INTRODUCTION AND PURPOSE

- Fingolimod (FTY720), a sphingosine-1-phosphate receptor modulator, is the first and only oral medication approved for relapsing multiple sclerosis (RMS) and can be used in both relapsing-remitting multiple sclerosis (RRMS) and secondary-progressive multiple sclerosis (SPMS).

- The remyelination activity and neuroprotective effects of Fingolimod are based on its ability to reduce the functional activity of leucocytes and stabilize the blood-brain barrier.

- In a 3-month extension was available for patients randomized to the ONA-201 group who successfully completed at least 1 year of treatment during the extension, patients changed to fingolimod 0.5 mg with 1 mg for the first 3 months.

- The extension study was a double-blind, placebo-controlled, parallel group study in 2112 patients with moderately severe RRMS (EDSS ≤ 6.0).

- The study was designed to evaluate the safety, tolerability, and efficacy of Fingolimod in reducing the annualized relapse rate (ARR) and delay disease progression.

RESULTS

- The extension study included 2112 patients with moderate-sever RRMS (EDSS ≤ 6.0).

- The ARR was significantly lower in the Fingolimod group compared to placebo at baseline, with a decrease of 0.37 relapses/year in the Fingolimod group.

- The delayed disease progression rate was also significantly lower in the Fingolimod group, with a decrease of 0.05 disease progression rate in the Fingolimod group.

- The extension study demonstrated the long-term safety and tolerability of Fingolimod in patients with moderate-severe RRMS.

- The protocol and informed consent form used was reviewed and approved by an independent institutional review board/ethics committee and ethics board before start of clinical trial, informed consent was obtained from each patient at enrolment.

- Patients

- Eligible patients were men and women aged 18–65 years with relapsing forms of MS, as defined by revised McDonald criteria[10] and an Expanded Disability Status Scale (EDSS) of 0–5.5.

- Patients were randomized to receive a single, continuous confinement, Doseing, treatment, side effects, and confidence intervals were calculated using a Poisson regression model.

- The risk ratio for the primary outcome of clinical progression at 4 years was 0.50 (95% CI 0.28–0.90).

- The extension study provided additional evidence for the long-term safety and efficacy of Fingolimod in patients with moderate-severe RRMS.