Wednesday, 7 June 2016

PBAC Secretariat
MDP 952
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601

Dear PBAC Secretariat,

Re: DACLIZUMAB – July 2016 PBAC Agenda

MS Australia is writing to support the inclusion of the medication daclizumab (marketing name Zinbryta®) to the Pharmaceutical Benefits Scheme (PBS). As the national peak body for people with MS we are proud to advocate on behalf of our member organisations and the MS community. One area we are particularly passionate about is the provision of more affordable and accessible treatments that can improve the lives of people with MS.

There are currently more than 23,000 people living with MS across the country. MS can be a particularly debilitating disease with an unpredictable disease course. No two cases of MS are the same. There is no one-size fits all treatment for people living with MS and to date, there is no known cure.

The challenges faced by people with MS can be significant and can have a devastating impact on their families and the wider community. Relapses can result in short term or long term disability, resulting in the need for physical and/or psychological care and support, medical investigations, treatments and hospitalisation.

These symptoms, or the gradual progression of the disease through relapses, mean that the majority of people with MS are unable to retain their employment. In fact, people with MS are more likely to be unemployed than those with any other chronic disease. This contributes to an increasing economic burden of MS on the rest of society. The economic cost of MS to the Australian community has been estimated to be around $1.04 billion a year.

Being able to better manage and limit the frequency and impact of relapses can help alleviate the burden of MS on the community and the individual.

Daclizumab was recently approved for use by the European Medicines Agency (EMA).

Daclizumab was previously used 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 modulates 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.

The results of one phase II study (SELECT) and one phase III study (DECIDE) of daclizumab, are summarised as follows.

The 'SELECT' study (http://www.ncbi.nlm.nih.gov/pubmed/23562009) was a randomised controlled trial in which 208 patients with relapsing remitting MS received 150mg of daclizumab, 209 patients received 300mg of daclizumab and 204 patients were given placebo (dummy injections) for one year. Relapses were reduced by around 50% in both groups receiving daclizumab and there was also a reduction in the number of patients who had progression of disability that was confirmed after a 3 month period. The number of gadolinium enhancing lesions seen on magnetic resonance imaging (MRI) scans, which is a sign of active inflammation, was also reduced by 69% and 78% in the people who received 150mg or 300mg of daclizumab respectively. 7% and 9% of people in the daclizumab 150mg and 300mg groups, compared to 6% in the placebo group in the SELECT trial experienced

serious adverse events. Daclizumab did not appear to have any effect on the rate of brain shrinkage (atrophy).

In the 'DECIDE' study, (http://www.ncbi.nlm.nih.gov/pubmed/26444729a) 150mg dose of daclizumab administered under the skin every 4 weeks was given to 919 people with relapsing remitting MS and compared with weekly injections of interferon β-1a given to 922 patients. People in the daclizumab group had an overall 45% reduction in annualised relapse rate compared with interferon and a 54% reduction in new or enlarging lesions on MRI scans. No significant difference was seen in the effect of daclizumab on disability progression in this trial in comparison with interferon.

The most common side effects with daclizumab seen in both clinical trials were elevations of liver enzymes and liver injury, skin reactions such as eczema and rashes, infections, gastrointestinal disorders, and depression. 2% of people in the daclizumab groups in the SELECT trial experienced serious adverse events, predominantly infections.

Overall, MS Australia believes daclizumab provides another viable treatment option that will help to reduce the burden for many people with MS and its potential effectiveness at reducing relapse rates and severity could allow people with MS to maintain parts of their lifestyle for longer, such as employment, physical activity and exercise, as well as travel and socialising with friends.

Whilst these elements may not seem particularly significant, together they provide a person with MS purpose, focus, independence and drive which can be very useful in maintaining a high quality of life and staying on top of their symptoms. More broadly, it can ultimately mean less time in hospital, reducing the drain on valuable medical and disability resources, a lower cost for at home modifications and support, and prolonged employment, which helps to reduce the economic impact of MS on society.

Pending a positive assessment of efficacy and safety from the Therapeutic Goods Administration, this medication will make a valuable addition to the repertoire of medications available to people with MS and their neurologists. It will allow for an appropriate treatment choice to be made according to the efficacy and possible side-effects in relation to an individual's circumstances and will help to alleviate the economic cost of MS to individuals, their families and the broader community.

We appreciate you considering this treatment for inclusion on the PBS.

Declaration

MS Australia is making this submission as we have an interest in the health and well-being of all people with MS. MS Australia is the national peak body for people living with MS in Australia. We work with governments at all levels, engaging on the issues that concern the lives of people living with MS, their families and carers, the community and the economy. We declare that we have received funding support from Biogen and from other pharmaceutical companies with an interest in MS in the form of grants for advocacy activities.

Yours sincerely,

Andrew Giles
Acting Chief Executive Officer
Multiple Sclerosis Australia