

# Breztri™ Aerosphere® now available in Canada for long-term maintenance treatment of COPD



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MISSISSAUGA, ON, Oct. 24, 2022 /CNW/ - Today, AstraZeneca announced the Canadian availability of Breztri™ Aerosphere® (budesonide/glycopyrronium/formoterol fumarate dihydrate), indicated for the long-term maintenance treatment to reduce exacerbations of chronic obstructive pulmonary disease (COPD) and treat airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema who are not adequately treated by a combination of an ICS/LABA or a combination of a LAMA/LABA.<sup>1</sup>

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# Understanding COPD Exacerbations

Chronic obstructive pulmonary disease (COPD) is a chronic lung disease that causes difficulty breathing and includes emphysema and chronic bronchitis.<sup>1</sup> However, COPD reaches far into the lives of patients, beyond breathlessness, and can lead to social isolation, loss of independence, impairment of daily activities, and can negatively impact mental health.<sup>2</sup>

## About COPD

3

rd leading cause of death worldwide<sup>3</sup>

2M

roughly 2 million Canadians are living with COPD<sup>4</sup>

4

In Canada, COPD is the 4th leading cause of hospitalization in people over 65<sup>5</sup>

## Causes of COPD<sup>6</sup>



Exposure to air pollution at work and in the environment (e.g., dusts and fumes)



Genetic factors (e.g., alpha-1 antitrypsin deficiency, a rare genetic disorder)



Smoking



Exposure to second-hand smoke

## The Impact of an Exacerbation

A COPD exacerbation, or flare-up, is when your COPD respiratory symptoms become much more severe.<sup>7</sup> A moderate exacerbation requires the use of antibiotics and/or corticosteroids, and a severe exacerbation can lead to hospitalization.<sup>8</sup>



1 in 3 COPD patients may be at risk of an exacerbation<sup>9</sup>



1 moderate exacerbation increases the risk of hospitalization by 21%<sup>10</sup>



1 in 3 patients with COPD died within 1 year of their first hospitalization<sup>11</sup>

## Cardiovascular Events and Comorbidities

Exacerbations dramatically increase the risk of a subsequent cardiovascular event.



The risk of a cardiovascular event is 10 times higher after a hospitalization<sup>12</sup>



The risk of a stroke increases to 50% within 6-10 days following an exacerbation<sup>13</sup>



The risk of a cardiovascular event is 2 times higher within 30 days following an exacerbation and increases by 80% within 3 to 12 months<sup>14</sup>

## Exacerbation Warning Signs and Symptoms<sup>15</sup>

Severe exacerbations are extremely dangerous and require immediate emergency medical intervention.



Increased shortness of breath or coughing



Chest pain



Change in mucus (amount, thickness, colour)



Sore throat



Cold or flu symptoms (headache, runny nose, sore throat, fever)



Swallow or grasp lips and fingernails

## Preventing an Exacerbation<sup>16</sup>

One exacerbation is one too many, as each can have devastating effects on physical, mental, and emotional well-being. However, steps can be taken to manage the risk, including:



Become smoke-free



Follow your COPD Action Plan



Exercise regularly (as able)



Take your COPD medications as prescribed



Keep always clear of mould



Even if an exacerbation is mild, one of the most crucial steps to take is to report the incident to your healthcare provider. Reporting the symptoms could flag the need for a change in treatment which could help prevent fatal outcomes.

To learn more about COPD management, visit [lunghealth.ca/COPD](http://lunghealth.ca/COPD).

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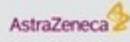
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AstraZeneca COPD Infographic (CNW Group/AstraZeneca Canada Inc.)





Breztri Aerosphere Inhaler (CNW Group/AstraZeneca Canada Inc.)

It is estimated that two million Canadians are living with COPD<sup>2</sup>, a lung condition which includes chronic bronchitis and emphysema, that causes debilitating bouts of breathlessness<sup>3,4,5</sup> largely due to the narrowing of the airways.<sup>6</sup> An exacerbation occurs when the symptoms of a person living with COPD intensify suddenly, requiring medical treatment.<sup>7</sup> In Canada, COPD is the eighth leading cause of hospitalization; and in people over 65 years old, it is the fourth leading cause of hospitalization.<sup>8</sup>

"Preventing exacerbations is a key clinical priority, as even a single exacerbation can cause further deterioration of a patient's lung function, increase the risks of hospitalization and premature death," said Dr. Jean Bourbeau, Respirologist and Professor in the Departments of Medicine and Epidemiology & Biostatistics at McGill University. "Triple fixed-dose combination therapies, like Breztri Aerosphere, have demonstrated benefits in reducing exacerbations and mortality for eligible patients and represent an important advance in the field."

About 70 per cent of exacerbations are not reported by patients to their physicians.<sup>9</sup> During a severe exacerbation, symptoms like shortness of breath and increased coughing suddenly intensify, airway muscles tighten significantly and cut off air supply. This can lead to blue lips or fingers, confusion, drowsiness, extreme shortness of breath and, when not treated, death.<sup>10</sup> One in four patients die within a year of a severe exacerbation.<sup>11</sup>

"Quality of life is everything for people living with COPD in Canada and their families," said Peter Glazier, Executive Vice President of the Lung Health Foundation. "We're pleased to know there is a new treatment option to help people live life to the fullest extent possible with COPD."

"The availability of Breztri Aerosphere in Canada marks a significant advance in care for COPD patients, and reinforces our commitment to this community," said Dr. Alex Romanovschi, Vice President, Scientific Affairs, AstraZeneca Canada. "We are proud of the potential Breztri Aerosphere has to help improve the clinical outcomes and the quality of life for people living with COPD."

Health Canada's approval was based on positive results from ETHOS and KRONOS Phase III trials in moderate to very severe COPD patients. In the ETHOS trial, Breztri Aerosphere showed a statistically significant reduction in the rate of moderate or severe exacerbations compared with dual-combination therapies (glycopyrronium/formoterol fumarate) and PT009 (budesonide/formoterol fumarate) over 52 weeks.<sup>12</sup> In the KRONOS trial, which included patients with no history of exacerbations in the prior 12 months, Breztri Aerosphere demonstrated a statistically significant reduction in the rate of moderate or severe exacerbation over 24 weeks vs. a dual-combination therapy (glycopyrronium/formoterol fumarate).<sup>13</sup>

Results from the ETHOS Phase III trial were published in *The New England Journal of Medicine* in June 2020<sup>12</sup> and results from the KRONOS Phase III trial were published in *The Lancet Respiratory Medicine* in September 2018.<sup>13</sup> In both trials, the safety profile and tolerability of Breztri Aerosphere were consistent with the profiles of the dual comparators.<sup>12,13</sup> The most frequently reported adverse reactions were pneumonia, oral candidiasis, muscle spasms, and dysphonia.<sup>1</sup>

## **About COPD**

COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness<sup>2,3,5</sup> and is the third leading cause of death globally.<sup>14</sup> Improving lung function, reducing exacerbations, managing daily symptoms, and reducing all causes of mortality are important treatment goals in the management of COPD.<sup>2</sup> A single COPD exacerbation can have a negative impact on lung function,<sup>15,16</sup> quality of life,<sup>17</sup> and increase the risk of hospitalization.<sup>18</sup> Additionally, even one COPD exacerbation that results in hospitalization is associated with an increased risk of death.<sup>19,20</sup> The risk of a stroke increases by 40 per cent within 6 to 10 days following an exacerbation.<sup>21</sup> In the year following an exacerbation, the risk of a cardiovascular event is four times higher within the first 30 days and increases by 90 per cent within 3 months to 12 months.<sup>22</sup> It is also 10 times higher following a hospitalization.<sup>22</sup>

## **Breztri Aerosphere<sup>1</sup>**

Breztri Aerosphere is a triple therapy in a single inhaler that demonstrates a statistically significant reduction in the rate of moderate or severe exacerbations. The triple therapy combines inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA), and a long-acting beta2-adrenergic agonist (LABA), to help reduce inflammation in the airways making it easier to breathe. Breztri Aerosphere was approved by Health Canada in July 2021.

Breztri Aerosphere is also approved for patients with COPD in Japan, China, and the US, and as Trixeo Aerosphere in Europe.

## **About AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business with a focus on the discovery, development, and commercialization of medicines that transform lives. Our core scientific focus is in the areas of Cardiovascular, Renal and Metabolic (CVRM) disease; Oncology; Rare Disease; Respiratory & Immunology; and Vaccine & Immune Therapies. AstraZeneca operates in more than 100 countries and its innovative medicines are used by millions of patients worldwide. In Canada, the company employs more than 1,200 people across Canada, including roughly 700 employees at our head office and clinical research hub in Mississauga, Ontario. For more information, please visit the company's website at [www.astrazeneca.ca](http://www.astrazeneca.ca).

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