PR–Fampridine Improves Mobility in Patients With MS

Written by Maria Vinall

Prolonged release (PR)-fampridine treatment resulted in sustained and clinically meaningful improvement in walking ability and balance throughout a 6-month treatment period in individuals with multiple sclerosis (MS). The Exploratory Study to Assess the Effect of Fampridine (BIIB041) on Walking Ability and Balance in Participants With Multiple Sclerosis study [MOBILE; NCT01597297; Hupperts R et al. ACTRIMS/ECTRIMS 2014 (poster P922)] evaluated the effect of PR-fampridine on walking ability, dynamic and static balance, and subjective impressions of well-being. Raymond Hupperts, MD, Orbis Medical Center, Sittard-Geleen, the Netherlands, presented the findings in a poster session.

Maintaining mobility is among the greatest concerns for patients with MS [Sutliff MH. *Curr Med Res Opin.* 2010]. PR-fampridine was approved to improve walking in MS based on the results of 2 pivotal trials [Goodman AD et al. *Ann Neurol.* 2010; Goodman AD et al. *Lancet.* 2009] that demonstrated consistent improvements on the Timed 25-Foot Walk (T25FW). The T25FW, however, may not fully assess all of the domains that control walking ability, including balance [Nogueira LA et al. *Mult Scler Int.* 2013].

MOBILE was a randomized, double-blind, multicenter, placebo-controlled, exploratory 24-week phase 2 study conducted at 24 sites in 6 countries. Patients (n = 132) aged 18 to 70 years, with progressive and relapsing MS and an Expanded Disability Status Scale (EDSS) score of 4.0 to 7.0, were randomly assigned (1:1) to PR-fampridine 10 mg BID (n = 68) or placebo (n = 64) for 24 weeks. Outcome measures included walking ability assessment using the 12-item Multiple Sclerosis Walking Scale (MSWS-12) and Patient Global Impression of Change (PGIC); mobility and balance assessment using the Timed Up and Go (TUG) test and Berg Balance Scale (BBS); and subjective impression of well-being assessment using the Multiple Sclerosis Impact Scale (MSIS-29), physical subscale (PHYS), and EuroQoL-5 Dimension 5-level instrument (EQ-5D-5L). Safety and tolerability were assessed by monitoring adverse events (AEs).

Mean age of the patients was 49.8 years; 54% were women. The mean EDSS score was 5.7. Baseline to week 24 improvements in the MSWS-12, TUG test, BBS, and MSIS-29 PHYS were greater following treatment with PR-fampridine compared with placebo. Benefits declined by the week 26 visit following discontinuation of treatment at week 24.

More patients treated with PR-fampridine vs placebo reported improvement on the PGIC at the week 2 visit: 31 patients (46%) for PR-fampridine vs 16 (26%) for placebo. No apparent differences between treatment groups were observed in the EQ-5D-5L utility index. The cumulative percentage of patients with a mean improvement in the MSWS-12 score and TUG test was greater in the PR-fampridine-treated patients compared with the placebo group.

Safety findings were consistent with the known safety profile of PR-fampridine. The number of patients who discontinued (PR-fampridine, n = 13; placebo, n = 12) was similar. AEs were the main reason for discontinuation in both groups (PR-fampridine, n = 7; placebo, n = 5). No seizures were reported, and serious AEs were reported by fewer patients treated with PR-fampridine (2/68; 3%) compared with placebo (5/64; 8%). The common AEs were nasopharyngitis and urinary tract infection.

In this study, PR-fampridine improved a broad range of objective and patient-reported measures of walking ability. An ongoing phase 3 study will seek to confirm these findings.

Improvement in UI With OnabotulinumtoxinA Maintained Over 4 Years in Patients With MS

Written by Emma Hitt Nichols, PhD

A long-term extension trial demonstrated improvement in urinary incontinence (UI) as a result of neurogenic detrusor overactivity (NDO) caused by multiple sclerosis (MS). Philip J. Aliotta, MD, Western New York Urology Associates, Cheektowaga, New York, USA, presented data from A Long-term Follow-up Study of Botulinum Toxin Type A in Patients With Overactive Bladder as a Result of Spinal Injury or Multiple Sclerosis trial [NCT00876447; Aliotta PJ et al. ACTRIMS/ECTRIMS 2014; (poster P905)].

NDO can occur in patients with MS, which results in UI [de Sèze M et al. *Mult Scler.* 2007]. Two randomized trials demonstrated that intradetrusor onabotulinumtoxinA was effective and well tolerated for the treatment of NDO in patients with spinal cord injury or MS who did not achieve adequate relief with an anticholinergic agent [Ginsberg D et al. *J Urol.* 2012; Cruz F et al. *Eur Urol.* 2011]. According to Dr Aliotta, the purpose of this 3-year extension study was to evaluate the use of onabotulinumtoxinA for the treatment of UI as a result of