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### **Stem cell-based therapy for the treatment of femoral head necrosis - first clinical experience**

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Osteonecrosis of the femoral head involves the death of cells in trabecular bone and marrow, fracture of subchondral bone, and often leads to total hip replacement. Retrospective clinical studies have shown that osteonecrosis in 80-90% of affected patients progresses to destroy the femoral head, usually within 2-3 years after diagnosis. There are no effective treatment options for terminating or reversing the disease process.

Reports using autologous bone marrow tissue injected percutaneously into the necrotic area have shown a high rate of success in early stage osteonecrosis. As a more standardized alternative to fresh bone marrow, Aastrom Inc. has developed a proprietary automated process to expand autologous bone marrow cells *ex vivo*. Bone Repair Cells (BRCs) are a mixture of stem and early progenitor cells including cells of hematopoietic, mesenchymal, and endothelial lineages derived from a small sample of the patient's own bone marrow. Clinically, the cells have been used to treat over 50 patients with BRCs formulated with osteoconductive matrices. Interim data reported on the first 20 patients who

completed the one year follow-up of a now completed 36 patient Phase I/II non-union fracture trial demonstrated excellent safety profile, and >90% callus formation and bone bridging in no-option patients.

A new procedure has been developed to deliver BRC/matrix compositions into the femoral head to treat osteonecrosis. This abstract outlines the clinical formulations, the surgical procedure, safety profiles and clinical outcome of the product in 3 compassionate use patients with necrosis of the femoral head.