Zinbryta receives TGA approval in Australia for use in relapsing MS

The Australian Therapeutic Goods Administration (TGA) has approved the registration of disease modifying multiple sclerosis (MS) medication, Zinbryta (daclizumab) on the Australian Register of Therapeutic Goods.

Zinbryta has been registered for the treatment of relapsing forms of MS to delay the progression of physical disability and to reduce the frequency of relapse.

Zinbryta was also recently approved for use by the European Medicines Agency and the US Food and Drug Administration.

Zinbryta was considered for reimbursement on the PBS by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) at its July 2016 meeting and MS Research Australia made a submission on behalf of the MS community, however, the PBAC deferred its recommendation on Zinbryta pending the outcome of the TGA's assessment of the drug.

We will now need to await the result of the PBAC evaluation of Zinbryta, and final sign off from the Government before we know whether and when Zinbryta may become available in Australia.

The assessment by the TGA was based primarily on the results of two phase III clinical trials of known as SELECT and DECIDE. You can read about the outcomes of these trials in our previous news item here.
Daclizumab is already in use clinically for the prevention of kidney transplant rejection and has been under investigation as a treatment for relapsing remitting MS for some time. It is a monoclonal antibody (a type of antibody that recognises a single specific target) that blocks the activity of interleukin-2, a chemical messenger of the immune system. It interferes with the activation and growth of immune cells. Daclizumab is given as an injection under the skin once a month.

MS Research Australia looks forward to the PBAC recommendation regarding this new MS medication. The addition of a further affordable treatment option for relapsing MS will be a welcome development that will enable people with MS and their doctors to find effective therapies suited to their individual circumstances.