ISOLATION OF ACELLULAR DERIVATIVES OF HUMAN AMNIOTIC FLUID IN SINGLE-USE IMPLEMENTATION

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We have developed a processing methodology to isolate a natural biologic, trademarked as SanaFluid, from amniotic fluid that is collected during C-section deliveries from qualified volunteer donors. SanaFluid is acellular liquid rich in cytokines, chemokines, and extracellular vesicles. We hypothesis that these biologically active constituents are responsible for the observed anti-inflammatory, immune-modulatory, and reparative properties of SanaFluid, and likely act at multiple stages of the wound healing to modulate the inflammatory, proliferation/granulation, re-epithelialization, and remodeling processes. The efficacy of SanaFluid has already been tested by topical administration in over 5,000 patients and over 50 intravenous administrations for various indications that include wound care, osteoarthritis, esophageal fistulas, entercutaneous fistulas, urethroplasty, and COPD. The outcome of these treatments has resulted in positive responses from a large number of recipients and has led to the execution of several clinical trials that are in progress.

Currently, SanaFluid is manufactured manually via sequential centrifugation and multi-filtration steps performed by trained technologists operating within a highly specialized aseptic facility. The intermediates in the production sequence are hand-transferred among different general-purpose instruments within an open facility. As a result of a lengthy and labor-intensive manual operation, consistent product quality is difficult to maintain, and the cost of production is high.

This presentation describes our progress in developing an automated manufacturing process to provide a consistent, less expensive product using single-use components. The envisioned automated system consists of a reusable instrument and a single-use closed-loop sterile cartridge, which together process amniotic fluid from a single donor to generate multiple aliquots of SanaFluid that are ready for therapeutic applications. We expect that in this format will standardize the manufacturing of SanaFluid by ensuring its consistent isolation from biologically diverse AF collections characterized by predictable and controllable quality and safety profiles, improved process robustness, and reduced bio-manufacturing costs.