EXPAND clinical trial

Mayzent® (siponimod)

EXPAND is a randomized, double-blind, placebo-controlled Phase III study comparing the efficacy and safety of Mayzent versus placebo in secondary progressive MS (SPMS) patients. The study shows Mayzent significantly reduced the risk of disability progression, including impact on physical disability and cognitive changes.

Patients in EXPAND were representative of an SPMS population

At study initiation:

48 years
mean age

living with MS
for 16 years

more than 50%
- have a baseline Expanded Disability Status Scale (EDSS) of 6.0 or more
- relied on a walking aid

Fundamental facts[1]

Largest clinical study in SPMS to date

1,651 people with SPMS diagnosis from 31 countries

Varying EDSS scores of 3.0-6.5

Cognition results

Treatment with Mayzent showed:

meaningful positive impact on **cognitive processing speed (CPS),** a core element of cognitive function, as measured by the Symbol Digit Modalities Test (SDMT) **in patients with SPMS[2]**

significant favorable outcomes in activity and progression of MS, including **cognitive function, MRI disease activity,** and **brain volume loss[1]**

Other results in comparison to placebo[1]

21% risk reduction of three-month confirmed disability progression (CDP)

33% reduction of three-month CDP in patients who had a relapse in two years prior to study

89% of patients free from gadolinum-enhancing lesions

26% risk reduction of six-month CDP

55% reduction of annualized relapse rate (ARR)

57% of patients free from new or enlarging T2 lesions

Safety profile overall consistent with the known effects of S1P receptor modulation

About Mayzent

In March 2019, the FDA approved Mayzent for the treatment of replasing forms of MS, to include clinically isolated syndrome (CIS*), replasing remitting disease and active secondary progressive disease. Mayzent is the only FDA-approved treatment for active SPMS with proven efficacy in a pivotal study of a typical SPMS population.

*Clinically isolated syndrome (CIS) is defined as a first episode of neurologic symptoms that lasts at least 24 hours and is caused by inflammation or demyelination in the central nervous system.

References:
1. Kappos L, Cree B, Fox R, et al. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomized, phase 3 study. Lancet. Published online March, 2018. http://dx.doi.org/10.1016/S0140-6736(18)30475–6.
2. Benedict R, Cree B, Tomic D, et al. Impact of Siponimod on Cognition in Patients With Secondary Progressive Multiple Sclerosis: Results From Phase III EXPAND Study. Abstract no. 004. Oral presentation at the 70th Annual Meeting of the American Academy of Neurology, Los Angeles, CA, April 21-27, 2018.

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