CSL Behring Receives FDA Approval to Extend Shelf Life of Hizentra to 30 Months

Provides added convenience for people with primary immunodeficiency who use subcutaneous immunoglobulin at home or in any proper setting that fits their needs

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CSL Behring announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) to extend the shelf life of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid, from 24 months to 30 months. Hizentra, the first and only 20 percent subcutaneous immunoglobulin (SCIg) approved in the U.S., is the only SCIg in the U.S. that can be stored at room temperature throughout its entire shelf life.

Hizentra is indicated for the treatment of primary humoral immunodeficiency (PI). PI is a group of disorders, usually genetic, that result from a dysfunctional immune system. This condition prevents patients from fighting off infections caused by common germs.

"Based on what we know patients and their healthcare providers need and want, CSL Behring continually strives to enhance the products in our extensive portfolio," said Lynne Powell, CSL Behring Senior Vice President, North America Commercial Operations. "The ability to store Hizentra without refrigeration for up to two and a half years is a milestone that provides added convenience to busy and active patients, while serving as another example of CSL Behring’s dedication to meeting customer needs."

Stabilized with L-proline, a naturally occurring amino acid, Hizentra can be stored at room temperature (up to 25°C [77°F]) for up to 30 months. Because no refrigeration is necessary, Hizentra is always ready to use without warming, offering patients and physicians convenience and portability.

"Since transitioning to Hizentra, I have the freedom to choose the time of day and in what setting I self-infuse my therapy," said Hizentra patient Jean Stefanic. "The convenience this product offers fits my busy schedule and helps me lead a normal life."

The sBLA for Hizentra was based on a study assessing the product’s stability for 30 months. Physicochemical, biological and immunological parameters were assessed under controlled conditions at 25°C (77°F). The data generated from this study demonstrated that when Hizentra is stored at room temperature (up to 25°C [77°F]) and protected from light, it is stable for up to 30 months.

Hizentra with 30-month shelf life packaging is expected to be available later this year. Current Hizentra patients are encouraged to contact their physician with any questions regarding the shelf
Hizentra is part of the immunoglobulin (Ig) franchise for CSL Behring. This comprehensive Ig product portfolio also includes the first proline-stabilized intravenous immunoglobulin. CSL Behring manufactures Hizentra at its state-of-the-art facility in Bern, Switzerland, where advanced technologies are applied to further ensure product safety and a robust and steady supply. This facility represents the long-term commitment of CSL Behring to patients around the world who use immunoglobulins to manage their medical conditions.