Ocrelizumab designated a ‘Breakthrough Therapy’ by FDA for primary progressive MS

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Genentech, a member of the Roche Group, announced in a February 16 press release that the experimental therapy ocrelizumab has been granted ‘Breakthrough Therapy designation’ by the US Food and Drug Administration (FDA) for the treatment of people with primary progressive MS. This designation means that once Genentech files for approval of ocrelizumab to treat primary progressive MS by the FDA, the review process can be expedited.

Breakthrough Therapy designation is intended to speed up the American review process of treatments for a serious condition when clinical evidence indicates that it may demonstrate substantial improvements over currently available therapies. Currently, there are no approved treatment options for primary progressive MS.

The designation was granted to ocrelizumab based on promising results in recent Phase III clinical trials for both primary progressive MS and relapsing remitting MS (see MS Research Australia’s earlier article on these results here). In these studies, ocrelizumab significantly reduced the risk of progression of clinical disability by 24% in 732 people with primary progressive MS, compared to placebo.
According to the release, Genentech plans to pursue marketing approval for both primary progressive MS and relapsing remitting MS, and will submit data from three phase III trials to the FDA in the first half of 2016.

Before becoming licenced and available in Australia, ocrelizumab will need to be assessed by the Australian Therapeutic Goods Administration (TGA). However, the decision by the FDA is encouraging as it may mean access to the treatment will be expedited around the world.

Identifying and fast-tracking treatment options for the progressive forms of MS is a key objective of the International Progressive MS Alliance. MS Research Australia is a managing member of the Alliance and has committed A$1.1 million over 2015-2017. Dr Alan Thompson, chair of the International Progressive MS Alliance Scientific Steering Committee commented, ‘An effective treatment for people with progressive MS would be truly life-changing. We await the detailed safety and efficacy data with great anticipation, and thanks to this expedited review process we are very much looking forward to hearing of ocrelizumab’s future developments and implications.’