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FDA breakthrough for Roche's MS drug

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Roche has announced that the US Food and Drug Administration (US FDA) has granted Breakthrough Therapy Designation for the investigational medicine ocrelizumab (OCREVUSTM) for the treatment of people with primary progressive multiple sclerosis (PPMS). There are currently no approved treatments for PPMS, a debilitating form of MS characterized by steadily worsening symptoms and typically without distinct relapses or periods of remission.

"Ocrelizumab is the first investigational medicine for MS to be granted Breakthrough Therapy Designation by the FDA," said Dr Sandra Horning, Roche's chief medical officer and head of global product development. "With no approved treatments for primary progressive MS, ocrelizumab has the potential to address an important unmet need. We are committed to working with the FDA to bring ocrelizumab to people with primary progressive MS as quickly as possible."

Breakthrough Therapy Designation is designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases and to help ensure people have access to them through FDA approval as soon as possible. The designation is based on positive results from the pivotal Phase III study (called ORATORIO), which showed treatment with ocrelizumab significantly reduced disability progression and other markers of disease activity compared with placebo. Top-line results were presented at the 31st congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in October 2015.

Roche plans to pursue marketing authorisation for both PPMS and relapsing multiple sclerosis (RMS), a more common form of the disease, and will submit data from three pivotal Phase III studies to global regulatory authorities in the first half of 2016.

OCREVUSTM is the proprietary name submitted to global regulatory authorities for the investigational medicine ocrelizumab.