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CSL files marketing plea for Privigen in Europe

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CSL submits market authorization application for Privigen in Europe

Singapore: Australian company CSL Behring has submitted a variation application to the European Medicines Agency (EMA) for the use of Privigen (immune globulin intravenous [human], 10 percent liquid for intravenous administration) in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP).

The CIDP is a rare neurological disorder of the peripheral nerves characterized by symmetrical weakness in the arms and legs that progressively worsens for longer than two months.

"The data contained in this application provide clinical evidence that Privigen is a safe and efficacious option for CIDP patients in Europe who are managing this very challenging condition," said Dr Russell Basser, senior vice president, Global Clinical R&D at CSL Behring. "If approved in Europe for use in treating CIDP, Privigen will represent a meaningful advance in many rare disease communities across the continent."

The CSL Behring European application is based on the results of the PRIMA study (Privigen Impact on Mobility and Autonomy), a single-arm study designed to evaluate the safety and efficacy of Privigen in 31 patients who have CIDP. In PRIMA, patients on Privigen had a clinically meaningful improvement in their disease by demonstrating a statistically significant change in their INCAT score at the completion visit-the primary endpoint, which was met.

Overall, 61 percent patients responded to Privigen, and of those patients who responded to Privigen in the PRIMA study, 50 percent did so within four weeks of being treated in the study. Privigen also demonstrated improvements on secondary endpoints, including objective measures of muscle strength of the hands at the completion visit. As seen in other intravenous immunoglobulin (IVIg) trials, headache was the most common adverse event in the PRIMA study.