Durability of the beneficial effect of MLC601 (NeuroAiD™) on functional recovery among stroke patients from the Philippines in the CHIMES and CHIMES-E studies

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Abstract

Background and Aim: A pre-specified country analysis of subjects from the Philippines in the CHInese Medicine NeuroAiD Efficacy on Stroke recovery (CHIMES) Study showed significantly improved functional and neurological outcomes on MLC601 at month (M) 3. We aimed to assess these effects on long-term functional recovery in the Filipino cohort.

Methods: The CHIMES-E (extension) Study evaluated subjects who completed three months of randomized placebo-controlled treatment in CHIMES up to two years. Blinding of treatment allocation was maintained and all subjects received standard stroke care and rehabilitation. Modified Rankin Score (mRS) and Barthel Index (BI) were assessed in-person at M3 and by telephone at M6, M12, M18, M24. Odds ratios (OR) with corresponding 95% confidence intervals (CI) for functional recovery using ordinal analysis of mRS and for achieving functional independence (mRS 0-1 or BI ≥ 95) at each time point were calculated, adjusting for age, sex, baseline National Institute of Health Stroke Scale (NIHSS), onset-to-treatment time (OTT) and pre-stroke mRS.

Results: The 378 subjects (MLC601 192, placebo 186) included in CHIMES-E from the Philippines (mean age 60.2 ± 11.1) had more women (p < 0.001), worse baseline NIHSS (p < 0.001) and longer onset to treatment time (p = 0.002) compared to other countries. Baseline characteristics were similar between treatment groups. The treatment effect of MLC601 seen at M3 peaked at M6 with OR for mRS shift of 1.53 (95% CI 1.05–2.22), mRS dichotomy 0–1 of 1.77 (95% CI 1.10–2.83), and BI ≥ 95 of 1.87 (95% CI 1.16–3.02). The beneficial effect persisted up to M24.

Conclusion: The beneficial effect of MLC601 seen at M3 in the Filipino cohort is durable up to two years after stroke.

Keywords

acute stroke, stroke recovery, clinical trial, long-term outcome, MLC601, Philippines

Introduction

The CHInese Medicine NeuroAiD Efficacy on Stroke recovery (CHIMES) study was an international, randomized, placebo-controlled, double-blind trial that compared MLC601 with placebo in 1099 subjects with