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FDA nod for ph II trial of Mesoblast's arthritis treatment

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Singapore: Australian regenerative medicine company Mesoblast has received clearance from the US Food and Drug Administration (FDA) to commence a phase II clinical trial evaluating a single intravenous infusion of allogeneic, or "off-the-shelf", Mesenchymal Precursor Cells (MPCs) for the treatment of active rheumatoid arthritis.

The randomized, double-blind placebo-controlled trial is expected to commence during the second quarter 2013, and will recruit across multiple sites in the US and Australia. The trial will compare the effects of a single intravenous infusion of allogeneic MPCs dosed at one or two million cells per kg compared with placebo in 48 patients who have had an incomplete or inadequate response to a biologic inhibitor of the TNF-alpha pathway for active rheumatoid arthritis. Safety and effectiveness of the MPC therapy will be assessed at multiple time points with the primary endpoints defined as three months.

Rheumatoid Arthritis is an autoimmune disease caused by aberrant activation of multiple immune pathways involving both monocytes and T cells, ultimately resulting in joint destruction. Existing biologic treatments target only single immune pathways, resulting in incomplete responses, need for chronic administration, and potentially unacceptable infectious adverse events.

In contrast, Mesoblast's MPCs have been shown in preclinical studies to have a broad immunomodulatory mechanism of action (MOA), simultaneously inhibiting T cells and monocytes involved in inflammation and autoimmunity. The broader effects of Mesoblast's MPCs on multiple
immune pathways suggest that they may be particularly useful agents for reducing the inflammation and permanent joint damage associated with progression of RA.

Findings show that MPCs can concomitantly inhibit both Th17 T cells and pro-inflammatory monocytes, and improve synovial tissue pathology. This provides a rationale for their potential use as both a first-line biologic treatment in those not responding to conventional anti-rheumatic
agents and in patients with incomplete responses to biologic inhibitors of the TNF-alpha pathway alone.

Mesoblast Chief Executive Prof Silviu Itescu said: "We believe that the broad immunomodulatory effects of our MPCs could provide a tangible benefit to patients with debilitating autoimmune diseases, including RA. This is the first in a series of

programs designed to establish the credentials of our intravenous product formulation for a broad-based spectrum of inflammatory and immunologic conditions."