News Release

EVUSHELD™ RECEIVES HEALTH CANADA APPROVAL FOR PRE-EXPOSURE PROPHYLAXIS (PREVENTION) OF COVID-19 IN IMMUNE-COMPROMISED INDIVIDUALS

Evusheld is the first long-acting antibody (LAAB) combination to receive Health Canada authorization for the prevention of COVID-19

MISSISSAUGA, ON, April 14, 2022 – AstraZeneca's *Evusheld* (tixagevimab co-packaged with cilgavimab), a long-acting antibody combination has received a Notice of Compliance from Health Canada for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (≥12 years of age weighing at least 40kg), who have not had a known recent exposure to an individual infected with SARS-CoV-2 and who are immune-compromised and unlikely to mount an adequate immune response to COVID-19 vaccination **or** for whom COVID-19 vaccination is not recommended. Pre-exposure prophylaxis with *Evusheld* is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.[1]

The approval follows AstraZeneca's announcement in February that it had signed an agreement with the Government of Canada for the supply of *Evusheld,* which is now in Canada. The approval by Health Canada was based on results from the *Evusheld* clinical development program, including data from the PROVENT Phase III pre-exposure prophylaxis trial which showed a 77% reduction in the risk of developing symptomatic COVID-19 compared to placebo at the primary analysis and an 83% reduction at a six-month median analysis, with protection from the virus lasting at least six months.[1-3] *Evusheld* was generally well-tolerated in the trial.[1-3]

"For people who have weakened immune systems, such as those living with cancer, transplant, dialysis, various genetic immune disorders or autoimmune conditions, or those receiving chemotherapy or certain types of immunosuppressive medications, vaccines alone may not offer sufficient protection against COVID-19," said Dr. Donald Vinh, Infectious Disease specialist and Medical Microbiologist. "These individuals may not consistently generate adequate antibody responses to vaccination against COVID-19, leaving them potentially vulnerable. Long-acting antibodies can complement vaccines and address this vulnerability gap, delivering more reliable protection. These long-acting antibodies are a highly welcomed tool, enabling us to provide another option to at-risk patients."

Approximately 2% of the global population is considered at increased risk of an inadequate response to a COVID-19 vaccine.[4,5] Additionally, more than 40% of those hospitalized with breakthrough COVID-19 infections after vaccination are immune-compromised.[6,7] This includes people with blood cancers or other cancers being treated with chemotherapy, and those taking medications after an organ transplant or who are taking immunosuppressive drugs for conditions, including multiple sclerosis and rheumatoid arthritis.[8-11]

"For vulnerable populations, such as those who are immune-compromised, *Evusheld* helps to address an unmet need in the ongoing fight against COVID-19," said Kiersten Combs, President of AstraZeneca Canada. "The key to ending the COVID-19 pandemic is protecting as many people as possible against infection, including those who may need an additional layer of protection to prevent COVID-19 than vaccines alone can provide. We welcome today's approval as an important step along this journey."

The recommended dose of *Evusheld* in Canada is 300mg, administered as two separate sequential intramuscular injections of 150mg of tixagevimab and 150mg of cilgavimab. Consideration should be given to increase the dose to 600mg in regions where Omicron BA.1 and Omicron BA.1.1 subvariants are circulating. A patient's healthcare professional will decide which dose will be appropriate to administer.

There is a growing body of evidence from multiple independent in vitro and in vivo (animal model) studies supporting the potential of *Evusheld* to protect against the BA.1, BA.1.1 and BA.2 Omicron SARS-CoV-2 subvariants in circulation around the world.[12-14] New data from Washington University School of Medicine demonstrated *Evusheld* retained potent neutralizing

activity against the emerging and highly transmissible BA.2 subvariant, which accounted for over 39% of variants of concern in Canada as of March 20th 2022.[15,16]

Evusheld is the only long-acting antibody combination with positive Phase III data in the prevention and treatment of COVID-19.[2,17] AstraZeneca is progressing with filings around the globe for potential emergency use authorization or marketing approval of *Evusheld* in both COVID-19 prophylaxis and treatment.

About *Evusheld*
Evusheld, formerly known as AZD7442, is a combination of two long-acting antibodies – tixagevimab (AZD8895) and cilgavimab (AZD1061) – derived from B-cells donated by convalescent patients after SARS-CoV-2 infection. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein[18] and were optimized by AstraZeneca with half-life extension and reduction of Fc effector function and complement C1q binding. The half-life extension more than triples the durability of its action compared to conventional antibodies;[19-21] data from the Phase III PROVENT trial show protection lasting at least six months.[1,3] The reduced Fc effector function aims to minimize the risk of antibody-dependent enhancement of disease – a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[22]

Evusheld has been granted marketing authorization in the European Union, and conditional marketing authorization in Great Britain and Australia for pre-exposure prophylaxis (prevention) of COVID-19. In the United States, *Evusheld* is authorized for emergency use for pre-exposure prophylaxis of COVID-19. *Evusheld* is also authorized for use and is being supplied in several other countries around the world.

About AstraZeneca Canada
AstraZeneca is a global, innovation-driven biopharmaceutical business with a focus on the discovery, development and commercialization of primary and specialty care medicines that transform lives. Our primary focus is on four important areas of healthcare: Cardiovascular, Renal and Metabolic disease; Oncology; Respiratory & Immunology; and Rare Diseases. AstraZeneca operates in more than 100 countries and its innovative medicines are used by millions of patients worldwide. In Canada, we employ roughly 1,100 employees across the country and our headquarters are located in Mississauga, Ontario. For more information, please visit the company's website at www.astrazeneca.ca.

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