Siponimod shows promise in phase III trial for secondary progressive MS

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In an announcement made on 25 August, the pharmaceutical company Novartis said experimental medication siponimod was able to reduce the risk of disability progression in people with secondary progressive MS.

Secondary progressive MS (SPMS) is a form of multiple sclerosis that often follows an initial period of relapsing remitting MS. It involves gradual and relentless accumulation of disability often in the absence of ongoing relapses. Unlike relapsing remitting MS which has a number of medications available that can reduce the risk of damaging relapses, there are currently no treatments available that are able to stop the accumulation of disability in SPMS.

The Phase III trial, known as EXPAND, was conducted at multiple trial sites around the world, including Australia, and tested the safety and efficacy of the medication, also known as BAF312, in people with SPMS.
Siponimod is an oral medication that belongs to the same class of drugs as fingolimod (Gilenya) and targets molecules found on the surface of cells known as the sphingosine-1-phosphate (S1P) receptor. This receptor is found on a variety of cells including some types of cells found in the central nervous system that may contribute to the ongoing damage to myelin and nerves that occurs in secondary progressive MS. The drug is able to enter the brain, potentially targeting these cells directly.

The phase III double-blinded, placebo-controlled study compared the efficacy and safety of BAF312 in comparison to placebo in people with SPMS. People in the trial were randomly assigned to receive either 2mg BAF312 per day or placebo, and with 1651 people enrolled it is the largest study conducted in SPMS to date. Participants were monitored using the expanded disability status scale (EDSS), with the primary outcome measure defined as a delay in progression of disabilities as measured by EDSS and confirmed over 3 months. Other outcomes looked at delaying progression of disabilities over a longer period of time, and changes in the timed 25-foot walk test and MRI measures.

The Novartis announcement confirms that the study met its primary target of delaying the time to reach a three-month confirmed disability progression in people receiving siponimod in comparison to those receiving placebo.

The company will present further details of the trial results at the upcoming European Committee for Treatment and Research in MS (ECTRIMS) conference in London in September and we will need to await publication of the full trial results before a full understanding of the potential of this new medication to treat secondary progressive MS is known.

However, this is a very encouraging development for people with secondary progressive MS, who currently have very limited treatment options.

View the Novartis media release here