FDA approves Zilbrysq for generalized myasthenia gravis

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The U.S. Food and Drug Administration has approved UCB' Zilbrysq (zilucoplan) for the treatment of adults with generalized myasthenia gravis.

Zilbrysq is a targeted peptide inhibitor of complement component 5 (C5) and is approved as a once-daily, self-administered, targeted therapy in

patients with anti-acetylcholine receptor (AChR)-antibody-positive generalized myasthenia gravis.

The approval of Zilbrysq is based on results from the Phase III RAISE study, in which patients were randomly assigned (1:1) to receive daily subcutaneous injections of 0.3 mg/kg Zilbrysq or placebo for 12 weeks.

Significant benefits were seen for the primary end point of improvements in symptoms and functional activities as measured by the Myasthenia Gravis-Activities of Daily Living at week 12. The most common adverse reactions in patients receiving Zilbrysq (≥10%) were injection site reactions, upper respiratory tract infection, and diarrhea.

"Until now, people living with generalized myasthenia gravis have only had access to C5 therapy intravenously, which can be inconvenient and time consuming," Iris Loew-Friedrich, chief medical officer at UCB, said in a statement. "Now … we hope a broad population of mild-to-severe adult patients with AChR-antibody-positive generalized myasthenia gravis will be able to have greater independence."

More information: More Information