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Japan Health Ministry approves immunoglobulins to treat CIDP

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Hizentra is the first and only subcutaneous immunoglobulin approved for the maintenance treatment of CIDP in Japan, based on findings from the longest controlled clinical CIDP study



Global biotherapeutics leader CSL Behring recently announced that Japan's Ministry of Health, Labour and Welfare has approved two of its immunoglobulin therapies for the treatment of patients with chronic inflammatory demyelinating polyradiculoneuropathy (CIDP).

Hizentra, previously approved to treat primary immunodeficiency, is now the first and only subcutaneous immunoglobulin (SCIG) approved for maintenance therapy to treat CIDP in Japan. Privigen, an intravenous immunoglobulin (IVIG), is now approved for both acute and maintenance therapy of CIDP in Japan.

The approval for Hizentra is based on the results of PATH (Polyneuropathy And Treatment with Hizentra) and its extension study, which comprise the longest CIDP research period to date and included a cohort of Japanese patients. The approval for Privigen is based on results from two Phase III clinical studies that focused on the use of immunoglobulin therapy for treating CIDP: the PATH study and the PRIMA (Privigen Impact on Mobility and Autonomy) study.

CIDP is a chronically progressive rare autoimmune disorder that affects the peripheral nerves and may cause permanent nerve damage. The myelin sheath, or the protective covering of the nerves, is damaged, which may result in numbness or tingling, muscle weakness, fatigue and other symptoms which worsen over time.

The effects of CIDP lead to significant activity limitations and a decreased quality of life. Approximately 30 percent of CIDP patients will progress to wheelchair dependence if not treated. Until now, the only immunoglobulin therapy available to treat CIDP in Japan was intravenously administered.

William Mezzanotte, Executive Vice President, Research & Development, CSL Limited reinforced a commitment to the CIDP patient community saying, "CSL Behring has dedicated years to studying CIDP to bring patients effective treatment options that fit their lifestyle. We are proud to offer Japanese patients with CIDP a balanced portfolio of immunoglobulin therapies with both Hizentra, a convenient option with proven efficacy and the flexibility and freedom to self-infuse, and Privigen, with its

long-proven track record of safety."