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Developing cell therapy products for commercial use

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Developing a cell therapy product for commercial use is a novel and complicated process. Determining the appropriate infrastructure for each stage of product development and testing can be crucial to taking the product to the clinic. Establishing appropriate timelines and meeting budgets demands can be a challenge for start-up companies with limited funding. This session will discuss the Bioheart experience in taking cell therapy products to the clinic and the challenges to ensure patient safety and financial security in the path the commercialization.

Autologous immature myoblasts form new contractile muscle in myocardial scar tissue. Over 2000 animal studies have demonstrated both safety and efficacy. Over 400 patients have enrolled in myoblast transplantation for heart repair clinical trials since June of 2000. Catheter delivery studies began in May of 2001. 94% of treated patients have improved in heart failure class while only 6% have worsened. 84% of treated patients exhibited improvements in measurable parameters such as exercise capacity testing while only 16% have worsened. LVEF at exercise measured by dobutamine stress echo has shown cell treated patients with 15% improvement. Phase II/III randomized double blinded placebo controlled studies are on-going. Interim results were shared demonstrating that cell treated patients improved 91.7 meters in exercise capacity testing while placebo patients on optimal CHF drugs declined 4 meters. Results from 23 years of animal studies and 11 years of clinical studies demonstrate efficacy with reasonable safety.

Biography

Ms. Comella has over 14 years experience in corporate entities with expertise in regenerative medicine, training and education, research, product development, and senior management. Ms. Comella has been a member of the Bioheart Inc. senior management team since 2004 and is currently serving as the Chief Scientific Officer. Bioheart is a publically traded company focusing on the discovery, development and commercialization of autologous cell therapies for the treatment of chronic and acute heart damage and peripheral vascular disease. Ms. Comella was appointed as Bioheart's Vice President of R&D and Corporate Development in December 2008. Since joining Bioheart in September 2004, she has played a major role in managing the product development, manufacturing and quality systems. In addition, Ms. Comella is currently and actively serving on multiple boards in the stem cell arena. She is co-founder and Chief Executive Officer of Stemlogix, LLC and Chief Scientific Officer of the Ageless Regenerative Institute. The Ageless and Stemlogix Programs involve education, training, technology and support in delivering regenerative medicine to clinicians and veterinarians. Ms. Comella has over ten years of cell culturing experience including building and managing the stem cell laboratory at Tulane University's Center for Gene Therapy. She also developed stem cell therapies for osteoarthritis at Osiris Therapeutics. Ms. Comella holds an M.S. in Chemical Engineering from The Ohio State University and a B.S. in Chemical Engineering from the University of South Florida.

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