
Comella is a world-renowned expert on regenerative medicine with a focus on adipose derived stem cells. She was named number 24 on Terrapin’s list of the Top 50 Global Stem Cell Influencers and number 1 on the Academy of Regenerative Practices list of Top 10 Stem Cell Innovators. Comella has pioneered stem cell therapies from various sources including cord blood, bone marrow, muscle, and adipose.

Entitled ‘Autologous Stromal Vascular Fraction in the Intravenous Treatment of End-Stage Chronic Obstructive Pulmonary Disease: A Phase I Trial of Safety and Tolerability’, the scientific paper was co-authored by Kristin Comella, Jesus A. Perez Blas, Tom Ichim, Javier Lopez, Jose Limon, and Ruben Corral Moreno. Below is a link and abstract to the paper: http://www.jocmr.org/index.php/JOCMR/article/view/3072/1877.

Background: Chronic obstructive pulmonary disease (COPD) is a consistently progressive, ultimately fatal disease for which no treatment exists capable of either reversing or even interrupting its course. It afflicts more than 5% of the population in many countries, and it accordingly represents the third most frequent cause of death in the US, where it accounts for more than 600 billion in health care costs, morbidity, and mortality. Adipose tissue contains within its stromal compartment a high abundance of adipose stem/stromal cells (ASCs), which can be readily separated from the adipocyte population by methods which require less than 2 h of processing time and yield a concentrated cellular preparation termed the stromal vascular fraction (SVF). The SVF contains all cellular elements of fat, excluding adipocytes. Recent clinical studies have begun to explore the feasibility and safety of the local injection or intravascular delivery
of SVF or more purified populations of ASCs derived by culture protocols. Several preclinical studies have demonstrated a remarkable ability of ASC to nearly fully ameliorate the progress of emphysema due to cigarette smoke exposure as well as other causes. However, no prior clinical studies have evaluated the safety of administration of either ASC or SVF in subjects with COPD. We hypothesized that harvest, isolation, and immediate intravenous infusion of autologous SVF would be feasible and safe in subjects with COPD; and that such an approach, if ultimately determined to be efficacious as well as safe, would provide a highly practical method for treatment of COPD.

**Methods:** In this study, an initial phase I trial evaluating the early and delayed safety of SVF infusion was performed. Twelve subjects were enrolled in the study, in which adipose tissue was harvested using standard liposuction techniques, followed by SVF isolation and intravenous infusion of 150 - 300 million cells. Standardized questionnaires were administered to study feasibility as well as immediate and delayed outcomes and adverse events as primary endpoints. Secondary endpoints included subjective wellness and attitudes towards the procedure, as well as willingness to undergo the procedure a second time. The follow-up time ranged from 3 to 12 months, averaging 12 months.

**Results:** Of the 12 subjects, only one experienced an immediate adverse event, related to bruising from the liposuction. No observed pulmonary or cardiac issues were observed as related to the procedure. There were no deaths over the 12-month study period, and none identified in the subsequent telephonic follow-up. Attitudes toward the procedure were predominantly positive, and 92% of the study subjects expressed a desire to undergo the procedure a second time.

**Conclusions:** This study is the first to demonstrate safety of SVF infusion in humans with serious pulmonary disease. Specifically, the use of intravenous infusion as a route to achieve pulmonary cellular targeting did not lead to clinical pulmonary compromise. The intravenous administration of SVF should be further explored as a potentially feasible and safe method for delivery leading to possible therapeutic benefit.
**Forward-Looking Statements:** Except for historical matters contained herein, statements made in this press release are forward-looking statements. Without limiting the generality of the foregoing, words such as "may", "will", "to", "plan", "expect", "believe", "anticipate", "intend", "could", "would", "estimate", or "continue", or the negative other variations thereof or comparable terminology are intended to identify forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date hereof. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The Company is subject to the risks and uncertainties described in its filings with the Securities and Exchange Commission, including the section entitled "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2016, and its Quarterly Reports on Form 10-Q.