



Media Contact: U.S. Stem Cell, Inc.
13794 NW 4th Street, Suite 212
Sunrise, FL 33325
Phone: 954.835.1500
Email: usstemcell@us-stemcell.com

For Immediate Release

U.S. Stem Cell, Inc. MARVEL Trial Receives Reactivation Status with the FDA

Sunrise, FL – April 10, 2017 – U.S. Stem Cell, Inc. (USCC), a Florida corporation and leader in novel regenerative medicine solutions and physician-based stem cell therapies for human and animal patients, has received reactivation status of the MARVEL phase II/III trial.

Following the passing of the 21st Century Cures Act, U.S. Stem Cell, Inc. has applied to the FDA for Regenerative Medicine Advanced Therapy (RMAT) Designation for the MyoCell product as part of the MARVEL trial. Our trial had previously been placed on “Inactive Status” as patients were not actively being enrolled. We placed a request to the FDA to reactivate the protocol and consider the therapy for RMAT designation. We have recently heard from the FDA who has notified us that the protocol has been placed on “Reactivation Status” after reviewing details on the protocol and data collected on patients to date. The FDA has also notified us that they are still reviewing our submission for RMAT. Thanks to the REGROW component of the Cures Act, The FDA will grant RMAT designation for a regenerative medicine therapy that is intended to treat, modify, reverse, or cure a serious or life-threatening disease and demonstrates preliminary clinical evidence that the product has the potential to address unmet medical needs for a disease. We believe that our MyoCell product meets these requirements as we have demonstrated clinical efficacy in both preclinical and clinical studies including our most recent MARVEL trial publication (review full publication here: <https://www.ncbi.nlm.nih.gov/pubmed/21982657>). If RMAT designation is granted, this could expedite the approval process with the FDA.

More information on the FDA’s new RMAT Designation can be found here: <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm537670.htm>

###

About U.S. Stem Cell, Inc.

US Stem Cell, Inc. (formerly Bioheart, Inc.) is an emerging enterprise in the regenerative medicine / cellular therapy industry. We are focused on the discovery, development and commercialization of cell based therapeutics that prevent, treat or cure disease by repairing and replacing damaged or aged tissue, cells and organs and restoring their normal function. We believe that regenerative medicine / cellular therapeutics will play a large role in positively changing the natural history of diseases ultimately, we contend, lessening patient burdens as well as reducing the associated economic impact disease imposes upon modern society.

Our business, which includes three operating divisions (**US Stem Cell Training, Vetbiologics and US Stem Cell Clinic**) includes the development of proprietary cell therapy products as well as revenue generating physician and patient based regenerative medicine / cell therapy training services, cell collection and cell storage services, the sale of cell collection and treatment kits for humans and animals, and the operation of a cell therapy clinic. Management maintains that revenues and their associated cash in-flows generated from our businesses will, over time, provide funds to support our clinical development activities as they do today for our general business operations. We believe the combination of our own therapeutics pipeline combined with our revenue generating capabilities provides the Company with a unique opportunity for growth and a pathway to profitability.

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.