

B.C. PHARMACARE'S PUBLIC INPUT QUESTIONNAIRE
FOR DRUGS BEING REVIEWED UNDER THE B.C. DRUG REVIEW PROCESS

Drug Under Review: ertugliflozin (Steglatro)

Date Submitted: September 19, 2018

Confirmation of Eligibility

1. I am a representative of a patient group that represents patients in British Columbia who have the medical condition or disease which the drug under review would be used for AND the patient group which I represent has registered with PharmaCare to give input.

YES

Contact Information

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Conflict of Interest Declaration

6. Does your patient group have any Conflicts of Interest to declare?

YES

7. Describe any Conflicts of Interest below.

Diabetes Canada receives unrestricted educational grants from, among others, manufacturers/vendors of medications, supplies and devices for diabetes and its complications. These funds help the organization to support community programs and services for people with diabetes and contribute to research and advocacy efforts across Canada. No sponsor was involved in soliciting or developing the content of this submission.

Questions on the Drug Under Review

8. Have you read the PharmaCare information sheet for this drug?

YES, I have read the information sheet.

9. Describe how the medical condition or disease which the drug under review would be used for affects the day-to-day life of the patients in your group.

Diabetes is a chronic, progressive illness with no known cure. 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 seizures that, in addition to being dangerous 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 complications such as 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 symptoms and avoid or delay secondary disease.

This submission contains patient input from online surveys conducted in October 2016 and April/May 2018. Each survey was open for two weeks to people across Canada and consisted of a self-administered questionnaire. The surveys were directed at people living with type 2 diabetes and caregivers of people with type 2 diabetes and inquired about respondents' lived experience with diabetes and diabetes medications, and expectations for new drug therapies in Canada. The more recent of the two surveys posed a number of questions specifically about the drug under review, ertugliflozin (Steglatro), and the combination medication ertugliflozin and metformin (Segluromet).

A total of 847 people participated in the October 2016 survey, with 86 reporting residence in British Columbia. Every respondent from British Columbia was over the age of 40, with the majority (67%, n=58) having lived with type 2 diabetes for over 10 years. Fewer people participated in the April/May 2018 survey – responses were collected from a total of 52 respondents. Of those who answered the question about province of residence, nobody reported living in British Columbia. All respondents in this survey were also over the age of 40 and the time living with diabetes ranged from 1 to 2 years through to over 20 years.

Most people surveyed talked about the negative impact diabetes has had on their lives. They reported constantly thinking about and planning around their disease, and talked about the stress this incites. They spoke about the ways that diabetes interferes with every aspect of life, from eating and exercising to working and socializing. People commented that diabetes makes it difficult to be flexible and spontaneous. Daily medication, constant

monitoring of blood sugar levels and frequent visits to health care providers were described as burdensome. People attested to the fact that diabetes is even more difficult to treat when someone is also dealing with comorbidity or disability.

Several respondents spoke about the blame they inflict upon themselves for their disease, the shame and guilt they feel, and the stigma they experience. Some talked about how tough it is to interact with people who know very little about diabetes or who offer unsolicited advice about its management. People shared that diabetes has adversely affected relationships and decreased independence. They also mentioned the significant and overwhelming financial burden the disease inflicts on individuals and families.

Many people mentioned dealing with, and being apprehensive about, disease symptoms, medication side effects and diabetes complications. Respondents described being chronically in pain and exhausted. They cited problems ranging from weight management issues, neuropathy and nephropathy, to amputations, changes to circulation, vision problems, and sexual difficulties, including erectile dysfunction. They also reported living with depression and anxiety.

Of the total responses to questions about symptoms and disease complications in the April/May 2018 survey (n=21), the following were said to have been experienced “sometimes” (“moderately”), “often” (“severely”) or “very often” (“very severely”):

- hyperglycemia (81%)
- hypoglycemia (40%)
- high blood pressure (62%)
- high cholesterol (53%)
- heart problems (30%)
- mental health problems (55%)
- kidney symptoms or disease (30%)
- foot problems (50%)
- eye problems (57%)
- nerve damage (50%)
- damage to blood vessels, heart or brain (25%)
- liver disease (30%)

Below are select quotes from British Columbians that demonstrate the challenges of living with diabetes:

“Life is very regimented....sometimes it can be frustrating to have no flexibility and always be on the same schedule, even on holidays.”

“I love to cook but it restricts the things I eat.”

“I am always having to keep track of my sugars and my food...I am concerned about my future and worry about complications.”

“Taking medication is a part of my daily routine and if I for any reason miss taking it can suffer low blood sugars which is very unpleasant. Diabetes also has an impact on my vision, and...if my blood sugars are high or uncontrolled for any reason my vision is not clear and my eyes feel very tired.”

"My mood is often flat or down, I am anxious about my health and taking medication while traveling is somewhat challenging."

"I am now experiencing problems due to long term diabetes such as heart issues and kidney problems."

"I can't eat whatever I want anymore. I have to remember to take medication. I have neuropathy in my feet."

"My fear is that I will not be able to afford [a particular antihyperglycemic agent] when I retire and no longer have medical coverage."

"I am concerned about further loss of health and possible complications in the future...I often get weary of the daily discipline required to manage diabetes daily in order to prevent or delay these possible future outcomes...I am concerned about possible financial hardships in the future. I currently have extended medical coverage for my medications but given how expensive some are...I may use up my lifetime maximum before I die and will have to cover much of the costs through my pension and savings."

"I have had type 2 diabetes for over 20 years. I think it has taken me that long to actually get it under control...I have found that family members try to understand but truly do not understand what a diabetic goes through everyday [sic]...The only one that truly understands is yourself."

10. What drugs or other treatments have the patients in your group used, either now or in the past, to treat the medical condition or disease which the drug under review would be used for?

Medications being used

Many respondents reported antihyperglycemic agents being part of their past or present medication history (or the history of the person for whom they provide care) in both surveys. A number of people mentioned having to take multiple medications as part of their prescribed treatment.

In the study conducted in April/May 2018, the following medications were reported as being currently in use by respondents: metformin, GLP-1 receptor agonists, SGLT2 inhibitors, DPP-4 inhibitors, combination of DPP-4 inhibitors and metformin, sulfonylureas and combination of TZDs and glimepiride. Insulins in use (or previously trialed) were reported as follows: long-acting, combination of long-acting (insulin glargine) with SGLT2 inhibitors, intermediate-acting, rapid-acting and premixed. Some respondents indicated that they had experience with certain medications in the past as part of a clinical trial (but are now no longer taking them). A small number reported stopping certain medications due to reasons other than the end of a clinical trial. The most commonly cited medications

in this group were sulfonylureas, DPP-4 inhibitors, short-acting insulin, premixed insulin, combination of DPP-4 inhibitors with metformin and TZDs. Respondents mentioned various reasons for stopping medications, including they were directed to do so by their prescribing physician (in some cases, they were switched to another medication or one was discontinued because of contraindication with other medications), they experienced intolerance/unpleasant side effects and the medication wasn't covered by their insurance.

Satisfaction with current therapy

Of those who responded to this survey question, over 45% said they were "better" or "much better" able to meet blood glucose targets in general, upon waking, and post-prandially on their current antihyperglycemic therapy than before. Several also stated that their current medication(s) helped them achieve hemoglobin A1c targets "better" or "much better" than their previous regimen. On current medications, the following were cited as being "somewhat worse" or "much worse" than before: ability to maintain or lose weight, thirst/dehydration and incidence of yeast infection/urinary tract infection.

When asked what factors were "quite important" or "very important" in choosing diabetes medications, 93% of respondents reported the following: keeping blood glucose at satisfactory level during the day or after meals and upon waking or after fasting, avoiding low blood sugar during the day, avoiding weight gain/facilitating weight loss, reducing risk of heart problems, and avoiding gastrointestinal issues (nausea, vomiting, diarrhea, pain), and urinary tract and/or yeast infections. At least 80% of respondents said it was "quite important" or "very important" for diabetes medications to help avoid low blood sugar overnight, help avoid fluid retention, and reduce high blood pressure.

Below are some direct quotes from British Columbians who responded to the April/May 2018 survey that describe what they like and dislike about current therapy:

"Pills are small enough to swallow easily."

- 40-54 year old person with type 2 diabetes, diagnosed 3-5 years ago, taking a DPP-4 inhibitor and SGLT2 inhibitor

"My levels are good across the board. I work with an endocrinologist which has been key to my success."

- 55-69 year old person with type 2 diabetes, diagnosed 11-20 years ago, taking a combination DPP-4 inhibitor and metformin, and SGLT2 inhibitor

"I enjoy the once a day injections over trying to manage pills over the course of the day."

- 40-54 year old person with type 2 diabetes, diagnosed 11-20 years ago, taking a GLP-1 receptor agonist, SGLT2 inhibitor and metformin

"If I use more insulin on certain days or situations then I feel fear about filling my prescription. Like i [sic] get judged on how much."

- 40-54 year old person with type 2 diabetes, diagnosed 6-10 years ago, taking metformin

and insulin (long-acting and rapid-acting)

“Constant testing, highs and lows.”

- 55-69 year old person with type 2 diabetes, diagnosed 11-20 years ago, taking a combination DPP-4 inhibitor and metformin, and insulin (long-acting and rapid-acting)
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11. If the patients in your group have tried the drug under review, please tell us about the effects they experienced.

Experience with Ertugliflozin

Ertugliflozin (Steglatro) has not yet received a Notice of Compliance from Health Canada. Consequently, few Canadians would have first-hand experience with the medication to report on. Of those who participated in the April/May 2018 survey and responded to the questions specific to ertugliflozin (Steglatro) (n=18), 50% said they have never tried ertugliflozin (Steglatro) and 50% said they weren't sure whether they had or not. Respondents did not provide any feedback on the population groups they felt this medication would especially help.

Experience with SGLT2 inhibitors

A total of 34 respondents from British Columbia reported their current regimen included an SGLT2 inhibitor, while others said they had been previously on an SGLT2 inhibitor. Another 6 people said they are currently taking a combination medication consisting of an SGLT2 inhibitor and metformin.

12. How do you think the patients in your group could benefit from using the drug under review? (For example: relief of existing symptoms; improvements in quality of life; or improvements to their condition and long-term health and well-being. Please provide details.)

Diabetes is a disease that requires intensive self-management. Diabetes Canada's 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada highlight the importance of individualized pharmacologic management of the condition. Specifically, after initiating healthy behaviour measures, the guidelines recommend selecting diabetes treatments based on a patient's degree of glycemic control and other considerations. To achieve optimal blood glucose levels, personalized therapy is essential. This includes careful consideration of medication selection, route of administration, frequency of self-monitoring of blood glucose, benefits and risks that the patient experiences and/or tolerates, and lifestyle changes the patient is willing or able to make. Our survey responses reinforce the message that different people with diabetes require different medications/treatment modalities to help effectively manage their disease. Their

unique clinical profile, preferences and tolerance of therapy should direct physicians to the most appropriate choice and combination of treatments for their disease management.

While current therapies have generally led to improvement for many people with diabetes in blood glucose and hemoglobin A1c control, respondents continue to hope for effective, affordable antihyperglycemic agents that they can access equitably, in a timely manner, and with minimal side effects to help them lead a normal life. Ertugliflozin (Steglatro) may help people to achieve better glycemic control, which could potentially improve lives and save millions of dollars in direct health-care costs. For this reason, ertugliflozin (Steglatro) should be an option for people living with diabetes.

13. Are there any additional factors your organization would like PharmaCare to consider during its review of this drug? (For example: does the drug meet any special patient needs that have not been met by other drugs or treatments; is the drug easier to use than other drugs; does the drug reduce visits to the hospital; does the drug reduce days off work or school; or are the drug's side effects acceptable or intolerable?)

When asked about their expectations for new diabetes therapies, respondents to the October 2016 and April/May 2018 surveys expressed a strong desire for medications that can normalize/stabilize blood glucose levels and improve hemoglobin A1c without causing weight gain or hypoglycemia. They wish for new treatments in a timely manner that have been proven to be safe, enhance weight loss and improve health outcomes. They want affordable drug options that, ideally, are covered by public and private plans. They want treatments that are easily administered, with few to no associated side effects, that cause the least amount of disruption to lifestyle and allow for flexibility with food intake and choices. They also want medications that minimize the risk of diabetes-related complications, help avoid polypharmacy and eliminate the need for injections. Several respondents hope future treatments will reverse or cure diabetes.

Below, respondents provided input on what they desire in new treatments, the improvements they'd like to see to therapies, and the impact these would have on daily life and overall quality of life:

"Help with managing my levels and avoiding nerve damage."

"I'd like to have a weekly or less often medication."

"Minimal side effects."

"Less meds mean less preparation [sic] time and less time per day for glucose level testing."

"Better focus at work, better memory retention."

"It would be nice to not have to take shots anymore. Would be nice to be able to just take pills again."

"I have been on a diet my entire life. If my diabetes medication could at least not make it harder for me to lose weight it would help in the quest to lose weight and enjoy the benefits of that weight loss."

"Peace of mind that there's is [sic] less chance of damage to my body. Less risk of complications like heart disease etc."

"Stable blood sugar and reduced worry about heart attack, stroke, blindness and dementia would make all the difference to my overall stress levels and mood. Losing weight would just make everything easier and move overall health into a positive trend."

"Expectations are that eventually there will be a medication that can be taken once a day that will help my pancreas produce the right amount of insulin to keep up with me (or possibly even cure the disease). I would hope that medications are made available to anyone living with diabetes and covered under by our government benefits."

