



## December 2023 Newsletter

Dear Friends:

As we end the fourth quarter of 2023, the John Paul II Medical Research Institute (JP2MRI)'s "Campaign for Cures" goal to raise \$1 million continues to need your support. As of this newsletter, JP2MRI has raised \$250,000 dollars and needs a strong final month of financial support to help us meet our research objectives and avoid delays. As many of you know, most secular medical research foundations receive millions of dollars annually and support the use of aborted fetal cells and embryonic stem cells in medical research. It may come as a surprise to learn that much of this support comes from pro-life individuals who are unaware of the values of the foundations that they are supporting. Additionally, over the past half century, virtually no established Christian organization has taken on the responsibility of creating alternative ethical research approaches. For the past two decades, JP2MRI has been the singular non-profit organization that has conducted research to replace morally-illicit cells used in biotechnology. JP2MRI conducts research to address unmet medical needs for neurodegenerative diseases, cancer, rare diseases and other unmet chronic conditions. You have recently received newsletters that have updated our progress in developing cell therapy for treating cancer and neurodegenerative diseases. The prior newsletters have highlighted our progress using stem cells called induced pluripotent stem cells (iPSC). Moreover, we have recently highlighted how JP2MRI has substantially reduced the cost of transforming iPSC into neural stem cells by developing in-house capabilities to manufacture high-quality neural peptides. These two milestones allow JP2MRI the ability to not only reduce the cost of research for neurodegenerative diseases, but also to reduce the cost of conducting stem cell research for treating cancers. In this newsletter, I will highlight a specific field of cancer research called Adoptive Cell Therapy (ACT). The Institute is now uniquely positioned to make an important contribution in this treatment option and needs your financial support to help us advance this important therapy.

### **What is Adoptive Cell Therapy (ACT)?**

ACT is a new and effective form of cancer treatment for blood cancers, with recent interest also gaining to apply ACT to attack solid tumors. In this treatment, a patient's blood is collected and specialized blood cells called T-cell lymphocytes are harvested. The T-cell lymphocytes are then genetically modified under laboratory conditions and a cell surface protein called Chimeric Antigen Receptor (CAR) is introduced, which allows the newly formed T-cell lymphocytes to specifically target a patient's cancer. The subsequent newly formed CAR-T cells are then infused back into a patient. CAR-T cells are now an approved Food and Drug Administration (FDA) cell therapy that is provided by the pharmaceutical industry. However, there are major scientific and ethical challenges with this treatment. First, CAR-T gene therapy requires cells from an aborted fetal cell line called HEK293 to produce viruses that deliver the CAR gene. Second, the cost of this cell therapy is over 400,000 dollars per patient since the treatment needs to be individually tailored. Moreover, there are also technical challenges, such as the cancer patient's own T-cells being deficient or absent in producing an ACT. The pharmaceutical industry has been struggling to find a new way to produce CAR-T cell therapy that can be manufactured from universal and off-the shelf (one-size fits all) iPSC that are free of viruses. However, this process is extraordinarily expensive and complex because of the vast number of peptides required to transform iPSC into T-lymphocytes, and the process being dependent on the use of viruses. Presently, no biopharmaceutical company has been able to solve this problem. Fortunately, due to support from our donors over the past two decades, JP2MRI is now poised to solve these ethical and scientific challenges as outlined below.

### **Developing a Safer iPSC-derived ACT That is Free of Viruses**

The biggest safety risk involving iPSC-based cell therapies is their dependency on cancer genes (oncogenes) and viruses during the manufacturing process. To address this challenge, JP2MRI helped develop the first and best-in-class virus and oncogene-free iPSC method in 2017. This novel method was published and achieved an Altmetric score in the top 97th percentile among 9 million peer-reviewed publications. This invention currently serves as the safest way to create iPSC. We are now capable of producing billions of these iPSC in order to have the scale necessary for a clinical trial.

### **JP2MRI has Access to Rare Adult Stem Cells Poised to Create Universal and off-the Shelf ACT**

JP2MRI has helped develop methods for harvesting and growing rare neonatal adult stem cells that are poised to create universal and off-the shelf ACT. These novel stem cells have a head start as universal donor cells since they can avoid immune rejection by the recipient – analogous to the concept of O-negative blood as a universal blood transfusion agent. These stem cells can also be genetically modified without the risk of having to use viruses.

## Eliminating the Financial Barrier for Converting iPSC into T-lymphocytes

As we highlighted in our October newsletter, historically there have been two barriers limiting the production of neural stem cells from iPSC: (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. As we stated in October, the Institute is now capable of producing 80-100 million neural stem cells for pennies on the dollar, while it costs other researchers over \$200,000 to purchase the required neural peptides from commercial suppliers just to produce sufficient stem cells necessary for a Phase 1 clinical trial. For a Phase 2 and Phase 3 clinical trial those costs increase by a factor of 10 and 100, respectively. This is a major breakthrough! The cost of producing specialized blood peptides to transform iPSC into T-lymphocytes is even more expensive than for creating neural stem cells. Fortunately, JP2MRI is also poised to significantly reduce this cost -an accomplishment we will achieve thanks to the financial support of our donors.

### Request for Support

Over the past two decades, JP2MRI has had to be resourceful and financially prudent in conducting research because we are a small organization. We have achieved every technical objective we have pursued and have a track record of success. We have reduced research cost by more than 75 percent compared to standards observed in industry, government and academia. We have solved technical problems that have eluded others. While our annual Campaign hopes to raise 1 million dollars, our fundraising goal has fallen short due to the distressed economy. We are constantly looking at ways to improve our fundraising without expending significant marketing dollars. One important method to accomplish this task is by asking our loyal donors in the next year to serve as ambassadors to help educate and encourage at least one friend or family member to financially support JP2MRI. Thank you very much for your continued support!

Kind regards and God Bless,



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## **John Paul II Medical Research Institute Annual Support**

**\$500      \$400      \$300      \$250      \$100      \$75      \$50      \$25      \$\_\_**

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