

FDA will review Primary Progressive MS treatment by the end of the year

8th July, 2016



Ocrelizumab (trading as Ocrevus) had been submitted to the pharmaceutical regulators in the US and Europe, but in news closer to home, Roche has also announced that ocrelizumab has also been submitted to the Australian Therapeutic Goods Administration for both primary progressive and relapsing multiple sclerosis.

There are currently no approved disease-modifying therapies to treat progressive MS, but that might be changing in the not too distant future.

On the 28th June 2016 Genentech announced that it had submitted OCREVUS™ (ocrelizumab) to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for approval to be used and marketed for the treatment of both relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS) in the US and Europe. This is a very encouraging development for people with primary progressive MS.

Ocrelizumab has already been granted “break through therapy” status by the FDA and now has been granted Priority Review Designation, which means the FDA approval could be granted before the end of the year. FDA approval is an important step for ocrelizumab however, before becoming licensed and available in Australia, it will also need to be approved by the Australian Therapeutic Goods Administration (TGA). However, the decision by the FDA is encouraging as it is likely that FDA approval will expedite access to the treatment around the world. Roche have also indicated that they will be seeking a PBS listing for Ocrevus in Australia, which would be a welcome development to ensure affordable access to this treatment option for Australians with MS.

The fast track 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 particular, these clinical trials for the first time showed an effect for a drug in reducing the risk of disability progression in people with primary progressive MS.

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.’

You can read the full article and statement from the Progressive MS Alliance [here](#).