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CSL Behring announces FDA approval of Privigen for the treatment of CIDP in adults

15 September 2017 | News

The FDA approval was based on results from two Phase III clinical studies that focused on the use of immunoglobulin (Ig) therapy for treating CIDP – the Polyneuropathy and Treatment with Hizentra (PATH) study, the largest controlled clinical study in CIDP patients to date, and the Privigen Impact on Mobility and Autonomy (PRIMA) study.

Global biotherapeutics leader CSL Behring announced that the U.S. Food and Drug Administration (FDA) has approved Privigen for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability. CIDP is a rare autoimmune disorder that affects the peripheral nerves and may cause permanent nerve damage.

"The FDA approval of Privigen for CIDP represents a significant milestone for individuals with this debilitating and progressive disease. It is a testament to our commitment to meet the needs of patients with disabling neurologic conditions, including CIDP," said Dr. Andrew Cuthbertson, chief scientific officer and director of Research and Development for CSL Limited. "As we focus on building a leading neurology franchise, we continue to advance clinical research to determine innovative and improved uses of immunoglobulin therapy that can benefit patients and improve their quality of life."

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In PATH, 207 patients receiving Privigen were studied for up to 13 weeks, and 73 percent responded to Privigen over the course of treatment, as measured by their adjusted score on the Inflammatory Neuropathy Cause and Treatment (INCAT) scale, which measures the ability to walk and perform tasks. In PRIMA (n=28), 61 percent of patients responded to Privigen over 25 weeks, as measured by their adjusted INCAT score.

"It is a priority in the care of CIDP patients to provide therapies that improve and maintain strength and function while at the same preventing relapses and minimizing side effects. However, current treatments do not work for all CIDP patients," said Dr. Mazen M. Dimachkie, Professor and Director of Neuromuscular Division, Executive Vice Chairman, Department of

Neurology at the University of Kansas Medical Center and an investigator in the PATH study. "Privigen's approval by the FDA for the treatment of CIDP means that people with CIDP and their treating physicians have gained another treatment option that is safe and effective in helping improve strength and motor function, while potentially delaying disease relapse."

"People living with CIDP can experience a progression of their disease, which may result in tingling, muscle weakness, fatigue and other symptoms that limit their daily activities and decrease their quality of life," said Lisa Butler, executive director of the GBS|CIDP Foundation International. "The approval of this intravenous immunoglobulin to improve disability represents an important treatment advance for the patients, caregivers and families who are struggling with CIDP. We are grateful for CSL Behring's efforts in this area and their commitment to advancing patient care for the CIDP community."