Unmet Medical Need: Diagnostic Test Methods for Quality Control of Stem Cell Products Intended for Cell Therapy

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Currently there are 15,000 to 20,000 cell therapy clinical trials using cell products manufactured by more than 100 different stem cell companies and university laboratories. Before they can become commercial products they must be evaluated by the FDA. Like pharmaceuticals, FDA has mandated that all cell products be fully characterized before they can be commercialized with both in-process and release testing. The industry is struggling with how to do testing on therapeutic product as complex as a living cell population. Therefore, an unmet need exists for a practical method to characterize a cell product for quality control purposes. The intent of this project is to investigate the utility of using Raman Spectroscopy as a means of determining the general biochemical content of cells to provide useful information for quality control purpose of cellular products. The goal of this testing is to ensure only cell products of appropriate quality are manufactured and released for clinical use. Diagnostic tests are also needed to ensure that cells manufactured for clinical trials on a small scale have not been changed by scaling the manufacturing process to commercial levels.

Specific endpoints to be examined are the applicability of Raman spectroscopy for FDA mandated tests of Cell Identity, Cell Purity, and Cell Potency/Biological Activity. It is intended to evaluate whether cells subjected to various biologically stressors that could jeopardize their therapeutic utility can be detected by changes in their Raman spectra. The reproducibility and sensitivity of using Raman spectral analysis will be evaluated in proof of concept experiments. Further, the utility of Raman spectral analysis to assess cell purity will be investigated by intentionally adding different cell populations to homogeneous cell populations to detect the ability of Raman technology to detect these “foreign” cell components. If warranted, the pilot study data will be presented to the FDA for comment, interest and guidance.

A successful outcome of the project may create the basis for spinning out a diagnostic startup company from the Center for Biophotonics Science & Technology and the Institute for Regenerative Cures or for other technology licensing opportunities. The project requires constructing a multidisciplinary team representing electrical, mechanical and software/firmware engineering, physics, cell biology, marketing, regulatory and business development disciplines.