Important Safety Information on
LEMTRADA® (alemtuzumab for injection) – Risk of Autoimmune Encephalitis and Vitiligo

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Audience
Healthcare professionals including neurologists, family physicians, emergency physicians, internists, cardiologists, multiple sclerosis nurses, and hospital pharmacists.

Key messages

During postmarketing use, cases of autoimmune encephalitis and vitiligo have been reported in patients treated with LEMTRADA.

What is the issue?
New safety information from post-market use of LEMTRADA has been reported and includes cases of autoimmune encephalitis and vitiligo. The LEMTRADA Canadian Product Monograph has been updated to include this new safety information.

Products affected
LEMTRADA® (alemtuzumab) 12 mg/1.2 mL (10 mg/mL), DIN 02418320.

Background information
LEMTRADA (alemtuzumab for injection) is indicated for the management of adult patients with relapsing remitting multiple sclerosis (RRMS), with highly active disease defined by clinical and imaging features, despite an adequate course of treatment with at least two other disease modifying treatments (DMTs), or where any other DMT is contraindicated or otherwise unsuitable.

Information for healthcare professionals
Cases of autoimmune encephalitis and vitiligo have been reported in patients treated with LEMTRADA. Patients who develop autoimmunity should be assessed for other autoimmune mediated conditions. Patients and physicians should be made aware of the potential later onset of autoimmune disorders after the 48 months monitoring period. Caution should be exercised in patients with a history of autoimmune conditions (in addition to MS).

Autoimmune encephalitis is confirmed by the presence of neural autoantibodies as well as a variety of clinical manifestations like subacute onset of memory impairment, altered mental status, psychiatric symptoms, neurological findings and seizures.

Patients with suspected autoimmune encephalitis should have neuroimaging (MRI), EEG, lumbar puncture and serologic testing for appropriate biomarkers (e.g. neural autoantibodies) to confirm diagnosis and exclude alternative etiologies.

Vitiligo is diagnosed clinically based upon the finding of amelanotic, nonscaly, chalky-white

macules with distinct margins. An assessment of the impact of vitiligo on the patient's psychological well-being and quality of life, if any, should be performed.

Report health or safety concerns

Managing and monitoring the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions and medical device incidents. Any case of serious or unexpected side effects in patients receiving LEMTRADA should be reported to sanofi-aventis Canada Inc. or Health Canada.

sanofi-aventis Canada Inc.,
2905 Place Louis-R.-Renaud
Laval (Québec) Canada H7V 0A3
Telephone number : 1-800-589-6215
Email : SanofiMedInfoCA@sanofi.com
To correct your mailing address or fax number, contact sanofi-aventis Canada Inc,

You can report any suspected adverse reaction 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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

Sincerely,

Amit Suri, MD
Medical Director, Neurology & Immunology
sanofi-aventis Canada Inc.