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**ACTIMUS—PHASE II CELL THERAPY TRIAL
IN PROGRESSIVE MS**

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We have recently completed a phase I trial of intravenous delivery of autologous bone marrow in progressive MS ('SIAMMS'). The possibility of repair was suggested by improvements in the neurophysiological secondary outcome measure. The 'Assessment of Bone Marrow-derived Cellular Therapy in Progressive Multiple Sclerosis' (ACTiMuS), due to commence in spring 2014, will examine the efficacy of intravenous delivery of autologous marrow in progressive MS.

A prospective, randomised, double-blind, placebo-controlled, stepped wedge design will be employed at a single centre. Eighty patients with primary (20) or secondary (60) progressive MS will be recruited and randomised to either early (immediate) or late (1 year) intravenous infusion of autologous, filtered bone marrow. The placebo intervention is infusion of autologous blood.

Participants will be followed up for a further year following the final intervention. The primary outcome measure is global evoked potential derived from multimodal evoked potentials. Secondary outcome measures include adverse event reporting, clinical (EDSS and MSFC) and self-assessment (MSIS-29) rating scales, optical coherence tomography (OCT) and brain and spine MRI. Outcomes will be analysed on an intention-to-treat basis. Laboratory studies performed in parallel with the clinical trial will further investigate the biology of bone marrow infusion in MS, including mechanisms underlying repair.