Thursday, 5 June 2014

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

Dear PBAC Secretariat,

Re: Lemtrada (Alemtuzumab) – July, 2014 PBAC Agenda.

MS Australia is writing to support the inclusion of the relapsing-remitting multiple sclerosis (MS) treatment, Lemtrada (Alemtuzumab) on the Pharmaceutical Benefits Scheme (PBS). As the national peak body for the MS community in Australia providing advocacy and communications support for our state member organisations, we are deeply concerned about the provision of more affordable and accessible treatments that can improve the lives of people with MS.

There are currently 23,000 people living with MS across the country with an additional 1,000 diagnoses every year. MS can be a particularly debilitating disease with an unpredictable course that affects people in different ways. For some people, it is a disease of differing severity with periods of unpredictable relapse and remission. For others it is a progressive decline over time. For all, it is life changing.

As such, MS Australia supports any treatment that has been deemed safe by the Therapeutic Goods Administration (TGA) that helps to minimise the impact of the disease to allow people with MS to live more fulfilling lives.

There are currently a number of treatment options for people with relapsing remitting MS, the most commonly diagnosed form of the disease (more than 80% of people diagnosed in Australia are diagnosed with relapsing-remitting MS). These treatments include injectable medications, a monthly IV infusion and oral medications. All of these treatments have played a part in improving the lives of people with MS across the country. However the fact is, no two cases of MS are the same, and there is no guarantee that a person with MS will experience a relief of symptoms from these treatment options currently available.

MS Australia
Level 26 Northpoint Building,
100 Miller St
NORTH SYDNEY NSW 2060
T: 02 9468 8390
F: 02 9411 7456

www.msaustralia.org.au

Multiple Sclerosis Australia
ABN 51 008 515 508

Lemtrada (Alemtuzumab) would provide another safe and effective treatment option for people with MS in Australia. It is an induction therapy and requires a very infrequent dosing schedule. Typically, five infusions are given over a one week period for the first dose, followed by a further three infusions, given over a three day period, 12 months later. It works by depleting the B and T cells of the immune system, subsequently reducing the autoimmune attack on myelin in the brain and spinal cord. Depending on patient response following this initial treatment period, further infusion treatments may be necessary although clinical trial data indicates the need for further treatment significantly diminishes over time.

Importantly, the treatment is not recommended for patients with a mild or inactive form of the disease or for those who are stable on their current therapy. It does however represent a viable treatment option for many people with active MS and particularly for people with aggressive forms of relapsing-remitting MS that can lead to severe disability in a shorter space of time following diagnosis.

Lemtrada (Alemtuzumab) has been shown in clinical trials to reduce relapse rates and to slow the rate of disability progression in people with relapsing remitting MS compared to another market available treatment, Rebif ® (interferon β-1a). In several clinical trials, Lemtrada (Alemtuzumab) demonstrated a significant improvement in relapse rates compared to Rebif®. Notably, 78% of patients receiving Lemtrada (Alemtuzumab) were relapse free 2 years after receiving treatment, compared to 59% of patients receiving interferon β-1a. Furthermore, more patients receiving Lemtrada (Alemtuzumab) than interferon β-1a reported reductions in disability that were sustained for 12 months, and fewer patients reported sustained accumulation of disability. These benefits were maintained over time, with 67% of patients showing sustained reductions in disability at follow up. Additional improvements were also found in brain atrophy and lesion load.

These findings place Alemtuzumab among the strongest disease modifying therapies available and provide an important option for people with an active form of the disease who are at risk of frequent, aggressive relapses which can leave them with permanent disability.

Indeed, the challenges faced by people with MS can be significant and can have a devastating impact on families, and the wider community. Relapses can result in short-term or long-term disability, resulting in the need for physical and 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 work. In fact currently more than 50% of people diagnosed with MS are unable to maintain employment beyond ten years of diagnosis. This contributes to an increasing economic burden of MS on the rest of society. Currently, the economic cost of MS to the Australian community is

estimated to be around $1.04 billion a year. This is an increase of $380 million since 2005.

Being able to better manage and limit the impact of relapses helps give people with MS greater certainty to get on with their lives, and disease modifying treatments like Lemtrada (Alemtuzumab) help them to maintain important 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 give 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 also mean less time in hospital, meaning less strain 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.

Lemtrada (Alemtuzumab) is not without side-effects. The clinical trials process identified a risk of secondary autoimmune adverse effects, but the risk of negative autoimmune events following treatment is mitigated by monthly monitoring of patients' blood serum for four years after treatment. This ensures early detection of changes, allowing prompt treatment and effective management.

MS Australia appreciates the PBAC considering this treatment for inclusion on the PBS. This medication will make a valuable addition to the medications available to people with MS and their neurologists giving them greater choice and flexibility to find the treatment option that helps them the most.

Yours sincerely,

Debra Cerasa
Chief Executive Officer