

October 2023 Newsletter

2023 “Campaign for Cures” Research Goal and Request for Support Update

Dear Friend:

As we begin the fourth quarter of 2023, the John Paul II Medical Research Institute (JP2MRI)’s “Campaign for Cures” initiative to raise \$1 million needs your support. As of this newsletter, JP2MRI has only raised a little over \$200,000 dollars and needs significantly more financial support to help us with our research objectives and avoid delays. Many of you will recall that JP2MRI’s global visibility grew exponentially in 2014 as a result of the “ALS Ice Bucket Challenge” going viral. At that time, many pro-life individuals started to financially support JP2MRI to take on the important responsibility of conducting medical research to find a treatment for Amyotrophic Lateral Sclerosis (ALS) consistent with an ethical research approach. There were two primary reasons why pro-life donors took an interest in JP2MRI: First, they discovered that secular medical research foundations were supporting the use of aborted fetal cells and embryonic stem cells for treating ALS and other neurodegenerative diseases, which conflicted with their moral and religious values. Second, they learned that there were virtually no established Christian organizations over the past half century that had taken on the responsibility of pursuing alternative ethical research approaches that would address these unmet medical needs. As one can imagine, it is a challenge for JP2MRI to carry the entire weight of this global problem. Despite the challenges, JP2MRI has always found a way to succeed. This year’s Campaign has been geared towards advancing our neurodegenerative disease research platform. For decades, there has been a great deal of hope among both stem cell researchers and the public that neural stem cells will aid in treating neurodegenerative diseases such as Parkinson’s disease, spinal cord injury and ALS. To date, neural stem cells have not yet achieved this promise. However, the field is constantly advancing and hopefully, like all research endeavors, will someday soon be able to help treat patients who currently have very limited options. Unfortunately, it is important to recognize that neural stem cells derived from embryonic stem cells and aborted fetal tissue are currently being utilized in clinical trials for the neurodegenerative conditions identified above. The purpose of this newsletter is to summarize important research milestones that JP2MRI has accomplished in our neural stem cell research efforts. The technology that we have developed to accomplish these milestones is not only ethical, but possesses significant advantages over the current scientific state of the art in the following ways: (1) Our neural stem cells are produced using novel pluripotent stem cells that convert quicker and offer a safer clinical profile; (2) Our proprietary technology enables JP2MRI to scale-up production of pluripotent stem cells in a sufficient quantity necessary for clinical trials; and (3) JP2MRI is able to differentiate pluripotent stem cells into neural stem cells at a fraction of the current manufacturing cost using our technology. We are proud to say that no organization in the world has accomplished these milestones!

Novel iPSC Technology

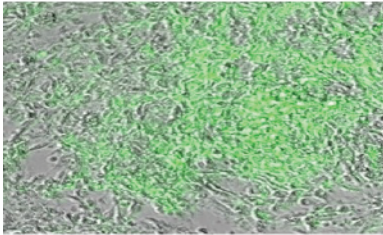
In 2006, Japanese Nobel Laureate Dr. Shinya Yamanaka discovered induced pluripotent stem cells (iPSC) as an alternative means of creating pluripotent stem cells that did not require the use of human embryos. However, to produce iPSC, his invention required using viruses and cancer genes. This methodology consequently came with safety risks, including possibly the risk of cancer. For years, no organization had figured out a way to produce iPSC without using viruses and cancer genes. Then in 2017 the Institute, in collaboration with Cellular Engineering Technologies (CET), solved this dilemma using a novel approach that we described in peer-reviewed publications. This method was recognized with a United States patent being issued and offers JP2MRI the freedom to develop iPSC-derived cell therapies. Publications referencing our technique were recognized in the top 3 percentile among 9 billion articles published in 2017.

Solving Production and Scale-up Challenges for Future Clinical Applications

In 2020, with the assistance of research funding from the National Institutes of Health (NIH), CET and JP2MRI collaborated to develop manufacturing methods to scale-up production of iPSC cells to levels as high as 10 billion cells. This was done to show proof of concept that we can produce enough iPSC for a clinical trial. JP2MRI and CET are now collaborating on a commercial operation that will produce clinical-grade stem cells for future clinical trials.

Eliminating the Cost Barrier Hurdle for Neural Stem Cell Differentiation

Historically there have been two barriers limiting the production of neural stem cells from pluripotent stem cells: (1) the absence of high quality human neural peptides; and (2) the cost of converting pluripotent stem cells into neural stem cells. In the womb, specialized neural peptides are required to convert pluripotent stem cells into neural tissue. These neural peptides have a very special chemical composition that has never been artificially synthesized by man, even when attempted by other researchers using aborted fetal cells. Last year, the Institute was able to develop new genetically engineered human adult stem cells which produce neural peptides that most closely match the chemical properties found in a mother's womb. This invention is now part of a Patent Cooperation Treaty (PCT) application with the United States Patent and Trademark Office. JP2MRI's objective is to use this technology to advance ethical gene therapy, biologics and vaccines. Most importantly, the Institute is now capable of producing 80-100 million neural stem cells at pennies on the dollar. It currently costs researchers over \$200,000 to purchase the required neural peptides to produce sufficient numbers of stem cells necessary for a clinical trial (i.e. - 2 million and 20 million dollars in neural peptide costs respectively to produce 10 and 100 times more neural stem cells). This is a major breakthrough! The figure below shows a microscopic photo image of neural stem cells that were converted from our iPSC. The green color represents the expression of a neural protein called Nestin, which validates that the iPSC have converted almost entirely into neural stem cells. Over the past two decades, the Institute has established a proven track record of research success at the interface between medical ethics and biotechnology. We have developed new benchmarks in the area of iPSC research by utilizing a novel method for manufacturing safer, better and cheaper iPSC than embryonic stem cells and neural stem cells. For over a half century, no organization has accomplished biotechnology that only uses morally-licit human cells.



Yet, much more research needs to be done to realize the full potential that this stem cell research will have on treating neurodegenerative disorders. That is why we are earnestly seeking your support for this important research endeavor in two ways: 1) Please continue to financially support this important work; and 2) Please act as an ambassador and help spread the word about our ethical research efforts within your network.

Thank you very much for your support!

Kind regards and God Bless,

Jay M. Kamath, J.D. / CEO
John Paul II Medical Research Institute

2500 Crosspark Rd., Suite W230
Coralville, IA 52241
(office): 319-665-3001
(fax): 319-887-2870
www.jp2mri.org

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