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ASIA EDITION

Alexion bags Japanese approval for Soliris

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Soliris is the first and only approved Complement Inhibitor in Japan as a Treatment for Patients with Myasthenia gravis, a Chronic and Debilitating Neuromuscular Disorder

Alexion Pharmaceuticals, recently bagged approval for its key candidate Soliris (eculizumab) fromthe Ministry of Health, Labour and Welfare (MHLW) in Japan as a treatment for patients with generalized myasthenia gravis (gMG).

Soliris is the first and only complement inhibitor approved in Japan as a treatment for patients who are anti-acetylcholine receptor (AChR) antibody-positive and whose symptoms are difficult to control with high-dose intravenous immunoglobulin (IVIG) therapy or plasmapheresis (PLEX).

In the Phase 3 REGAIN study and its ongoing open-label extension study, Soliris demonstrated treatment benefits for patients with anti-AChR antibody-positive gMG who had previously failed immunosuppressive treatment and continued to suffer from significant unresolved disease symptoms, which can include difficulties seeing, walking, talking, swallowing and breathing. These patients are at an increased risk of disease exacerbations and crises that may require hospitalization and intensive care and may be life-threatening.

“Soliris represents an important treatment advance for patients in Japan with anti-AChR antibody-positive gMG who continue to suffer from significant unresolved disease symptoms despite existing treatment options,” said John Orloff, M.D., Executive Vice President and Head of Research & Development at Alexion. “We are proud that these patients will be able to benefit from our deep understanding of complement biology, which allowed us to develop Soliris as treatment for this debilitating neuromuscular disorder.”

Chronic uncontrolled activation of the complement system, a part of the immune system, plays a major role in the debilitating symptoms and potentially life-threatening complications for patients with gMG who are anti-AChR antibody-positive.By selectively and effectively inhibiting the terminal complement cascade, Soliris targets a critical underlying cause of the disease.

“It is exciting that patients with gMG in Japan whose symptoms are difficult to control will now have a new treatment option,”

said Professor and Chairman Hiroyuki Murai, M.D., Ph.D., Department of Neurology at the International University of Health and Welfare, School of Medicine, Tokyo, Japan and an investigator in the clinical development of this new indication. “I am pleased that the Ministry appreciated the ability of Soliris to improve patients’ symptoms, their ability to carry out activities of daily living and their quality of life.”

“This approval is great news for patients with gMG in Japan who fail to adequately respond to existing therapies and continue to face significant disease symptoms,” said Michiyo Sakurai, President of the Japanese Myasthenia Gravis Association, Kyoto, Japan. “The inability to carry out activities of daily living can be very debilitating and frustrating for these patients and their families and friends. They welcome this new therapy option and the hope that it provides to them.”

Japan’s MHLW based its approval of this new indication of Soliris on comprehensive clinical data from the Phase 3, randomized, double-blind, placebo-controlled, multicenter REGAIN study (ECU-MG-301).

Soliris is also approved in the EU for the treatment of refractory gMG in adults who are anti-AChR antibody-positive, and in the U.S. for the treatment of adult patients with gMG who are anti-AchR antibody-positive.

Myasthenia gravis (MG) is a debilitating, chronic and progressive autoimmune neuromuscular disease that can occur at any age but most commonly begins for women before the age of 40 and men after the age of 60