Patient Input for CADTH CDR and pCODR Programs

| Name of the Drug and Indication | Insulin lispro biosimilar (Admelog), Diabetes Mellitus, type 1 & 2 |
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| Name of the Patient Group | Diabetes Canada |
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1. About Your Patient Group

Diabetes Canada is a national health charity representing 11 million Canadians living with diabetes or prediabetes. The organization leads the fight to end diabetes by helping those affected live healthy lives, preventing the onset and consequences of the disease, and working to discover a cure. It has a heritage of excellence, innovation and leadership. It is supported in its efforts by a community-based network of volunteers, employees, health care professionals, researchers and partners. By providing education and services, advocating on behalf of people with diabetes, supporting research and translating it into practical applications, the organization is delivering on its mission. For more information, please visit: www.diabetes.ca.

2. Information Gathering

This submission was completed using data from patient input surveys conducted in October 2016 and October 2017 that were distributed through social media (Facebook, Twitter and LinkedIn) and e-blasts. The former survey was available online from October 12 to October 26, 2016 and solicited feedback from people living in Canada. Among other topics, this survey inquired about respondents' lived experience with diabetes and expectations for new drug therapies for diabetes in Canada. The group of respondents consisted of 790 people living with type 2 diabetes and 57 people who identified as a caregiver to someone with type 2 diabetes. Of those who responded to questions related to age and time since diagnosis (n=379), 71% were over 55 years of age (with 40-54 year olds comprising an additional one-quarter of survey respondents) and 60% had been living with diabetes for 11+ years (with another 26% having been diagnosed 6-10 years ago).

The latter online survey was open to the public from October 16 to October 30, 2017. It solicited feedback from people living in Canada with type 1 or type 2 diabetes and their caregivers. This survey inquired about the impact diabetes has had on respondents' lives, their experience with various antihyperglycemic agents, including the drug under review (insulin lispro biosimilar [Admelog]), and their opinions about biosimilar biologic drugs for diabetes management. A total

of 16 survey respondents reported having been diagnosed with type 1 diabetes, 16 reported having been diagnosed with type 2 diabetes, and 5 were caregivers to someone with type 1 or type 2.

In the October 2017 survey, among those who provided a response to age and duration of illness related questions (n=27), 7% had been living with diabetes for less than 1 year, 30% have been living with diabetes for 1-10 years, 26% had been living with diabetes for 11-20 years, and 37% had been living with diabetes for over 20 years. The majority of people who provided age-related data (n=27) were over 25 years old (89%), with the biggest groups of respondents falling within the 25 to 39 year age category (26%) and the 40 to 54 year age category (33%).

3. Disease Experience

Diabetes is a chronic, progressive disease with no known cure. Type 1 diabetes occurs when the body produces either very little or no insulin. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body does not effectively use the insulin that is produced. Common symptoms of diabetes include extreme fatigue, unusual thirst, frequent urination and weight change (gain or loss).

Diabetes requires considerable self-management, including eating well, engaging in regular physical activity, maintaining a healthy body weight, taking medications (oral and/or injectable) as prescribed, monitoring blood glucose and managing stress. Poor glucose control is serious and problematic. Low blood glucose can precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to being dangerous conditions in and of themselves, may also contribute to a motor vehicle, workplace or other type of accident causing harm. High blood glucose over time can irreversibly damage blood vessels and nerves, resulting in blindness, heart disease, kidney problems and lower limb amputations. The goal of diabetes management is to keep glucose levels within a target range to minimize acute symptoms and avoid or delay complications.

For most survey respondents, diabetes has negatively affected all aspects of their lives and limited activities and opportunities, including travel and career. They described the disease as "very scary", a "struggle", and "always in your face". Many expressed frustration and anger with the daily challenge of maintaining normalcy. They described diabetes as a disease that "interrupts daily life", forces them to live in a very regimented way and makes their schedules inflexible. A number of respondents talked about loss – of their driver's license, of their employment, of their independence and their sense of spontaneity. Life with diabetes was characterized as "miserable" and "a constant battle every day". The word "suffering" was used to describe people's experience. Management was "hectic", "horrendous" and a "constantly overwhelming learning curve".

Many respondents indicated they are experiencing complications as a result of diabetes, including nerve damage, ulcers, foot problems, heart/circulation problems, eye/vision problems, and kidney problems. Others disclosed fatigue and a lack of energy. Feelings of depression and anxiety were often cited. Several also mentioned the hardship of dealing with diabetes alongside other comorbid conditions.

In the October 2017 survey, respondents (n=32) reported "sometimes", "often" or "very often" experiencing the following symptoms or conditions in the present tense:

- hypoglycemia (70%)
- high blood pressure (59%)
- high cholesterol (50%)
- mental health problems (52%)
- kidney symptoms or disease (32%)
- foot problems (45%)

- eye problems (45%)
- nerve damage (45%)
- damage to blood vessels, heart or brain (23%)
- liver disease (6%)
- endocrine disorders (20%)

Frequent yeast infections and joint problems were also cited as issues.

There was a lot of emphasis on the psychological and emotional impacts of diabetes on the lives of respondents and their family members. These come as a result of having to adjust to changes in diet and lifestyle, deal with a variety of stressors, maintain daily medication and treatment regimens, manage strain on relationships, and cope with financial burden. For individuals who have to manage diabetes and care for other members of the family, it is particularly difficult.

Several people spoke about the stigma related to diabetes and their experience explaining the disease to others. They commented that people "don't get it", "stare...as you inject insulin" and "do not understand" diabetes. Respondents shared that they get "tired of educating people all the time". Diabetes was described as a condition that just "isn't fun to have to live with".

Below are more quotes from the October 2017 survey respondents that are illustrative of the impact diabetes has on all aspects of life:

"I am a type one diabetic for 27 years since the age of 8, and just recently underwent a kidney transplant due to complications of diabetes so I guess you can say [diabetes] affected my life in a huge way."

"The financial cost makes life with diabetes unbearable at times."

"I would run into trouble working nights and eventually took early retirement because I was constantly low and couldn't control my sugars."

"As I was diagnosed at the age of 13 it directly impacted my parents as they had to take time off work to assist me in my new diagnosis. This also impacted them following this transition on a daily basis by taking the extra time to carb count or prepare special meals for me...My disease also impacts my sleep, as I cannot sleep if my blood sugar is too high or too low or needs to be treated throughout the night. This illness has also impacted myself and my family financially as my health insurance does not cover the costs of all my health supplies. When my blood sugar is too high or too low it can be extremely difficult to focus or read which impacted my academic studies and work performance."

"Diabetes has had a huge impact on my life since being diagnoses[sic] 8 years ago. Everyday tasks that I took for granted are now more difficult and take a ton of extra work."

"How has it not [affected life]? Near-death experiences, increased expenses, lost employment revenue, and many, many, many sleepless nights."

"My health has deteriorated since being diagnosed with type 2. I have had surgery for a diabetic ulcer on my toe. I have sever[sic] peripheral nerve damage in my legs. My eyes have now show[sic] nerve damage as of 6 months ago. My mobility is limited. Because of high costs of

drugs my finances are affected. I am self employed[sic] and not fully covered. My moods are affected. I am depressed. I can't do the activities with my children like I used to."

"Constant worry about highs and lows, reduced life expectancy of my wife, stress and mood swings.

"Life has become challenging due to the rigid nature of diet, meal times, sugar checks, doctors[sic] appointments, etc..."

"Constantly need to be in tune with my blood sugars and manage risk as much as possible. Not always easy when you're also trying to raise a young family and drive your career. I'm also concerned about the risk that my children could inherit genetic factors that influence progression to type 1 diabetes."

4. Experiences With Currently Available Treatments

A total of 647 people with diabetes and caregivers that responded to the October 2016 survey indicated experience with diabetes medications. The medications being taken at the time of the survey included Metformin (371), GLP-1 agonists (312), SGLT2 inhibitors (165), combination of SGLT2 inhibitors with Metformin (45), DPP-4 inhibitors (72), combination of DPP-4 inhibitors and Metformin (147), sulfonylureas (140), TZDs (10), combination of TZDs with Metformin (17), combination of TZDs with glimepiride (4), meglitinides (9) and acarbose (9). Some respondents indicated that they stopped using medications due to reasons other than the end of a clinical trial. The most commonly cited medications in this group were TZDs (97), sulfonylureas (94), GLP-1 agonists (94) and DPP-4 inhibitors (92). There were 309 respondents who reported taking insulin.

More than half of the respondents on antihyperglycemic agents noted improvement in meeting target blood glucose levels (fasting, post-prandial, upon waking) and hemoglobin A1c levels after initiation on their current medication regimen, as compared to before. About two-thirds of respondents indicated they were either "satisfied" or "very satisfied" with the medication or combination of medications they are currently taking for their diabetes management.

In the more recent survey conducted in October 2017 specifically focusing on rapid-acting insulin use, 28 respondents had experience with the following rapid-acting insulin analogues: insulin lispro (Humalog) (16), insulin glulisine (Apidra) (1) and insulin aspart (NovoRapid) (11). When asked about whether or not their diabetes was well-controlled on the insulin(s) they are current taking, 17 responded "yes", 4 responded "no" and 9 responded "not sure/don't know".

Several people mentioned cost as a barrier to accessing rapid-acting insulin analogues for diabetes management. Others said that poverty and a lack of insurance made it difficult to obtain insulin.

Below are some direct quotes from respondents to the October 2016 survey who commented on what works well, and not so well, with current therapies:

"The meds I am currently taking are working quite well." (person with type 2 diabetes, diagnosed 11-20 years ago, aged 55-69 years, who takes Metformin, a GLP-1 agonist and insulin and tried one other drug in the past as part of a clinical trial, noted improvement in ability to meet blood glucose and hemoglobin A1c targets, maintain/lose weight and decrease level of thirst)

"With the present combination of medications now, I am achieving the same or better results than before." (person with type 2 diabetes, diagnosed more than 20 years ago, aged 55-69 years, who takes Metformin, a sulfonylurea and a GLP-1 agonist and tried in the past but

stopped two other drugs, noted improvement in ability to meet blood glucose and hemoglobin A1c targets, maintain/lose weight and avoid hypoglycemia)

"[A particular antihyperglycemic agent] has been excellent, has decreased very substantially my need for both basal & bolus insulin as well as other medications, reduced hypoglycemia & achieved weight loss." (person with type 2 diabetes, diagnosed more than 20 years ago, aged 70 years and over, who takes Metformin, a GLP-1 agonist, an SGLT2 inhibitor and insulin and tried six other drugs in the past as part of a clinical trial, noted improvement in ability to meet blood glucose and hemoglobin A1c targets, maintain/lose weight and decrease level of thirst)

"Needles to administer insulin twice daily is painful but necessary. Current medications do not cause adverse side effects." (person with type 2 diabetes, diagnosed 6-10 years ago, aged 55-69 years, who takes a combination of SGLT2 inhibitor and Metformin, and insulin and tried in the past but stopped two other drugs, noted improvement in ability to meet blood glucose and hemoglobin A1c targets, avoid hypoglycemia, maintain/lose weight, decrease level of thirst and avoid side effects such as gastrointestinal disturbances, yeast infections and urinary tract infections, upper respiratory infections, bone fractures and organ damage)

"I have had poor control of my blood sugars over the years. I have tried products that either did nothing or caused more problems. [One particular medication] is assisting with better control. However, if my husband's health plan from work didn't cover it, I wouldn't be able to take it as [it is costly]. I take a lot of meds and wish I didn't have to." (person with type 2 diabetes, diagnosed more than 20 years ago, aged 40-54 years, who takes Metformin, a GLP-1 agonist and insulin and tried in the past but stopped five other drugs, noted improvement in ability to meet blood glucose and hemoglobin A1c targets, avoid hypoglycemia and decrease level of thirst)

5. Improved Outcomes

When asked about what they hope new diabetes medications can help address, the majority of respondents to the October 2016 survey said they would like stable blood glucose levels and improved glycemic control without weight gain. They expressed the desire for new treatments to enhance weight loss and improve health outcomes at an affordable cost. They also wished for medications that would help them avoid polypharmacy and eliminate the need for injections while minimizing risk of any short-term medication-related side effects or long-term disease-related side effects. Several respondents hope future treatments will reverse or cure diabetes.

Below is some input respondents provided regarding their expectations for future diabetes therapies:

"I hope they get cheaper so we can afford the ones that work the best."

"I'd like to take one pill a day and not have to worry about my blood sugar."

"I hope it will help control blood glucose from going to[sic] high and I hope it helps from getting any stroke or heart attack."

"I hope the new medications will be trial tested to determine efficacy for all patients."

"I hope that the new medication will be included in most general health plans so that the patient does not have to pay [high costs]."

"Keep our islet cells working in our pancreas to keep our blood sugars in normal range."

"Give [people with diabetes] part of their lives back through better management and care."

"Reduce the need to take so many medications simultaneously."

"Make [diabetes] go away somehow, someday, someway[sic]."

6. Experience With Drug Under Review

Admelog has not yet received a Notice of Compliance from Health Canada. This significantly limits the number of people with diabetes living in Canada who would have first-hand experience with this drug. Of the 28 respondents to the October 2017 survey who reported being prescribed a rapid-acting insulin analogue as part of their treatment regimen, none had ever used Admelog. There were 2 respondents who reported being "somewhat familiar" with the drug and 1 who was "a little familiar" with it; the rest of respondents (29) said they were "not at all familiar" with Admelog.

7. Companion Diagnostic Test

Question 7 is not applicable to this submission.

8. Biosimilar

If the drug in review is a biosimilar (also known as a subsequent entry biologic), please outline any expectations or concerns held by patients, caregivers, and families about the biosimilar. If the biosimilar was less expensive than the brand name drug, what would the impact be for patients, caregivers, and families?

Survey respondents were asked to provide input on how they think Admelog would compare to Humalog on several different measures. If they were previously unfamiliar with Admelog, respondents were encouraged to provide their best guess in responding to the questions. The data showed the majority of respondents were unsure of, or had not formulated an opinion on, how Admelog compares to insulin lispro (Humalog).

With respect to the reduction of daytime hypoglycemia and overnight hypoglycemia, in both cases, 34% of respondents believed Admelog would be comparable to Humalog, 3% believed it would be better and 6% believed it would be worse. The remaining 56% of respondents stated they didn't know or had no opinion. When questioned about Admelog's effectiveness at slowing the progression of diabetes complications, 28% thought it would be the same as Humalog, 3% thought it would be better and 6% thought it would be worse. The remaining 63% of respondents stated they didn't know or had no opinion. About 32% of respondents assumed Admelog would have the same side effects as Humalog, while 3% thought it would have more side effects and 6% thought it would have fewer side effects. The rest (58%) indicated they weren't sure or had no opinion.

Regarding Admelog's cost compared to Humalog, 25% of respondents anticipated Admelog would be similarly affordable, 3% anticipated it would be more affordable and 9% anticipated it would be less affordable. The remaining 63% of respondents stated they didn't know or had no opinion. When posed the question of whether or not they would try Admelog if Humalog was hypothetically part of their treatment regimen, 43% said they would do so if the cost of Admelog was lower. About 23% of respondents said they may switch from Humalog to Admelog if the price of the two drugs was the same, while 6% reported they would switch even if Admelog cost more than Humalog. Another 6% said they would not switch to Admelog, regardless of its cost; 47% had no opinion. A total of 77% respondents said Admelog should be made publically

available to Canadians with diabetes through the provincial drug plans; the rest of respondents (33%) were not sure.

When asked whether Admelog could replace the original product (Humalog) once a patient has been on Humalog for a period of time (i.e. a one-time switch) almost half (46%) of respondents replied "yes, with physician approval". Many respondents were not sure or had no opinion on inter-changeability of Admelog and Humalog which emphasizes the need for engagement and education of patients on this issue.

Respondents provided the following comments regarding their impressions of, and expectations for, Admelog:

"For me to use Admelog it would have to work exactly like Humalog and cost less."

"I'm hoping that it will act more quickly than [other rapid-acting insulins] so that I don't spike as high after a meal."

"Help keep blood sugar levels even."

"Hopefully cost would be more affordable for those with out[sic] benefits."

"It will probably cost slightly less than Humalog. It will be good for it to be available in case there are ever drug shortages, etc."

The following general comments were also provided:

"A lower priced insulin would be beneficial to ALL!"

9. Anything Else?

Diabetes is a disease that requires intensive self-management. To achieve optimal blood glucose levels, individualization of therapy is essential, including selecting the drug or combination of drugs, route of administration (oral, injection, pen or pump), how frequently the patient monitors blood glucose and adjusts dosage, the benefits and risks that the patient experiences and/or tolerates, and the lifestyle changes the patient is willing or able to make. Our survey responses reinforce the understanding that different people with diabetes require different medications/treatment modalities to help effectively manage their disease. Their clinical profile, preference and tolerance of therapy can direct physicians to the most appropriate choice and combination of drugs.

Many people with diabetes hope for less dependence on insulin and medications. While current therapies have generally led to improvement for many people with diabetes in terms of blood glucose and hemoglobin A1c control, respondents hope for better, more affordable antihyperglycemic agents to help them lead a normal life. Insulin lispro biosimilar (Admelog) may help people to achieve glycemic control, which could potentially improve health outcomes and may provide this at more affordable therapy. For this reason, insulin lispro biosimilar (Admelog) should be an option for people living with diabetes.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

- 1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.
 - No, there was no assistance or influence of any kind from outside the patient group in the completion of this submission.
- 2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.
 - No, there was no assistance or influence from outside the patient group in the collection or analysis of data for this submission.
- 3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
 - Please find attached a list of organizations who have provided financial support to Diabetes Canada, along with the amount provided.

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Seema Nagpal, BSc Pharm, MSc, PhD

Position: Epidemiologist and Senior Leader, Public Policy

Patient Group: Diabetes Canada

Date: November 16, 2017



Appendix: Organizations and foundations that made donations to the Canadian Diabetes Association (Diabetes Canada) in 2015. Source: CDA (Diabetes Canada) 2015 Annual Report; available at http://www.diabetes.ca/getmedia/0204ddb9-8942-4033-9dca-21547d2d8007/2015-cda-annual-report.pdf.aspx

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(Ladies Section)

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