HEALTH CANADA GRANTS MARKETING AUTHORIZATION WITH CONDITIONS (NOC/C) FOR GILEAD'S VEKLURY® (REMDESIVIR) FOR THE TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19)

– Veklury is the First Approved Treatment Option for COVID-19 in Canada –

MISSISSAUGA, ON, July 28, 2020 – Gilead Sciences Canada, Inc. today announced that Health Canada has issued a marketing authorization with conditions (Notice of Compliance with Conditions, or NOC/c) for Veklury® (remdesivir). Under this conditional authorization, Veklury is indicated for the treatment of COVID-19 in adults and adolescents aged 12 years and older and weighing at least 40 kg, with pneumonia requiring supplemental oxygen.

"We appreciate Health Canada's expedited review of Veklury in recognition of the urgent need to treat COVID-19 patients in Canada," said Melissa Koomey, General Manager, Gilead Sciences Canada. "We are thankful for their collaboration and leadership, as we together work to respond to this public health emergency."

Veklury has been studied in hospitalized COVID-19 patients spanning a wide range of disease severity. The conditional marketing authorization for Veklury is supported by the U.S. National Institute of Allergy and Infectious Diseases' global Phase 3 trial of remdesivir (ACTT-1)1. Authorization in Canada was under the NOC/c guidance based on an acceptable safety profile and the promising nature of the efficacy of the treatment.

Gilead is working with the Public Health Agency of Canada (PHAC) and Health Canada to provide Veklury for Canadians over the coming weeks.

About Veklury

Veklury (remdesivir) is a nucleotide analog with broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens. Multiple ongoing international Phase 3 clinical trials are evaluating the safety and efficacy of remdesivir for the treatment of SARS-CoV-2, the virus that causes COVID-19. In recognition of the current public health emergency and based on available clinical data, remdesivir has been approved as a treatment for patients with severe COVID-19 in Japan, Taiwan, Hong Kong, India, Singapore, Australia, the United Arab Emirates and the European Union. Outside of these regions, remdesivir is an investigational, unapproved drug.

The U.S. National Institute of Allergy and Infectious Diseases' global Phase 3 trial of remdesivir study, evaluating remdesivir versus placebo, showed remdesivir was superior to placebo in improving time to recovery in adults hospitalized with COVID-19 and with evidence of lower respiratory tract infection[1].

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1 Beigel JH, et al. Remdesivir for the treatment of Covid-19 – preliminary report. N Engl J Med. 2020. DOI: 10.1056/NEJMoa2007764.

Ongoing clinical trials continue to evaluate the safety and efficacy of remdesivir, including studies of remdesivir in combination with anti-inflammatory medicines and in special populations including pediatric patients.

Veklury has received marketing authorization under the NOC/c policy for its indicated uses, pending the results of confirmatory trials to verify its clinical benefit. Patients should be advised of the nature of this authorization.

The Canadian Product Monograph for Veklury is available at www.gilead.ca.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead Sciences Canada, Inc. is the Canadian affiliate of Gilead Sciences, Inc., and was established in Mississauga, Ontario, in 2006.

Gilead Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors. Remdesivir is an investigational drug that has not been approved by the FDA for any use, including for the treatment of COVID-19. There is the possibility of unfavorable results from ongoing and additional clinical trials involving remdesivir and the possibility that Gilead and other parties may be unable to complete one or more of such trials in the currently anticipated timelines or at all. Further, it is possible that Gilead may make a strategic decision to discontinue development of remdesivir or that FDA and other regulatory agencies may not approve remdesivir, and any marketing approvals, if granted, may have significant limitations on its use. As a result, remdesivir may never be successfully commercialized. In addition, Gilead may face challenges related to the allocation and geographical distribution of existing and future supply of remdesivir. If Gilead is unable to sufficiently scale up manufacturing of remdesivir in the currently anticipated timelines, Gilead may be unable to meet global supply needs. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information about Gilead Sciences, visit the company's website at www.gilead.com, follow Gilead on Twitter (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

Related Links: www.gilead.ca