



# Healing MS

THE IMSMP NEWSLETTER TO ADDRESS THE NEEDS OF OUR PATIENTS  
AND KEEP YOU INFORMED OF THE LATEST RESEARCH TREATMENTS  
AND WAYS TO HEAL

## On the Road to Repair *The Evolution of a Stem Cell Trial*

As many of you know, our Phase I stem cell trial results were recently published in *EBioMedicine* and because of the encouraging data we will be commencing Phase II of our study. We wanted to provide some detailed information about how our Phase I trial proceeded, and what we hope to accomplish in Phase II.

In FDA Phase I clinical trials, the main goal is to prove the safety of an investigational drug therapy or device. Our Phase I study began in 2014, 20 patients were enrolled, and all 20 patients received 3 treatments of mesenchymal stem cell neural progenitors (MSC-NPs) each given 3 months apart from one another. By 2016, the treatment portion of Phase I concluded, with no serious adverse events reported. In addition to proving MSC-NP treatment to be safe, we were encouraged by signs of efficacy from this therapy. Three months after study patients received their final stem cell treatment, 75% of them demonstrated physical improvements upon neurological examination and testing.

With Phase I proving to be safe and well tolerated, the FDA gave Tisch MSRCNY the greenlight to go ahead with our plans for Phase II. Phase II will consist of 50 patients receiving stem cells in a placebo-controlled double-blind study. This means neither the patient nor the assessing neurologist will know whether or not the patient received a stem cell treatment or placebo. The study has a crossover design, meaning that study patients who received a placebo in the first year will crossover into the MSC-NP treatment group in the second year (and vice versa). The goal is that we will hopefully prove that MSC-NPs are an efficacious treatment option for MS patients with disability.

In anticipation of this endeavor, Tisch MSRCNY began plans to build a technologically advanced stem cell lab to handle the increased volume of patients and the stringent requirements involved in manufacturing their stem cells. The new \$5 million Regenerative Medicine Laboratory includes a state-of-the-art cGMP (current good manufacturing practice) cell production facility. Biospherix created a specialized unit, called an isolator, which is a closed environment for cell processing.

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### Welcome to the Regenerative Medicine Laboratory



### INSIDE THIS ISSUE

- A Look at Phase II and the Regenerative Medicine Laboratory
- Is Coffee Good for Your Brain?
- Making Meaning in Your Life with an MS Diagnosis
- Thank You to Our Donors

## CLINICAL RESEARCH

### On the Road to Repair Cont'd

This specialized technology is ideal for cell processing because it limits contamination from the environment and consistently keeps the cells under the conditions they grow best throughout the entire manufacturing process. The new lab includes 2 isolators to handle the needs of our Phase II study.

In addition, we have also expanded our stem cell team by several members in an effort to streamline our standardized operating procedures, as well as best practice protocols. Furthermore, two new patient treatment rooms have been built across the hall from our cell culture room to make lab bench to bedside table methods flow seamlessly.

Tisch MSRCNY has been preparing for this landmark opportunity with hopes that the new Regenerative Medicine Laboratory will be fully operational by the summer of 2018. We appreciate your support as we continue to raise the additional \$4 million needed to fund Phase II.

## REGENERATIVE MEDICINE LAB PERSONNEL

### Meet Jennifer Francis, Quality Assurance Associate at Tisch MSRCNY

#### **Q: Can you tell us a bit about your background and why you wanted to work at Tisch MSRCNY?**

I have a background in chemistry and went into the pharmaceutical industry right after college. Throughout my career, I worked in a large pharmaceutical company where I was part of the quality control lab. I then moved to a smaller company where I was exposed to manufacturing and learned every aspect of managing a facility that produces commercial and clinical trial drugs.

I really fell in love with Tisch MSRCNY when I came to interview. Meeting Dr. Harris and seeing how committed Tisch MSRCNY was to curing multiple sclerosis made this environment very attractive to me, I could feel how much love for the patients was in this establishment. Furthermore, moving into the Phase II stem cell trial meant developing a quality system from scratch, which is an amazing opportunity and challenge for any quality professional. The fact that a state-of-the-art facility was being built was a huge bonus and sounded very exciting.

#### **Q: What is your role here at the Center?**

My role is to ensure that our stem cell therapy is compliant with the regulations required by the FDA. Although Tisch MSRCNY has such an impressive and multifaceted research program, my role is to transition the stem cell team into operating the same way a pharmaceutical company does. We've had to incorporate all new concepts, practices, and mentalities, which isn't easy to do. I'm so impressed with how the stem cell team was able to learn and adapt so quickly.



**Jennifer Francis**

#### **Q: How do you think the new technology will improve our Phase II trial?**

The isolators are an incredible investment. They are ideal for manufacturing stem cells, and also have the capability to actively monitor the quality of our process and integrity of our product. The manufacturing process designed by Dr. Harris already yields a very reliable product, but working in the Biospherix isolators will eliminate variables normally out of our control. I think we will minimize variability beyond the normal extent of standard stem cell manufacturing.

#### **Q: Can you explain some of the biggest differences in the facilities we used for Phase I and how it will change in Phase II?**

Operating in the research lab was perfect for Phase I and meeting the basic regulations. Phase II includes a larger number of patients, meaning our compliance level had to increase. I have to say the isolators and new facility goes far beyond the level of compliance needed for Phase II.

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**CONT'D - Q: How does the new Regenerative Medicine Laboratory inspire you?**

The Regenerative Medicine Laboratory is everything quality assurance would want in a facility. The hard work that went into planning our new quality system and operations goes hand in hand with the facility design. Any technicians or personnel I've had on site was blown away at how beautiful and compliant our facility is, which always makes me happy to hear. The best way I can describe the Regenerative Medicine Laboratory is that it parallels Dr. Sadiq's and Dr. Harris' high standard of commitment to patient care.

**A NOTE FROM THE NURSES**

**Listen to Your Body**

As part of taking control of your disease, listening to your body can truly help with managing your care. If you notice any changes in your MS symptoms or any new fluctuations in your body, please keep in mind that our nursing team is here to help. First and foremost, give a call to our nurses' phone line so we can help assess what is going on. We offer various clinics and management visits at the Center that specialize in different symptoms such as fatigue, bladder, bowel, and pain. We also offer injection training for those patients or caretakers that may need a refresher visit and are always available to provide education on wound care and fall prevention. Additionally, if there are health issues we cannot address in our office, we will refer you to an outside facility to make sure you get the care you need. Lastly, if there are any nursing topics you'd be interested in learning more about in our next newsletter, please give a call to the nurses' line to share your suggestions. We would love to hear from you.

**NEWS ON NATUROPATHY**

**Good Morning! Coffee is Neuroprotective!**

Coffee has been shown to be neuroprotective in multiple sclerosis, Alzheimer's and Parkinson's, three of the most common neurodegenerative diseases. Most studies on the beneficial effects of coffee focus primarily on caffeine, however, coffee also contains many additional molecules with neuroprotective properties. Caffeine benefits the brain's ability to change and adapt to new information (synaptic plasticity), improves memory and reduces mood issues triggered by chronic stress. From human and animal studies, the neuroprotective effects of caffeine seem to be related to protecting the blood-brain barrier, controlling the immune cells of the central nervous system, and reducing inflammation, excitotoxicity, and cell death. For more information on neuroprotective foods, schedule an appointment to see Dr. Bates, the IMSMP's naturopathic doctor.

\*References for research studies available upon request.



**Dr. Saud A. Sadiq reviews plans in front of isolators in the Regenerative Medicine Laboratory**



**Dr. Deneb Bates, IMSMP's Naturopathic Doctor**



## SOCIAL WORK NEWS

### Making Meaning in Your Life with an MS Diagnosis

Carol Morgenstern has been a patient of Dr. Sadiq's since 1999 and has been working with Emily Brien, a social worker at the IMSMP. Emily had the privilege of discussing with Carol and her husband, Paul, their love for travel and their new travel blog. The topic of traveling, and finding accommodations, is of concern to many patients at the IMSMP. In this edition of, "Making Meaning in Your Life with an MS Diagnosis," Carol and Paul share how traveling has been meaningful in their lives together, and how they have not allowed challenges to stop them.

#### Paul Morgenstern:

"Nothing thrills us more than to explore the world, whether it be alone, with friends, or with our family and their children. Since our first trip to Paris in 1991, we have explored France, Italy, Spain, England and more, trying our best to plan new adventures yearly. It was on that first trip to Paris that Carol had her first MS symptoms. We were walking from our hotel all the way up to the Basilica of *Sacr -C eur*, in the Montmartre section of Paris, when her foot gave out and then a few days later, recovered. So, began Carol's MS journey that soon brought us to Dr. Sadiq. It became increasingly more difficult for Carol to walk any distance independently even with a cane or walker. Hesitating at first, we understood that a wheelchair was necessary to reasonably get around to see and experience new places. We realized that the consolation of sitting in a wheelchair was far more desirable than sitting at home."

#### Carol Morgenstern:

"In 2005 I was in my first motorized wheelchair, and Paul developed a heart condition. It forced us to take stock and make some lifelong decisions about traveling and living our lives in general. However, as the movie *Shawshank Redemption* put it, 'get busy living or get busy dying.' We chose living and were determined that no matter the difficulties we would try to lead as normal a life as possible, for as long as possible. We figured out how to travel under varying circumstances and continue to look at each 'new normal' and adjust our journey. It's been an incredibly wonderful and fulfilling adventure. We continue to travel with a lightweight motorized wheelchair. We've learned the ins and outs of all aspects of travel, from making reservations, getting to the airport, the terminal process, the flight, getting from the airport to your hotel, to getting around town, we have experienced it all.

We are looking forward to our trip to Italy this summer where we've rented a villa in Tuscany and will be joined by friends and family. You can't imagine the joy of spending time there, of seeing the sights, cooking, relaxing and enjoying each other's company."

Because of the experiences they have had, Carol and Paul have started a travel blog at [www.accessibleglobaltravel.com](http://www.accessibleglobaltravel.com). They decided to share their stories with others in an effort to encourage people with MS to enjoy a world they may have thought was not available to them. Their hope is that you will share their experiences and perhaps add to it by telling yours. There is also a place to ask any questions that you may have. Bon Voyage!



**Paul & Carol Morgenstern on the northeast coastline of Spain in the beautiful city of San Sebastian**

### Citywide Accessible Dispatch Service



The New York City Taxi and Limousine Commission manages a program that provides wheelchair accessible yellow and green taxi dispatching services for trips originating anywhere in the five boroughs. Passengers pay the normal metered taxi fare in NYC from the point of pick-up to destination. There are no extra costs to passengers.

There are four ways to request a NYC wheelchair accessible taxi:

\* Use the mobile app "**NYC Accessible Dispatch**," powered by iCabbi and available free at the **Apple App Store** or the **Android App Store**

\* Order online at [mtm.ridewithzoom.com](http://mtm.ridewithzoom.com)

\* Call the dispatch center directly: **(646) 599-9999**

\* Call **311**

## PHYSICAL THERAPY & REHABILITATION

### High-Level Performers by Dr. Stephen Kanter

As I enter my 10<sup>th</sup> year at the IMSMP, I reflect back on my career as a physical therapist, working with all kinds of patients who are considered, “high performers.” A high performer has the desire and willingness to work toward reaching one’s highest level of abilities. I have had the privilege to work with many high performers at the IMSMP.

Many patients believe that physical rehabilitation (PT, OT, SLP) is only successful if someone returns to their previous level of functioning. However, success is getting the most gains in physical performance while keeping a healthy overall body, mind, and spirit.

As a physical therapist, including my work with professional athletes, I’ve seen many people who were as healthy or in some cases, healthier after they rehabilitated from an injury. However, many did not reach their pre-injury levels yet, this did not stop them from prospering in their professional and personal lives. They were still high

performers and put in the time and effort to be such. If you swap out the word “injury” with “MS,” there are real and relevant parallels in rehabilitation that suggest the reason why people with MS should participate in exercises and activities that challenge them.

At a recent sports medicine seminar, I attended a lecture by Dr. Michael Zito, a renowned sports psychologist, where I learned about areas that influence an athlete’s (or patient’s) ability to function at their highest level. Included in his lecture is what he refers to as, “signs of positive adjustment to injury” and “signs of poor adjustment to injury.” Again, by swapping out the word *injury* with *MS*, its application is parallel in the two populations.

Signs of positive adjustment include strong compliance with treatment, completion of a home program, motivation and determination to improve, and having high, yet reasonable expectations. Signs of poor adjustment include obsession with the return to a



**Stephen Kanter, DPT, ATC**

previous level of activity (regardless of readiness or ability), negative predictions about success in returning to function, the guilt of letting others down, and withdrawal from significant others (family, friends, close acquaintances).

For 2018, all people with MS should make it their goal to be a high performer. Motivation and determination to improve your physical abilities coupled with a strong adherence to your PT/OT plan of care can yield positive results. Being consistent in your physical therapy is as important as being consistent with your medication. Make it a priority and show up for yourself and your health.

## TEAM TISCH MS NEWS



### Are You Ready to Join Team Tisch MS?

In 2017 Team Tisch MS members raised over \$100,000! TTMS is now starting strong in 2018 with the recruitment of new team members and sponsorship partners to expand on the success of our program.

With athletes from all over the world, including Joao Goncalves from Spain who is already planning his first marathon, to our first Jr. Team Tisch MS member, Hannah Kanter, our team is heating up! We have our first TTMS cyclist who is excited to promote Tisch MSRCNY in a whole new category of racing! TTMS new member benefits include team social events, and seminars with health professionals to promote overall wellness for our athletes. Do you want to race to repair MS?

If you or someone you know is planning to participate in races or events anywhere in the world, and wants to support Tisch MSRCNY and their research to reverse the damage, discover the cause and develop the cure, please join our team!

To learn more or to join us, send an email to [tms@tischms.org](mailto:tms@tischms.org) and start **Racing to Repair MS**.

For more information about supporting or sponsoring TTMS please contact Dr. Stephen Kanter at [tms@tischms.org](mailto:tms@tischms.org) or by phone at (646) 557-3843.

## DEVELOPMENT DEPARTMENT NEWS

### Inspiring Events by Patients & Friends

#### 6<sup>th</sup> Annual Friends of Joey Renda Poker Tourney Hits Jackpot

Over 100 friends and family traveled from near and far including, Toronto, Boston, and Washington D.C., to the Flemington Elks Lodge in Flemington, NJ on October 21<sup>st</sup> for the 6<sup>th</sup> Annual *Friends of Joey Renda Cards for a Cure Texas Hold 'Em Poker Tournament*. Along with fundraising, the night was filled with fun: a buffet dinner, poker, pizza, drinks, raffles, prizes, lots of laughs and a great time had by all.

While the 3 top finishers that night were celebrated for their win, the biggest winner of the evening is the research at Tisch MSRCNY. Thanks to the Renda's for the tremendous effort to create a very special event again this year, raising over \$21,000 for MS research.



**L to R: Rob Machado, Maria Renda, Joe Renda, Michael Renda, Tom Malloy**

#### Cheers for MS

Looking for ways to give our research a boost, on November 6<sup>th</sup> Genevieve Bouchard partnered with the Staples Cheerleaders to host a full day of shopping and fun at her Westport, CT boutique, Scout & Molly's. Together they raised over \$2,000 to support the Tisch MS Research Center of New York. We can ALL cheer for that!



**Genevieve Bouchard (center) with shoppers at her boutique**

#### Thinking About Hosting a Fundraiser?

Fundraising can be, well, fun. Whether it's a poker night, a shopping event, or a cocktail party, bringing your community of family, friends, and colleagues together for a cause can be a great way to celebrate, and do good at the same time! Not sure where to begin? We can help with fundraising tips, materials and marketing ideas.

If you are interested in hosting a fundraiser to benefit Tisch MSRCNY, please call Lisa or Meaghan at (646) 557-3900, or email [Development@Tischms.org](mailto:Development@Tischms.org).

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