11 September 2020

- Press Release -

LFB Announces the Presentation of the PRISM Study Results During a Symposium at the ICNMD Virtual Congress

LFB IVIg 10% is efficacious and well tolerated in the treatment of CIDP patients

Les Ulis (France) — September 11th, 2020 — LFB announces the presentation of the PRISM study results in Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) patients on September 12th during the 16th International Congress on Neuromuscular Diseases (ICNMD). Due to the COVID-19 pandemic, the congress is held virtually from 11th to 14th September 2020.

During this symposium, Dr Helmar Lehmann, Professor in Neurology at Cologne University Hospital (Germany), will discuss recent developments in the era of clinical and paraclinical surrogates of treatment responses to IVIg in CIDP patients. Then, Dr Yusuf Rajabally, Professor in Neurology at Queen Elizabeth Hospital, University Hospitals Birmingham (United Kingdom), will focus on optimization of therapeutic strategies for these patients. And finally, Dr. Eduardo Nobile-Orazio, Professor of Neurology at the Milan Hospital University (Italy), will present the results of the PRISM study performed with LFB IVIg 10%. The study manuscript was recently accepted for publication in the *Journal of the Peripheral Nervous System* and is available online ahead of print [1].

About PRISM

The PRISM study (NCT02293460) is an international, single arm, open-label, multicenter, Phase 3 clinical trial designed to evaluate the efficacy and safety of LFB IVIg 10% in the initial and maintenance treatment of CIDP patients.
Based on the doses recommended in the EFNS/PNS guideline [2], LFB IVIg 10% was administered at 2 g/kg over 2 to 5 days for the first course, then at 1 g/kg over 1 to 2 days every 3 weeks for the rest of the study. The primary efficacy endpoint was Responder rate at End of Study (EOS) visit [*Response was defined as an improvement of ≥1 point on the Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale between baseline and EOS*]. The responder rate was compared with the responder rate of a historical placebo group (33.3%) from the ICE study [3].
Results from this clinical trial confirmed the efficacy and safety of LFB IVIg 10% in the treatment of CIDP patients (N=43). The overall response rate at EOS was 76.2% (95% CI [60.5-87.9%]). The superiority of LFB IVIg 10% compared to the historical placebo control was demonstrated ($p<0.0001$).
Results of one of the secondary endpoints of this study may suggest that CIDP patients (Ig-pretreated or naïve) should be maintained on IVIg treatment for a longer time (6 months) before considering other alternative therapy. The median time to response was 15 weeks (95% CI [8.9 - 19.1]) and 29% of the patients were responsive at a later time point (after Week 12 and until EOS visit). The safety was in line with the use of IVIg in CIDP.
This Phase 3 trial study is sponsored by LFB. More details can be found in the study manuscript available at https://onlinelibrary.wiley.com/doi/full/10.1111/jns.12408

About CIDP

CIDP is a rare neurological disorder in which there is inflammation of nerve roots and peripheral nerves and destruction of the fatty protective covering (myelin sheath) over the nerves. This affects how fast the nerve signals are transmitted and leads to loss of nerve fibers. This causes weakness, paralysis and/or impairment in motor function, especially of the arms and legs.

About LFB

LFB is a biopharmaceutical group that develops, manufactures and markets plasma derived products and recombinant proteins for the treatment of patients with serious and often rare diseases. LFB was founded in 1994 in France and is among the leading European biopharmaceutical companies providing mainly hospital-based healthcare professionals with blood-derived therapeutics with the vision to provide treatment options to patients in three major areas: immunology, haemostasis, and intensive care.
LFB currently markets 15 products in more than 30 countries.
Please visit www.lfb-group.com for additional information.

References:

[1] Nobile-Orazio E et al. An international multicenter efficacy and safety study of IQYMUNE® in initial and maintenance treatment of patients with chronic inflammatory demyelinating polyradiculoneuropathy: PRISM study. J Peripher Nerv Syst 2020 Aug. doi: 10.1111/jns.12408. Online ahead of print.

[2] European Federation of Neurological Societies/Peripheral Nerve Society Guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society--First Revision. Joint Task Force of the EFNS and the PNS. J Peripher Nerv Syst 2010 Mar;15 (1).

[3] Hughes RAC, Donofrio P, Bril V, et al. Intravenous immune globulin (10% caprylate chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial. Lancet Neurol 2008;7:136–144.

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