Common Drug Review
Patient Group Input Submissions

Alemtuzumab (Lemtrada) for the management of adult patients with relapsing remitting multiple sclerosis (RRMS), with active disease defined by clinical and imaging features, who have had an inadequate response to interferon beta or other disease-modifying therapies.

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Consumer Advocare Network — permission granted to post.
Multiple Sclerosis Society of Canada — permission granted to post.

CADTH received patient group input for this review on or before December 2, 2014

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Consumer Advocare Network

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Lemtrada (alemtuzumab)
Name of the patient group		Consumer Advocare Network
Name of the primary contact for this submission:		[redacted]
	Position or title with patient group	[redacted]
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Permission is granted to post this submission		Yes

1.1 Submitting Organization

The Consumer Advocare Network (Advocare) is a registered not-for-profit organization set up in 1999 to provide education and support to patient groups to promote engagement in healthcare policy and decision-making. Advocare provides regular training and produces education materials for use by patient groups and also provides input to health policy makers and healthcare providers. In 2012, Advocare created the Canadian Expert Patients in Health Technology, a network of individuals committed to promoting informed patient engagement at all levels of health policy and decision-making.

1.2 Conflict of Interest Declarations

With reference to this submission, the Consumer Advocare Network has received unrestricted educational grants over the past 10 years to develop materials and workshops on health technology assessment, including patient engagement with the Common Drug Review, from Canada's Research-Based Pharmaceutical Companies (Rx&D), Merck Canada, Pfizer Canada, Sanofi, Janssen-Ortho, Amgen Canada, Lilly Canada, Hoffman-LaRoche, and Wyatt Health Management as well as in-kind support from the University of Alberta to develop and conduct trainings.

Durhane Wong-Rieger is a volunteer with the Consumer Advocare Network; she is paid by the Canadian Organization for Rare Disorders and the Institute for Optimizing Health Outcomes, both of which also receive unrestricted funding from these entities for other programmes. She has no conflict of interest to declare in the preparation of this submission.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Initial information was collected from multiple sclerosis (MS) patients and carers who approached the Consumer Advocare Network for assistance in making a patient submission. Some were on Lemtrada; others were waiting to start or for approval. They expressed the need for distinct input representing those for whom Lemtrada might fill an unmet need as a result of experienced ineffectiveness of other therapies and/or intolerability due to adverse effects or impact on their lives.

Initial information was collected through individual interviews with patients and carers as well as nurses supporting MS patients and those at Bayshore Healthcare, which had been engaged to provide infusions of Lemtrada as well as other MS drugs. Advocare developed a survey that was posted on Survey Monkey; email and telephone requests were sent to selected nurses to provide the link to interested patients. We also sent the link to the MS Society, with the option for them to make it available to potentially interested individuals. Given the very short time frame between the request for assistance and the submission deadline, we felt this was the most efficient way of reaching interested patients. We also offered to speak with other individual patients and carers and conducted additional interviews.

In all, there were 12 interviews conducted, including patients using Lemtrada and waiting for access. We were able to extend the survey deadline thanks to CADTH agreement for an extension to the submission filing date; however, most responses were received by the initial deadline of November 28th. There were 63 responses to the survey, although the summary statistics for each question may represent a different number since not all participants responded to all questions. Interviews were conducted in both English and French (mostly English), and the survey was posted in English only.

Overall, most respondents were patients who identified themselves as having relapsing- remitting MS (82%); about 5% said their MS was progressive (including primary and secondary); and 5% were caregivers. The predominate age categories for the patients were 40 to 60 years of age (53%) and 30 to 40 years of age (42%), with just 3% over 60 years old and 2% under the age of 30. About 80% were female and 20% male. The range of time since diagnosis was from one year to 15 years, or more. Based on feedback provided, most respondents were from British Colombia, Ontario, Alberta, and Quebec.

The respondents were not representative of the MS patient population in Canada nor are they meant to represent all patients with similar characteristics. This submission is a summary of the responses of a group of self-identified patients and carers.

2.2 Impact of Condition on Patients

The following statistics summarize the survey response to the question about symptoms (current or in the past). The most frequent or severe symptom was pain, with 50% having experienced severe or very severe pain and the remaining 50% reporting moderate pain. Second was numbness or weakness (in one or more body parts), with 47% reporting severe or very severe and 47% indicating it was moderate. About 50% reported severe or very severe electric shock sensations from the neck, and about 30% reported none of these. Finally, about 43% reported severe or very severe fatigue, and about 36% said their fatigue was moderate. Other symptoms reported were: {temporary} loss of sight, depression, brain fog, muscle spasms and/or cramping, and over-active bladder.

The following represents summaries from the interviews and/or open-ended survey questions.

Most respondents indicated serious limitations in their physical activity exacerbated by fatigue and pain; this was accompanied by mental distress. *"Sometimes just brushing my hair is too much effort." "Last year, relapse paralyzed the right side of my body." "I used to be happy, involved in sports; used to be happy." "I have lots of pain and am on codeine, Lyrica." "I can no longer walk for more than a few blocks without resting."*

Another frequently expressed theme was the uncertainty around disease management. Many had suffered relapses after one, two, or eight years of remission. *"I still live in fear of the unknown daily." "I worry that I will progress to the point where I am incapable of caring for myself."*

Most respondents reported that MS had had a significant impact on their work or career, even if they had been on treatment and/or the disease was in remission. "MS was the end of career progression." *"As an independent contractor, I have to hide my illness from the public and my employer as I have a deep fear they will sever my contract."* Especially poignant were the comments from a young pilot, *"I have been working as a pilot for the last eight years, flying in Africa for the United Nations World Food Program and Médecins Sans Frontières. After my diagnosis I lost my aviation medical clearance, and I have been unable to work since. Every change in medication means I have to demonstrate I am stable and symptom-free for at least three months before I can regain clearance."*

Finally, patients talked about the tremendous impact on their daily lives. *"MS has completely changed my life from an intelligent multi-tasker to a simple confused individual." "I live alone; it is all I can do to take care of housework and 3 dogs; I am only 36 and feel like 90." I am still young and want children but it is not possible to try for a baby while on these medications."*

2.3 Patients' Experiences With Current Therapy

Almost 90% of these respondents have been on treatment, and many have experience with several drugs.

Of those on treatment, 92% have used corticosteroids, all in the past and none currently. About 58% have used interferon beta 1a (Avonex or Rebif)) in the past, and none currently. One-third of respondents were previously on interferon 1b (Betaseron or Extavia), and again none currently. About 42% have used glatiramer acetate (Copaxone) but only 8% are currently on this therapy.

About one-fourth are on teriflunomide (Aubagio), and 8% discontinued previous use. Currently, about 8% are on either dimethyl fumarate (Tecfidera) or fingolimod (Gilenya). About 4% are on natalizumab (Tysabri) and another 8% have used it in the past. One patient reported use of mitozantrone in the past.

Finally, 15% reported they have used Lemtrada (currently or the past.).

When asked about effectiveness in treating symptoms, about 90% said corticosteroids had been effective or at somewhat effective. Among those who had received interferon beta (1a or 1b), about 42% said it had been "not at all" effective while between 20% and 40% said it had been somewhat effective or had stopped working. About one-third of those on Copaxone said it was effective; the same percentage said it was somewhat effective; while one-third reported it had either stopped working or had never worked.

All those on Gilenya said it was effective, although one had only started so was unsure. Half of those on Aubagio said it was either effective or somewhat effective, while half said it had not worked. All

patients on Tysabri said it was effective. Similarly, all patients on Lemtrada said it was effective, although some said they had just started so said it may be too early to really tell.

Patients reported challenges with side effects to the most frequently used therapies. About two-thirds of those who had used corticosteroids rated the level of side effects as "much" or "very much"; no one said they had no side effects. Similarly, about 75% to 85% said they were "much" or "very much" affected by side effects with interferon beta. With Copaxone, about 50% rated side effects as "much" or "very much"; while one-third said they had only "some" side effects. In contrast, side effects with dimethyl fumarate, fingolimod, natalizumab and teriflunomide were rated as "little" or "none."

Finally, for those on Lemtrada, about two-thirds rated side effects during the infusion period as "much" or "some" but none afterwards. One-third reported no adverse effects during infusions.

Despite the fact that past treatments had stopped working for many of the respondents, most credited their previous treatments with giving them respite from their symptoms, reducing the severity of symptoms (on-going basis or during relapse), or delaying a relapse. Some indicated that they would have been willing to tolerate the side effects if the drugs had continued to work.

Others indicated that the side effects made the treatments intolerable, in particular, those associated with interferon beta. *"The Rebif was dreadful, the side effects were intolerable. My husband was in a much worse condition than he ever was with the MS itself. He was exhausted and had flu-like symptoms after each shot, which was 3 times a week."* About half of the respondents expressed concerns with the burden of regular injections. *"The pain of the shots and the side effects make it not worth it to me."*

Finally, several respondents said they felt they had run out of options. *"Tysabri has the risk of PML, which is significant. It also requires monthly infusions that are inconvenient." "Copaxone caused injection site reactions and required me to inject myself daily. Mitizantrone knocked me down flat out!"*

2.4 Impact on Caregivers

Only 5% of respondents were caregivers; however many patients also spoke about the impact on their families. Caregivers expressed concerns about the impact of the disease on the patient, including the experience of pain, fatigue, and limited activity, as well the inability to continue with their previous work, family and social life. Patients talked mostly about the frustration of being a burden or worry to the family. *"My mother has said she can't accept it and says MS has taken over her life, our relationship, and as such, she isn't able to provide much support." "MS has changed his [my husband's] life as well. My limitations restrict his life choices. He has gone through much grief, as he has been witness to my struggles. Our extended family has also experienced stress and worry."*

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Same interviews and surveys as described for other sections were used to collect reported information in this section.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

All respondents to this survey were aware of Lemtrada as a potential treatment for MS, with almost two-thirds indicating they had "much" or "very much" knowledge. About half also knew of Lemtrada as a treatment for another disorder.

Respondents spoke about the expectations that the drug would manage symptoms, reduce or eliminate relapses, and decrease or eliminate lesions (thereby halting disease progression). However, they were mostly realistic about the possible limitations of benefits. *"I am hoping that it will "reset" my system and prevent further damage. If it doesn't stop further damage, I am hopeful that it will slow the progression. I know that damage cannot be undone or reversed." "I expect (hope) that it will prevent additional relapses in the future, or at least limit them to only the occasional episode." "I hope that it will just stop my attacks and allow my body to 'recover' on it's own."*

Patients also spoke about the benefit of not having to take regular injections or medications. *"t would be excellent to have such minimal treatment in comparison to injections or daily pills that are a constant reminder I have an incurable disease." "I have a real fear of needles so taking a regular injection, once a day or even once a month was a nonstarter. I am on an oral drug but if that doesn't work, I would definitely want to try Lemtrada."*

Patients using Lemtrada spoke about the physical benefits. *"Since taking Lemtrada, I have better mobility. I have physical control."* Some said they noticed immediate benefits. *"With previous treatments, I still had a lot of nerve pain; suddenly, no pain." "Even after a short while, I noticed that I am walking well, and I would say my gait much improved. The distance is getting better; I can now walk a few blocks."* Others said they had just started so could not be sure but they had had no increased symptomology or relapses. Finally, patients spoke about the psychological (emotional) impact of having a drug that they could take "just once or twice" and "then getting on with your life." *"Not having a daily reminder that you have MS has given me back my life. I feel like a normal person again." "It's the closest thing to a cure."*

Patients reported that they had been fully apprised of potential side effects during infusion with Lemtrada. Some were expecting the worse, and in some cases the reactions were better and in other cases worse than expected. All said the short-term impact was worth the possible long-term benefits. *"I thought I was fine during the first three days when I was also receive steroid injections but when those stopped, the fatigue really hit me. I slept almost 20 hours." "The treatment was really rough, probably because my immune system was already compromised by my previous treatment." "I am still suffering from moderate to severe headaches on a regular basis. My vision has blurred moderately. Overall, I am feeling moderate to significant fatigue and weakness. This has not affected my desire to continue with Lemtrada. I am dealing with these side effects by having to take a lot of tylenol, migraine medication, a lot more bed rest, a new pair of eye glasses, and alternative therapies."*

All indicated they were aware of the potential long-term risks, including impact on thyroid functioning and platelets (bleeding). None of those responding were deterred by the potential risks. *"I know all of the possible side effects and I can deal with them; I know how to treat thyroid disease but not MS." "I believe with the regular monitoring the risk is minimal, because you can do something about them if they are caught early." "For sure, the requirement for regular blood work is a bother but nothing compared to other treatments."*

Section 4 — Additional Information

We asked the nurses about their concerns that patients would comply with regular monitoring, especially if their symptoms or relapses subsided. Were those some patients for whom Lemtrada would not be an option? They indicated that they would need to provide on-going support and follow-up. According to the nurses, most patients are highly motivated and recognize the risks so they felt regular monitoring would not be an issue. Among patients on Lemtrada now, none had failed to comply with regular monitoring. However, if a patient did not comply (after follow-up reminders), they would have no problem with recommending that treatment be terminated, since it represented a risk to the patient.

Multiple Sclerosis Society of Canada

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Alemtuzumab (Lemtrada)
Name of patient group	Multiple Sclerosis Society of Canada
Name of primary contact for this submission:	[redacted]
Position or title with patient group	[redacted]
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Telephone number(s)	[redacted]
Name of author (if different)	
Patient group's contact information:	
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Address	150, 9405 50 Street, Edmonton, AB T6B 2T4
Website	www.mssociety.ca

1.1 Submitting Organization

The Multiple Sclerosis Society of Canada (MS Society) is the only national voluntary organization in Canada that supports both MS research and services for people with MS and their families. The mission is to be a leader in finding a cure for multiple sclerosis and enabling people affected by MS to enhance their quality of life. The mission is reflected in the organization's two major programs which provide hope for the future through the support of MS research into the cause, treatment and cure of the disease and hope for today through services that assist people with MS and their families. An estimated 13,500 volunteers carry out service programs, fundraising events, public awareness campaigns and government relations activities. The MS Society has a membership of 20,500. The MS Society is governed by a National Board of Directors comprised of 14 volunteer members who are elected annually. The seven regional divisions and nearly 120 chapters are also governed by elected volunteer boards of directors.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

In 2013, the MS Society received educational grants from the following companies: Bayer, Biogen Idec, EMD Serono, Novartis, Pfizer, Genzyme – A Sanofi Company, Allergan, and Teva Neuroscience. The contributions totalled less than two per cent of the MS Society's overall revenue and are subject to strict policies that prevent any control or influence by the donor on MS Society decision-making.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

Nothing to declare. This submission was developed and prepared solely by MS Society staff.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information in this section was obtained from publicly available information about the impact of MS and through an online survey posted from November 6, 2014 to November 28, 2014 for the purpose of gathering information for this submission. This survey had 579 respondents and invited feedback from people affected by MS (including those diagnosed with MS and their informal caregivers) who may or may not have had experience with alemtuzumab, either through participation in a clinical trial or through access from their prescribing physician.

A link to this survey was posted on the MS Society website and sent via usual MS Society communications channels to members — predominantly those with MS, and their families. Respondents with MS answered a series of questions about themselves, how MS impacts them, their experience with existing drug therapies, and their expectations of future therapies. Caregivers answered a similar but shorter series of questions.

In this survey, 79% were women and the rest were men. Most respondents had MS (90%), whereas the rest identified themselves as caregivers (10%). All respondents were over 18 years of age, with the majority falling between the ages of 35 to 64 years. The vast majority of respondents have been living with MS for more than 5 years with 23.1% living with MS for 5-10 years, 28.4% for 11-20 years, and 21.2% for more than 20 years. The remaining participants (27.2%) report living with MS for less than five years. The majority of respondents (66%) report a diagnosis of relapsing-remitting MS with 21.6% reporting secondary progressive MS and 8.4% reporting a diagnosis of primary progressive MS.

Limitations to the survey: It should be noted that this survey did use random recruitment methods and cannot be interpreted as reflecting the views of all people with MS or caregivers in Canada. Instead, it provides the views of those who chose to answer the survey at a particular point in time.

2.2 Impact of Condition on Patients

MS is an unpredictable, often disabling disease of the central nervous system, the latter of which is composed of the brain and spinal cord. The disease attacks the myelin, a protective covering wrapped around the nerves of the central nervous system. When this happens, the usual flow of nerve impulses along nerve fibres (axons) is interrupted or distorted. The result may be a wide variety of MS symptoms, depending upon what part or parts of the central nervous system are affected. Common symptoms are difficulty in walking, fatigue, difficulty with coordination of arms or legs, loss of vision, numbness or tingling, memory or attention problems, and pain.

Based on data collected from previous surveys conducted over the last several years by the MS Society of Canada (for CADTH submissions and other MS Society of Canada work) participants consistently report the same multiple effects of MS that impact their lives, with the following mentioned most frequently: fatigue, difficulty in walking, memory or attention problems, bladder problems, numbness or tingling, heat intolerance and sensitivity, and MS-related pain. These symptoms significantly impact the quality of life of those affected by MS – not only those diagnosed with it but their friends and family as

well. In response to a question in the survey, 98% of respondents said MS had negatively affected their lives "somewhat" (43.2%) to "a lot" (54.1%). Only 2.7% said it had not affected their lives at all.

2.3 Patients' Experiences With Current Therapy

Health Canada has approved ten therapies that reduce the frequency and severity of MS relapses. Some of the drugs also have some data to support that they may have an effect on slowing the accumulation of disability over time. They are: AVONEX (interferon beta-1a), BETASERON (interferon beta-1b); EXTAVIA (interferon beta-1b); COPAXONE (glatiramer acetate); GILENYA (fingolimod); Rebif (interferon beta-1a), TYSABRI (natalizumab), TECFIDERA (dimethyl fumarate), AUBAGIO (teriflunomide) and LEMTRADA (alemtuzumab). In addition, there are a number of drugs that are used to help relieve MS symptoms such as spasticity, fatigue, and pain. The focus of this document will be on the disease-modifying therapies (DMTs). Unfortunately, no DMT has yet been approved to treat primary-progressive MS — the type of MS that shows steady progression at onset. The fact that there are no current therapies for progressive forms of MS was brought up numerous times by respondents in the survey as a concern and an area they would like focused on.

In the survey, more than half of the respondents were currently using a DMT (54%). The largest number of respondents in the survey reported using COPAXONE (33.6%), with other usage, as follows: REBIF (15.1%); TECFIDERA (13.9%) GILENYA (13%); AVONEX (8.8%); TYSABRI (7.6%); AUBAGIO (6.3%); and BETASERON (3.4%). Just less than half (44.1%) of the respondents indicated that their DMT has been successful in managing their disease; however, almost the same amount (43.3%) were not sure if their DMT had been effective. Significantly fewer, (12.6%) indicated their medication had not been effective.

Although 22% of respondents reported that they have not experienced any side effects from their DMT, many indicated experiencing side effects including (from most commonly reported to least commonly reported): injection site reactions (pain, swelling, redness, breakdown of fatty tissue/lipoatrophy), headache, flu-like symptoms (fever, chills, muscle ache, chills and sweating), flushing, gastrointestinal symptoms (upset stomach, abdominal pain, nausea, vomiting, and diarrhea), back pain, skin rashes or hives, infections (urinary, sinus, upper respiratory), and abnormal blood or liver tests. Other side effects not listed in the survey that respondents noted include: fatigue, hair loss, muscle cramping and depression.

Just over half (57.5%) of respondents indicated that they have not experienced any challenges in accessing their current DMT. However, the remaining participants reported several challenges that make it difficult for them to access their DMT. The greatest challenge reported was the high cost of the treatment, with 30.9% indicating this was a challenge for them. Additional challenges included: difficulty with administration of the drug (injections or remembering to take daily dose) (16.7%), access to public insurance (provincial drug programs) (10.7%), access to private insurance (9.9%), difficult to take time off work for administration of drug (3%), and limited transportation to get to and from treatment centre (2.6%). Additional factors mentioned by participants included anxiety associated with needles, rotation of injection sites, and concerns with insurance coverage. There were also comments in the survey that indicated that the current DMTs did not work and respondents did not see any benefit in taking them.

Following is a sampling of respondent comments about their current DMT (other than Lemtrada):

- *"Tecfidera is easier for me than injections because of my spasticity but trying to remember to eat at the right time and take dosages a specific number of hours apart can be difficult at times."*

- *"[The] side effects [are] difficult to manage but trying to get through so I don't have to go back to needles."*
- *"I find myself dreading the day of the week on which I do the shot and absolutely hating the 24/36 hours afterwards when I just feel blah."*
- *"Being unable to access a potentially helpful medication because of the high cost of the medication is both frustrating and depressing. If a drug offers any relief at all from the debilitating effects of MS it should be available to everyone."*

2.4 Impact on Caregivers

The care and assistance that many people with MS receive from their spouses, other family members, and friends is a key factor in their ability to maintain their quality of life and independence in the community. Caregivers assist in many tasks — some that are medical and others that are non-medical — that enable the person with MS to have as normal a life as possible. In the MS Society survey, over half (51.3%) of caregivers reported they assisted in administering medications all or some of the time. When asked if providing assistance impacted their own daily routines, 36.4% reported that it did all the time and 21.2% reported that it did sometimes; 75% of caregivers responded that there are negative effects from the current DMT on the person they care for at least sometimes.

Following is a sampling of responses from caregivers related to assisting with therapy and the effects on the care recipient.

- A respondent commented on their family member's condition after therapy: "*Extreme fatigue on the day of the injection. She also must take a day off work for her injection."*
- *"My husband will get affected with severe flu-like symptoms, full body aches, and is generally incapacitated for 24 hours after the administration of his drugs. As a young family, his contribution to child care and help around the home is definitely affected by his drug therapy."*
- *"The disease impacts my wife's ability to work and perform other duties in the house. This in turn impacts my ability to work and, as a small business owner, this impacts my ability to earn income for the company."*

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Same as 2.1.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

Since its Health Canada approval, alemtuzumab has been mainly accessed through clinical trials. Of the 579 respondents of this survey, only ten reported having experience with alemtuzumab. Respondents indicated that the dosing timeline with taking courses of the drugs 5 days during the first year and 3 days during the second year, created a sense of 'greater freedom' in living their lives. In addition, they reported that alemtuzumab lead to less hospital visits, fewer relapses and the ability to remain in the workforce. One respondent commented:

- *"Lemtrada is more effective than many other treatments available today. I believe that everyone who has relapsing-remitting MS should be given a chance to try to this treatment. Where the cost of other drugs can add up over time, the cost of Lemtrada is HUGE as an upfront cost. It is a shame to deprive people of medication that can make the difference over the willingness to live and go on or not. This medication changed my life. It has brought me back and given me hope for a future. Please*

pass this gift on to as many people as possible and assist those in need for financial assistance or find ways for these large drug companies and our governments to subsidize the costs of Lemtrada."

- *"Given my experience with Lemtrada stopping, or at the very least significantly slowing, the progression of my MS, as well as being someone who was previously using one of the statistically "better" disease modifying therapies... The unmet need is giving MS patients the latest "better" chance to live a normal life. Not having to perform self-injections all the time, not having to deal with the various side effects of said injections, not having to burden family members during relapses, being able to live without the constant reminder of their situation. With Lemtrada, I have gone days even weeks without having the fear of my MS progression to occupy my thoughts. I no longer am bothered by the side effects of the disease modifying therapy on a daily basis. I have been able to live a normal life and reduce (if not stopped) the growing burden on the health care system that my MS was causing."*

The vast majority of respondents of the MS Society survey had no experience with alemtuzumab however 12.7% of respondents indicated that their neurologist recommended alemtuzumab as a treatment due to demonstrated intolerance or ineffectiveness of other DMTs on the market. More than half of the respondents (54.9%) indicated that they did not know if they would be willing to trade the risk of potential adverse effects of alemtuzumab for the perceived benefits, 28.1% said they would be willing to trade the risks for the benefits and 17.1% said they would not be willing to take the risk. This data may reflect a lack of knowledge about alemtuzumab or the awareness of some of its known adverse effects as compared with the known safety profiles and side effects of older DMTs.

Comments regarding mode of administration and side effects are also important to take into consideration. When asked what a new DMT should do better than existing therapies, their comments included: lower and/or limited side effects, be more affordable, be more convenient (e.g., no refrigeration), and improve everyday function.

Respondents who had been treated with alemtuzumab identified the following common side effects: infusion-associated reactions (headache, rash, fever, nausea, hives, itching, insomnia, chills and flushing), fatigue, bruising and tingling sensations. Although no fewer side effects were reported compared with the other DMTs, the administration of the medication annually, as compared with daily, weekly or monthly medication schedules means that individuals do not experience side effects as frequently as those treated with other DMTs. Side-effects of MS medications can negatively impact a person's ability to perform their job, meet regular family, recreational or social commitments and maintain a quality of life they aspire to keep while living with MS.

- *"The ability for a short term treatment versus a daily or weekly treatment allows a person with MS to operate without having the illness contribute to a general feeling of poor health."*

Of the ten respondents who have been treated with alemtuzumab, they identified minimal challenges related to access. This is due largely to the fact that most respondents who have been treated with alemtuzumab received the medication through participation in a clinical trial. One respondent stated that they had no issues accessing the treatment thanks to a good benefit plan paired with a supportive family and employer and another respondent commented that they faced an access challenge in that they had to wait a lengthy period before seeing their neurologist and initiating treatment.

It should be noted that patients choose different therapies depending on their life circumstances (family, work, functional ability), not just for the sake of convenience. For example, some individuals

don't have the functional ability to inject themselves, thus relying on family and friends. This promotes an environment of dependency.

Section 4 — Additional Information

People with MS must cope with a disease that is relentlessly unpredictable. Each day, they face the possibility that they may experience another symptom or another relapse. The current MS therapies have provided people with a way of reducing relapses and possibly slowing the progression of disability. The potential choice of more MS drugs that have greater efficacy and a different and finite timeline for dosing is exciting and potentially life-changing for many people with MS.

In RRMS, it is known that the frequency of relapse is highly variable but tends to be more frequent in the first few years of disease onset. The therapeutic aims of MS drugs are to lower the frequency of relapses, decrease the lasting effects of relapses, prevent or decrease disability that is the result of disease progression, and promote tissue repair. Thus this committee should support interventions that are the most efficacious early on in the disease, take into account the variability that exists in the MS population, as well as the need to consider choice. Respondents in the survey commented on the importance of having options of several therapies to match an individual's disease and life situation.

In the survey, respondents were offered the chance to provide feedback to the CDR Committee about the impact of MS and the various treatment options on their lives. Here is a sampling of the comments:

- *The daily injections are still very expensive even with additional coverage, and often times you have to try more than one therapy to get even minimal results. For patients, like myself, who are on a disability pension this is a terrible burden. The ability to have any kind of therapy provide lasting relief from symptoms in a short amount of time has had a very positive impact on my life. It has given me the hope that I may be completely symptom free and that I may be able to return to my "normal" life."*
- *"With little to no progression of my MS, I have required SIGNIFICANTLY LESS medical intervention - whether it be unscheduled MRIs to identify new lesions, therapies for new or worsening symptoms - comparatively to what I required prior to being treated with Lemtrada.*
- *"Without my current therapy I have no doubt that I would not be doing as well as I am. But I could not be doing the current therapy I am without the aid of Pharmacare or my health benefits through work. These medications are so expensive - there is no way I could afford it without this help. These therapies can greatly improve quality of life. Without having reimbursement approval on drugs it really hinders the progress people suffering from this illness can make."*
- *"They need to know without MS drug therapies many people like myself would not be able to function normally. I am a professional with full drug coverage for my MS medication. I work full time and am the primary wage earner for my family. If I did not have coverage for my drugs I would not be able to afford them and as a result my MS symptoms would prevent me from working and supporting my family and this would add hardship to my family and costs to our government system. There needs to be a reimbursement program available for people who do not have coverage for their MS drugs so that they can continue to function normally and contribute to our society for as long as possible."*
- *"It is always cost prohibitive to try a new drug. For those of us who have had no luck with other therapies, there are many hoops to go through. Pharmacare decides which drugs will be covered so our choices are basically made for us. Sometimes we are forced to take therapies because we are desperate and have limited choices."*