Important Safety Information
Importation of US Clinical Trial-Labelled Remdesivir for Injection
Due to Shortage of Canadian-Labelled Remdesivir

2020/09/08

Audience
Healthcare professionals including infectious disease physicians, internal medicine staff, pharmacists, chiefs of medicine in hospitals, intensive care unit (ICU) and emergency room (ER) medical staff.

Key messages

- **On July 27, 2020, Health Canada authorized VEKLURY® (remdesivir) with conditions to treat COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen. The product has not yet been marketed in Canada.**
- **Given the medical necessity of this product in Canada, Health Canada has added Remdesivir from the US intended for clinical trials with English-only labelling to the List of Drugs for Exceptional Importation and Sale.**
- **The temporary importation of US clinical trial-labelled Remdesivir for Injection will provide earlier access to this product for Canadian patients ahead of the Canadian-labelled VEKLURY being marketed.**
- **Healthcare professionals are advised that:**
    - **The US clinical trial-labelled Remdesivir for Injection is the same as the Canadian approved product, VEKLURY (remdesivir) powder for solution for infusion, in actual drug product content, strength (100 mg/vial), form (powder), presentation (vial) and route of administration (intravenous).**
    - **The US clinical trial-labelled product should be used in the same way and for the same indications as the Canadian authorized VEKLURY.**
    - **The Canadian Product Monograph, which is available on Health Canada's Drug Product Database (https://health-products.canada.ca/dpd-bdpp/newSearch-nouvelleRecherche.do?lang=) or at Gilead Sciences Canada, Inc. (www.gilead.ca/en), should be used for complete product information.**
    - **The US clinical trial-labelled Remdesivir for Injection is provided without an outer carton or package insert.**

- **Important information is absent from the vial label: the brand name (VEKLURY), "single use vial" and sterile notations, preparation instructions, concentration when reconstituted, and storage conditions after reconstitution.**
- **The US clinical trial-labelled Remdesivir for Injection vial includes the following statements on the label: "For Clinical Trial Use Only" and "Caution: New Drug - Limited by Federal (USA) law to investigational use". In addition, the directions for use on the vial label refer to the clinical study protocol which is not provided with the product. These statements should be disregarded.**

What is the issue?
There is an increased demand and shortage of VEKLURY (remdesivir) worldwide, as a result of the COVID-19 pandemic. VEKLURY is the first drug that Health Canada has authorized with conditions for the treatment of patients with severe symptoms of COVID-19 but has not yet been marketed in Canada. Given the medical necessity of this product, Health Canada has added US clinical trial-labelled Remdesivir for Injection, powder for solution for infusion, 100 mg/vial (5 mg/mL when reconstituted) to the List of Drugs for Exceptional Importation and Sale (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html).

Products affected
Remdesivir for Injection, powder for solution for infusion, 100 mg/vial (5 mg/mL when reconstituted) US clinical trial-labelled
United States manufacturer: Gilead Sciences, Inc.
Canadian Importer and Distributor: Gilead Sciences Canada, Inc.

Background information
VEKLURY (remdesivir) is indicated for the treatment of COVID-19 in adults and adolescents (aged 12 years and older with a body weight of at least 40 kg) with pneumonia requiring supplemental oxygen.

VEKLURY was issued marketing authorization with conditions (Notice of Compliance with Conditions) on July 27, 2020, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information on the marketing authorization of VEKLURY, please refer to Health Canada's Notice of Compliance with conditions Web site (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/conditions.html).

Although VEKLURY has been authorized in Canada, it has not yet been marketed. While Gilead Sciences Canada, Inc. is preparing to market VEKLURY in Canada, the temporary importation of US clinical trial-labelled Remdesivir for Injection will provide access to this product for COVID-19 patients and help mitigate the current

market shortage. Gilead Sciences Canada, Inc. expects that Canadian-labelled product in both official languages (English and French) will become available by the end of October 2020.

The importation of the US clinical trial-labelled Remdesivir for Injection poses a risk for medication errors due to significant labelling deficiencies, the absence of a package insert, and label references to the drug being used as part of clinical trials.

Information for healthcare professionals
Healthcare professionals are advised that:

- The US clinical trial-labelled Remdesivir for Injection is the same as the Canadian-approved product, VEKLURY (remdesivir) powder for solution for infusion, with respect to the actual drug product content, strength (100 mg/vial), form (powder), presentation (vial) and route of administration (intravenous).
- The US clinical trial-labelled product should be used in the same way and for the same indications as the Canadian authorized VEKLURY.
- The Canadian product monograph for VEKLURY (remdesivir), which is available in English and French on Health Canada's Drug Product Database (https://health-products.canada.ca/dpd-bdpp/newSearch-nouvelleRecherche.do?lang=) or at Gilead Sciences Canada, Inc. (www.gilead.ca/en), should be used for complete product information including information on directions for use, preparation and storage.
- Remdesivir for Injection, with clinical trial labelling in English only (see Appendix A), is being made available as an interim measure to ensure immediate supply for Canadians.
- The US clinical trial-labelled Remdesivir for Injection will be provided without an outer carton or package insert.
- Important information is absent from the vial label including the brand name (VEKLURY), "single use vial" and sterile notations, preparation instructions, concentration when reconstituted, and storage conditions after reconstitution.
- The US clinical trial-labelled Remdesivir for Injection vial includes the following statements on the label: "For Clinical Trial Use Only" and "Caution: New Drug - Limited by Federal (USA) law to investigational use". In addition, the directions for use on the vial label refer to the clinical study protocol which is not provided with the product. These statements should be disregarded.
- Gilead Sciences Canada, Inc., should be contacted for any questions at CA-Safetymailbox@gilead.com or 1-866-207-4267, although the labels include the contact information of the US manufacturer.

Hospitals should also be aware that no barcode or Drug Identification Number (DIN) is included on the US clinical trial-labelled Remdesivir for Injection. A facility-

generated sticker or overlabel may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered.

Action taken by Health Canada
The Minister of Health signed the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19 (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.html). Drugs included on the List of Drugs for Exceptional Importation and Sale referenced in the Interim Order are eligible for the exceptional importation and sale provisions provided for in the Interim Order. Health Canada has added Remdesivir for Injection to this list, which permits the importation and sale of Remdesivir for Injection with clinical trial labelling.

Health Canada has worked with Gilead Sciences Canada, Inc. to prepare this alert for Remdesivir for Injection. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site (https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php). This communication update will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

Report health or safety concerns
Health Canada's ability to monitor the safety of marketed health products depends on healthcare providers and consumers reporting adverse reactions and medical device incidents. Any adverse reaction in patients receiving remdesivir should be reported to Gilead Sciences Canada, Inc. or Health Canada.

Gilead Sciences Canada, Inc.
E-mail: CA-Safetymailbox@gilead.com
Toll free phone #: 1-866-207-4267

To correct your mailing address or fax number, contact Gilead Sciences Canada, Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax.

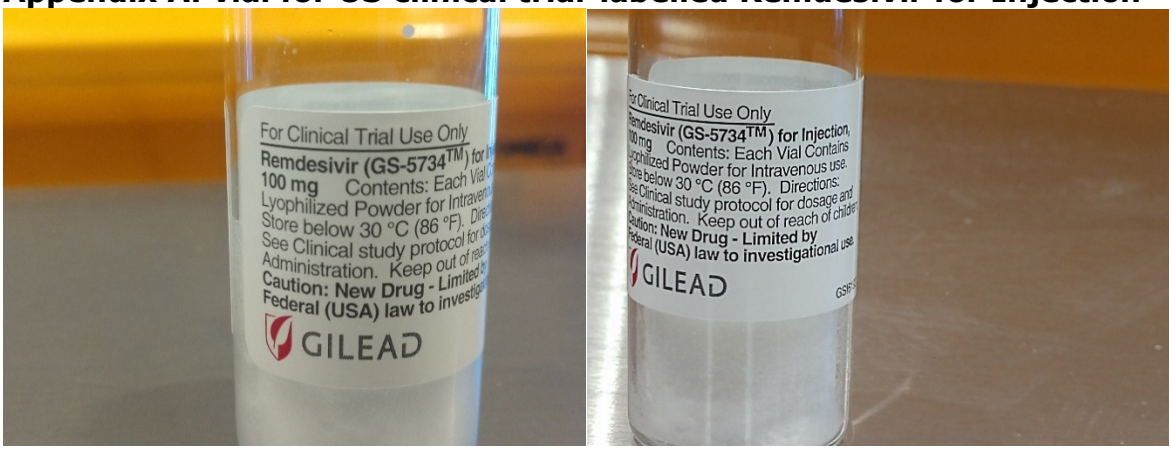
For other health product inquiries related to this communication, contact Health Canada at:
Regulatory Operations and Enforcement Branch
E-mail: hc.hpce-cpsal.sc@canada.ca

Original signed by
Raymund Rama
Director, Regulatory Affairs

Gilead Sciences Canada, Inc.

VEKLURY® is a registered trademark of Gilead Sciences, Inc. or its related companies.

Appendix A: vial for US clinical trial-labelled Remdesivir for Injection



For Clinical Trial Use Only
Remdesivir (GS-5734™) for Injection, 100 mg
Contents: Each Vial Contains Lyophilized Powder for Intravenous use. Store below 30 °C (86 °F).
Directions: See Clinical study protocol for dosage and Administration. Keep out of reach of children.
Caution: New Drug - Limited by Federal (USA) law to investigational use.
Sponsor: Gilead Sciences, Inc., 333 Lakeside Drive, Foster City, CA 94404, USA. Tel.: +1 800 445 3235

Protocol: _____
Patient ID: _____
Investigator: _____
Site No.: _____

Lot: LLLLLLLLL
Expiry Date: MM/YYYY

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