PRESS RELEASE



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Two new options for self-administration of NUCALA now approved in Canada, making it the first anti-IL5 biologic to offer patients with severe eosinophilic asthma a choice of how and where to receive treatment

Mississauga, ON – NUCALA (mepolizumab) has been approved in Canada in two new formats – a pre-filled auto-injector and a pre-filled safety syringe – for use by healthcare professionals, patients and their caregivers. These new formats provide the option for patients to self-administer NUCALA athome, upon approval and training from their healthcare professional, for the treatment of severe eosinophilic asthma (SEA) or eosinophilic granulomatosis with polyangiitis (EGPA)¹.

NUCALA is the first anti-IL5 biologic to be licensed in Canada for at-home administration, and the first respiratory biologic to be approved for administration through an autoinjector. IL-5 plays an important role in regulating the function of eosinophils, an inflammatory cell known to be active in asthma and EGPA.

Dr. Alex Romanovschi, Country Medical Director, GSK Canada, said: "Severe asthma is a chronic and potentially life-threatening disease that can make daily activities a challenge. GSK has a long and established history in respiratory health innovation, with treatments for asthma, COPD and other respiratory diseases. We are pleased to provide NUCALA's two new formats to Canadians living with severe asthma."

About asthma

Asthma is a chronic lung disease that inflames and narrows the airways². The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment.

About severe asthma and eosinophilic inflammation

Severe asthma is a chronic disease with symptoms that can be life-threatening³. Approximately 250,000 Canadians live with severe asthma⁴ and can have several underlying causes including eosinophilic inflammation.⁵ It is estimated the cost of asthma to the Canadian economy will climb to \$4.2 billion by 2030.⁶ Studies suggest about 60% of severe asthma patients may have eosinophilic airway inflammation.⁷ In a sub-set of severe asthma patients, the over-production of eosinophils (a type of white blood cell) is known to cause inflammation in the lungs. Interleukin-5 (IL-5) is the main promoter of eosinophil growth, activation and survival and provides an essential signal for the movement of eosinophils from the bone marrow into the lung.

About eosinophilic granulomatosis with polyangiitis (EGPA)

Eosinophilic granulomatosis with polyangiitis, formerly known as Churg-Strauss Syndrome, is a chronic rare disease that is caused by inflammation in the walls of small-to-medium sized blood vessels (vasculitis). Approximately five people out of every one million will be diagnosed with EGPA each year worldwide, with an estimated prevalence of approximately 14-45 per million. The mean age of diagnosis is 48 years, and the disease can be life-threatening for some patients.

¹ NUCALA Canadian Product Monograph, October 2019

 $^{^{2}}$ Global Initiative for Asthma. Pocket Guide for asthma management and prevention. Updated 2014

³Asthma Canada: Severe Asthma <u>here</u>

⁴ Asthma Canada: Severe Asthma link here

⁵ Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective *J Asthma Allergy*. 2014; 7:53-65.

⁶ Asthma Canada: Severe Asthma link here

⁷ GlaxoSmithKline Data on File (Document Number: 2015N248497_00). 2015.

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About NUCALA (mepolizumab)

NUCALA contains the active substance, mepolizumab, a monoclonal antibody that works by blocking a specific protein called interleukin-5. By blocking the action of interleukin-5, NUCALA limits the production of more eosinophils from the bone marrow and lowers the number of eosinophils in the blood, lungs and tissues⁸.

NUCALA is approved in Canada, the US, Europe and in over 20 other markets, as an add-on maintenance treatment for adult patients with severe eosinophilic asthma. In Canada, the US, Japan and a number of other markets, it is also approved as add-on maintenance treatment for patients with a rare blood vessel disease associated with increased eosinophils, called Eosinophilic Granulomatosis with Polyangiitis (EGPA). NUCALA has been studied in over 3,000 patients in 21 clinical trials, across a number of eosinophilic conditions.

Please consult the <u>Product Monograph</u> at www.gsk.ca for complete safety information. The Product Monograph is also available by calling 1-800-387-7374.

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⁸ NUCALA Canadian Product Monograph, October 2019