results from the global Phase 3 *inMIND* clinical study. This trial evaluated the efficacy and safety of the regimen in 652 patients, including 548 participants with R/R FL. Notably, 54 Australians participated across 12 local trial sites across the country.

In 2021, ST entered into an exclusive distribution agreement with Incyte to commercialise Minjuvi in Australia, New Zealand and Singapore.

In Australia, Minjuvi is also indicated 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).