January 1st, 2009

RE: Vivaglobin® (Immune Globulin Subcutaneous (Human)) available in January 2009 for Primary Immunodeficient (PID) patients throughout Canada

Dear Healthcare Provider,

CSL Behring is pleased to provide you some important information on Vivaglobin®, Immune Globulin Subcutaneous (Human), a pasteurized, polyvalent human normal immunoglobulin for subcutaneous infusion. Vivaglobin® can now be prescribed for all PID patients who may benefit from this treatment option.

Vivaglobin® is indicated for the treatment of patients with primary immune deficiency (PID) who require immune globulin replacement therapy. Vivaglobin® is contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations, in persons with selective immunoglobulin A (IgA) deficiency who have known antibody against IgA and in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.

Vivaglobin® has been shown to be safe and effective in PID patients. This new subcutaneous immunoglobulin (SCIG) preparation allows a trained patient to administer their therapy at home. Compared to the hospital based IVIG therapy Vivaglobin® has been shown to be:

- The preferred option for patients
- Not only cost saving but the most cost-effective treatment option

Subcutaneous immunoglobulin is infused under the skin, where it is absorbed slowly. Therefore the monthly dose is typically split into smaller doses for more frequent infusions. The recommended weekly dose of Vivaglobin® is 100 to 200 mg/kg body weight administered subcutaneously. Doses may be adjusted over time to achieve the desired clinical response and serum IgG levels.

Subcutaneous administration of Vivaglobin® is an efficacious and safe way of administration that offers flexibility to patients who:

- For Medical Considerations:
  - Require a more stable or higher trough level (for example for those patients that feel fatigued prior to the next IVIG infusion)
  - Require a different mode of administration of immune globulins in order to potentially decrease systemic adverse reactions with their current IVIG preparations or who have venous access issues
- For Quality of Life Considerations:
  - Have a busy schedule and cannot afford the time/money to go to the hospital for their infusions
  - Prefer to self infuse in the comfort of their home or while travelling
  - Live far away from the infusion centres
  - Wish to schedule their therapy around their life and not their life around their therapy

CSL Behring offers tools / resources and training for health care professionals who wish to train their PID patients to use Vivaglobin® at home.
Vivaglobin® is supplied as a sterile 16% (160 mg/mL) protein solution containing at least 96% immunoglobulin G (IgG) to be administered by the subcutaneous route. Vivaglobin® is manufactured from large pools of human plasma by cold alcohol fractionation and is not chemically altered or enzymatically degraded. It is currently available in 10 ml vials (3 mL vials are expected to be available later in 2009). Vivaglobin® must be stored refrigerated and contains no preservatives. Each product vial comes with a peel-off label that can be inserted into the patient’s infusion diary to help with the traceability of this product. The shelf life is 24 months.

For over 100 years, CSL Behring has been a global leader in the biotherapeutics and plasma protein therapeutics industry. CSL Behring provided the world’s first intact IV immunoglobulin and continues to lead the industry in introducing new advances in manufacturing high-quality plasma-derived treatments. It is the only biotherapeutic company in Canada to offer both immune globulins for intravenous and for subcutaneous administration. CSL Behring operates one of the world’s largest plasma collection networks, ZLB Plasma and is committed to saving lives and improving the quality of life for people with rare and serious diseases, worldwide.

If you have any questions or require any additional information regarding Vivaglobin®, please contact your local Area Manager or the CSL Behring office in Ottawa at 1-866-773-7721. Our bilingual and highly dedicated team is ready to serve you.

We hope that Vivaglobin® will contribute in offering a new solution for some of your patients with PID. Full prescribing information is available on request.

Sincerely,

Marie Christine Roberge
National Immune Globulin Manager
CSL Behring Canada Inc.

References