International Progressive MS Alliance
UPDATED (6/28/16) Public Statement –

U.S. FDA Grants Priority Review for Ocrelizumab (proposed brand name OCREVUS™) in Primary Progressive and Relapsing MS – *Decision expected by December 28, 2016*

There are currently no approved disease-modifying therapies to treat progressive MS, but a recent announcement from Genentech, a member of the Roche group, announced that the U.S. Food and Drug Administration (FDA) accepted for review the company's Biologics License Application (BLA) for OCREVUS™ (ocrelizumab) for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS), and granted the application Priority Review Designation.

The FDA grants Priority Review Designation when considering new drugs that, if approved, would be significant improvements in the safety or effectiveness compared to standard treatments. This also means that FDA will consider the OCREVUS™ (ocrelizumab) application in an expedited manner with a decision within 6 months of submission, rather than the standard review process which typically lasts up to 10 months. With this designation, the FDA expects to make a decision by December 28, 2016.

The OCREVUS Marketing Authorization Application (MAA) has also been validated by the European Medicines Agency (EMA). Priority Review Designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in the safety and effectiveness of the treatment of a serious disease.

In September, 2015 the company announced that the experimental monoclonal antibody, ocrelizumab, significantly slowed progression of disability compared to placebo in a Phase III ORATORIO trial involving 732 people with primary progressive MS.

Additional data from the trial reported 10 October, 2015 at the European Committee for Treatment and Research in MS (ECTRIMS) in Barcelona showed that, compared to placebo, ocrelizumab significantly reduced the risk of progression of clinical disability by 24% compared with placebo, and over 120 weeks it also reduced the time required to walk 25 feet by 29%, decreased the volume of brain lesions by 3.4%, and reduced the rate of whole brain volume loss by 17.5%. While this impact against progression was modest, this is the first large-scale clinical trial to show positive results in people with primary progressive MS.

In February 2016, the FDA granted Breakthrough Therapy Designation to OCREVUS for the treatment of PPMS. OCREVUS is the first investigational medicine to receive Breakthrough Therapy Designation in MS.

"We are encouraged with the continued focus of the regulatory agencies and progress being made to bring forth treatments for this disabling form of MS," said Professor Alan Thompson, Chair of the International Progressive MS Alliance Scientific Steering Committee. "While the reported effects for ocrelizumab on progression are modest, the data clearly indicate that this treatment has potential benefit and is not only a source of hope, but also an important milestone that will further inform development for effective treatments for everyone with progressive forms of MS."

The Alliance will continue to monitor all potential area of progress and increased understanding in order to accelerate the development of treatment for people with progressive MS.

As appropriate:

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