The Miami Project continues its Schwann cell transplantation clinical trials
Friends,

In a year that has seen me face some extremely trying times personally as I struggled with some health issues that eventually affect all of us battling paralysis, I could not be more proud of the progress of the researchers at The Miami Project to Cure Paralysis. A few short years ago we were fortunate to have FDA approval for our groundbreaking Schwann cell Safety Trial for those who are recently injured, and have now transplanted cells into several patients. We are happy to report that all of the subjects have reacted well to the transplant and none have encountered any adverse reactions. The positive news on the Schwann cell front has given us confidence to ask the FDA for approval to proceed with a transplantation trial using a patient’s own Schwann cells for those suffering from chronic spinal cord injuries. The application has been submitted and we are anticipating an affirmative response in the very near future.

In addition to the Schwann cell trial, we are proud to say that we have FDA approval for four other clinical trials targeting paralysis for a total of five trials. The field of SCI research has never been more exciting, and The Miami Project is at the epicenter of the excitement. With our Clinical Trials in full swing, and more coming as we continue to gain additional knowledge, The Miami Project has never been better positioned to find a cure. Our basic scientists are creating the pipelines that are translating to the clinic and it’s all happening in one place, Miami.

Another exciting area is the Kids Neuroscience Center (KNC) at The Miami Project. The KNC houses a number of programs and research projects that directly impact and assist in improving the quality of care and advances in research for children with traumatic and acquired brain and spinal cord injury. Dr. Gillian Hotz has directed the Center since its inception with a busy clinical, training and education, research, community outreach and prevention program. The focus of the injury prevention programs has been to decrease brain and SCI injuries in children.

Their premier injury prevention programs include WalkSafe, a pedestrian safety skills program for elementary school age children, BikeSafe, a bicycle safety skills program for middle school age children, SkateSafe, a skateboarding safety skills program for children and adolescents, and a comprehensive Countywide Concussion Care Program focusing on youth leagues and high school athletes. Their goal is to help kids have fun, safely play a sport they love, and get back in the game.

The Miami Project is truly a comprehensive research center, and together we are going to deliver on the promise my father made to me that we will never quit until a cure is found. I am more confident than ever that the future is brighter for all suffering from spinal cord and brain injuries because of your support of our work. It’s only because of all of you, our friends, that The Miami Project will find a cure!

Respectfully,

Marc A. Buoniconti, President
The Buoniconti Fund and The Miami Project
Dear Friends,

This is an UNBELIEVABLE time for The Miami Project’s research programs and for medical history! The Food and Drug Administration (FDA) gave permission to The Miami Project to begin a revolutionary Phase 1 clinical trial to evaluate the safety of transplanting human Schwann cells in patients with acute (recent) spinal cord injuries (SCI). The University of Miami’s Institutional Review Board (IRB) approved this research on human subjects. Miami Project scientists believe Schwann cells are key to finding cures for paralysis. The first three (3) participants in this Phase 1 clinical trial had successful transplantations and are in the rehabilitation process.

I vow never to give up until millions worldwide WALK again. We ARE changing medical history!

The Miami Project has submitted data to the FDA to initiate a Schwann cell transplantation clinical trial in participants with CHRONIC spinal cord injury (those paralyzed for a year or more). There are millions of people living with paralysis due to SCI that will benefit from this procedure. The cost for each chronic participant is projected at around $250,000 and The Miami Project and The Buoniconti Fund are committed to raising the funds needed to sponsor this trial. Exciting findings in the pre-clinical studies with Schwann cells in chronic injuries have shown extremely promising repairs in the nervous system.

In 1985 my son Marc became a quadriplegic, suffering a paralyzing injury after making a tackle in a college football game. In the emergency room as Marc was fighting for his life, I looked into his big brown eyes and I read “Help me Dad!” What could I do? I needed to do something, but what? He’s my son and I love him more than life itself. I felt so helpless. As a result of Marc’s life altering tragedy, The Miami Project was born to help Marc and the thousands like him to have hope that one day they would walk again. The millions of paralyzed around the world look to The Miami Project to find a cure to reverse paralysis and restore motor function. Our Human Clinical Trials Initiative is on the cusp of changing the way paralysis is treated! This is why The Miami Project exists. For 29 years supporters of the Great Sports Legends Dinner have raised incredible funds and awareness for The Miami Project’s groundbreaking spinal cord injury research. I want to sincerely THANK The Buoniconti Fund’s dedicated Board of Directors, the Great Sports Legends, Honorees, Dinner attendees, and all those who have advanced the efforts to find a cure for paralysis. I vow never to give up until millions worldwide WALK again. We ARE changing medical history!

Nicholas A. Buoniconti, Co-Founder
The Buoniconti Fund and
The Miami Project
Dear Friends and Colleagues,

This year has been the most exciting to date in the history of The Miami Project to Cure Paralysis. We currently have obtained five FDA-approved clinical trials targeting spinal cord injury. Our Phase 1 safety trial to evaluate autologous human Schwann cell transplantation in subacute injury subjects is ongoing. We have successfully transplanted millions of Schwann cells into three subjects. We have submitted new data to the FDA to seek permission to test this therapy in chronically injured individuals. Another FDA approved trial using Schwann cells targets peripheral nerve injury to promote regeneration. One subject has been treated and is recovering. Deep brain stimulation is being evaluated for the first time to target neuropathic pain in spinal cord injured subjects. This FDA approved program will provide new strategies for targeting this quality of life issue. Our brain-machine interface FDA approved program is merging biological and biomedical disciplines to allow individuals to move their upper extremities, thereby enhancing independence. Finally, a trial to test the efficacy of adult mesenchymal stem cells has been approved by the FDA for a single subject. Together these trials represent the most comprehensive program in the world testing experimental therapies for spinal cord injury.
The beneficial effects of therapeutic hypothermia in our patient populations with brain and spinal cord injury continue to be demonstrated. Treated spinal cord injured individuals are showing long term benefits. A specific group of severe brain injured subjects that may benefit most from early cooling has been identified. These neuroprotection programs are examples of how basic and translational studies have been successfully moved into the clinic.

Multiple clinical programs including our Miami Project “Boot Camp” are actively investigating other aspects of spinal cord injury that may also improve function. Our ultimate goal is to combine the state-of-the-art rehabilitation and conditioning strategies with cell therapies and other regenerative approaches to target functional recovery, neuropathic pain, male fertility, spasticity and bladder function. The Miami Project is committed to developing whole life strategies that can maximize quality of life and good health as our scientists continue to strive to develop new therapeutic interventions.

Discovery research which fuels our translational and clinical programs is discovering new molecular and cellular mechanisms underlying cell death, axonal regeneration, and circuit repair. Ultimately, this knowledge will be combined with our current therapeutic interventions to maximize functional recovery. The clarification of critical gaps in our knowledge regarding axonal regeneration and circuit plasticity will improve our chances of developing successful cures for paralysis.

The Miami Project to Cure Paralysis was established in 1985 to develop novel therapies to improve function in paralyzed individuals. Most recently, our discoveries have been successfully translated to people and are changing the way we provide clinical care. Our program is indeed unique in that it continues to concentrate on multiple areas of medical research including education, discovery, translational and clinical trials. These are indeed exciting times within The Miami Project and we thank our friends, colleagues, and research participants for their long-term support and commitment to our research.

Barth A. Green, M.D., F.A.C.S
Founder and Chairman
The Miami Project to Cure Paralysis
Professor and Chairman, Department of Neurological Surgery
Professor, Departments of Orthopaedics and Rehabilitation Medicine
University of Miami Miller School of Medicine

W. Dalton Dietrich, III, Ph.D.
Scientific Director
The Miami Project to Cure Paralysis
Kinetic Concepts Distinguished Chair in Neurosurgery
Senior Associate Dean of Discovery Science
Professor of Neurosurgery, Neurology, and Cell Biology & Anatomy
Vice-Chair for Research, Neurological Surgery
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Schwann Cell Update

First

“The safety of autologous human Schwann cells (ahSC) in subjects with subacute spinal cord injury (SCI)”

This is our 1st Phase I clinical trial and it began in November 2012. It is specifically targeting people with new spinal cord injury (SCI). People who have sustained a trauma-induced SCI between thoracic levels T3-T11 and whom are neurologically complete are preliminarily eligible. However, they have to meet several other criteria and be enrolled no later than 30 days after their injury. This is a dose escalation treatment trial, meaning that we will test 3 different doses: 5 million, 10 million, and 15 million Schwann cells. There will be a total of 8 participants. So far, we have transplanted three (3) participants; the first two received the 5 million cell dose and the third one received the 10 million cell dose. Thus far, there have been no treatment-related adverse effects in the three transplanted subjects, which is excellent news.

Second

“Long-term safety monitoring of recipients of subacute autologous human Schwann cells (ahSC)”

Once participants in the subacute trial reach 1 year post-transplantation they transition into this long-term monitoring trial. In this trial, participants are monitored annually for an additional four (4) years. At years 2 and 5 post-transplantation they come see us for a full evaluation, including a neurological evaluation, MRI, and pain assessment. Evaluations at years 3 and 4 post-transplantation

Schwann Cell Clinical Investigation Program

Image of Human Schwann cells labeled with S100 anybody (green) and Fibronectin(red)
occur via the telephone. These first two participants will be approaching their year 2 evaluation in the coming months.

Third

“Transplantation of autologous human Schwann cells (ahSC) for peripheral nerve repair — Compassionate Use”

In September of 2013, we sought expanded access approval from the FDA to evaluate the safety and efficacy of Schwann cell transplantation after severe peripheral nerve injury. We received approval for compassionate use in a single subject with acute sciatic nerve transection with significant loss of peripheral nerve tissue at the posterior mid-thigh level. The standard of care medical treatment for these types of severe injuries is to surgically remove several segments of the patient’s sural nerve and insert (graft) them between the severed ends of the sciatic nerve. The experimental portion was to supplement these autografts with a collagen matrix wrap containing cultured autologous Schwann cells suspended in autologous plasma. As mentioned above, only one subject has been approved for treatment, and that treatment has occurred and is being monitored. That participant is currently between 9-12 months post-transplantation. As with the subacute SCI trial participants, no treatment-related adverse effects have been observed. If this continues to hold true, we will be seeking funding and FDA approval to increase the number of participants in this experimental bridging approach targeting return of leg function.

Fourth

“The safety of autologous human Schwann cells (ahSC) in subjects with chronic spinal cord injury (SCI) receiving rehabilitation”

In parallel to these studies, over the last two years, we have been compiling additional data sets to submit to the FDA regarding a 2nd Phase I trial targeting chronic SCI. We conducted preclinical experiments in which we transplanted Schwann cells into rodents and pigs with chronic SCI. Similarly, we conducted a human study to evaluate the multi-system effects of an exercise conditioning and rehabilitation combination strategy in individuals with chronic SCI. During the first half of 2014 we analyzed all of the rodent, pig, and human chronic data. In July 2014, we submitted a 2nd Phase I trial plan to the FDA targeting transplantation of autologous human Schwann cells in individuals living with chronic SCI. That trial will also be primarily focused on safety, but in addition it will involve a preliminary evaluation of the efficacy of combining Schwann cells with exercise and rehabilitation. We believe that this combination of cell therapy with intense rehabilitation prior to and following cell transplantation will enhance our chances of seeing improved recovery in the chronic setting. We are currently in discussions with the FDA regarding the full data submission. Once approved by the FDA, we will begin seeking required institutional approvals at the University of Miami. After which we will begin screening for potential participants. We cannot start screening until all of those approvals are obtained.

Fifth

“Long-term safety monitoring of recipients of chronic autologous human Schwann cells (ahSC)”

Once participants in the chronic trial reach 6 months post-transplantation they will transition into a separate long-term monitoring trial. In that trial, participants will be monitored annually for an additional four and a half years.

For information about any of the Schwann cell clinical trials, please contact The Miami Project Education Department at 305-243-7108 or mpinfo@med.miami.edu.

A laminectomy to expose the spinal cord
Deep brain stimulation (DBS) involves a surgical procedure to implant a “brain pacemaker”, which is a device that sends different patterns of electrical stimulation to particular regions of the brain. DBS is already approved by the Food and Drug Administration (FDA) for use in individuals with advanced Parkinson’s disease, essential tremor, dystonia, and obsessive compulsive disorder whose symptoms are inadequately controlled by medication. We wrote an article in our 2013 Research Review magazine about the basic science evaluating the usefulness of DBS after spinal cord injury (SCI) to modulate pain. The region in the midbrain that is target by DBS is called the Periaqueductal Gray, or PAG; electrical stimulation to this region triggers the release of the body’s natural pain relieving molecules.

Led by neurosurgeon Dr. Jonathan Jagid, our multi-disciplinary team is conducting an FDA-approved Feasibility Clinical Investigation of the Medtronic Activa PC DBS device targeting reduction of neuropathic pain and improvement in autonomic dysreflexia in persons living with chronic SCI. The study is a collaboration between the University of Miami and the Miami Veterans Administration Hospital and it is funded by the Department of Defense.

Individuals that meet the above criteria will undergo more extensive screening as well. Up to 12 participants will be implanted with the device. The implantation involves 2 surgeries, 1st to target the correct area of the brain to implant the leads. The 2nd to implant the remainder of the device including extension cables and pacemaker. So far, one participant has been implanted and more are in various stages of screening.

The primary end goal of the trial is to determine whether DBS can immediately block or reduce ongoing or intermittent SCI pain without acute or long-term adverse reactions.

If you or someone you know is interested in learning more about this trial and qualification, please call us at 305-243-7108.

The team:
Dr. Jonathan Jagid – Neurosurgeon, PI
Dr. Ian Hentall – Basic scientist, Co-PI
Dr. Bruno Gallo – Clinical Neurophysiologist
Dr. Alberto Martinez-Arizala – Head of the SCI Clinic at the Miami VA
Dr. Eva Widerström-Noga – Expert in SCI-induced pain
Letitia Fisher – Clinical coordinator
Alberto Vitores – Regulatory coordinator
Dr. Michael Wang is a Professor in the Departments of Neurological Surgery and Rehabilitation Medicine and is also a faculty member of The Miami Project. Dr. Wang is an integral member of the spine neurosurgery team at the University of Miami. Clinically he specializes in spinal cord injury (SCI), minimally invasive spine surgery, spinal cord tumors, total disc replacement, spinal reconstruction, syringomyelia, and surgery for neuropathic pain. He is recognized nationally and internationally for his clinical expertise.

Dr. Wang is also an integral component of two clinical trial programs at The Miami Project. In collaboration with Drs. Allan Levi and Barth Green, he is studying the clinical effects of mild hypothermia treatment in acute cervical spinal cord injury. They are currently working with the National Institutes of Health for funding of a multi-center randomized, prospective study on the effects of hypothermia in SCI.

He is the Principal Investigator of a clinical trial evaluating SCI biomarkers to predict the effects of both injuries as well as therapeutic interventions. The goal is to identify breakdown products in the samples that are early predictors of the degree of neurologic impairment. Biomarkers are frequently used in modern medicine, with examples including cholesterol or PSA (prostate specific antigen) level monitoring. It is anticipated that with the identification of specific biomarkers for SCI, researchers and clinicians will be able to: 1) give the patient a more accurate medical prognosis immediately after injury; 2) more effectively triage patients and research participants into specific therapeutic or investigative interventions; and 3) reduce the feedback time from interventional trials, increasing study efficiency and safety. This trial is funded by the Department of Defense and his co-investigators are Drs. Ross Bullock, Helen Bramlett, Dalton Dietrich, Robert Keane, Pablo de Rivero Vaccari, and Stephanie Adamczak. We first reported on this trial in the 2012 Project magazine. They are continuing to collect blood and spinal fluid samples from acutely spinal cord injured people who are already undergoing spinal fluid drainage as a part of their necessary clinical treatment.
International Spinal Cord Injury (SCI) Conference in Saudi Arabia

Faculty of The Miami Project worked extensively over several months with leaders of the Sultan Bin Abdulaziz Humanitarian City to organize a scientific conference targeting SCI clinical care and research, with the goal of improving the quality of life of people living with SCI in the Kingdom of Saudi Arabia. The Miami Project provided expertise and guidance regarding clinical research and advanced care for SCI.

The leadership and faculty of The Miami Project have been working for a couple years with the leadership of the Humanitarian City to develop a mutually beneficial working partnership. This conference was the first concrete activity of that partnership. The conference was held March 4-6, 2014 at the Sultan Bin Abdulaziz Humanitarian City (a rehabilitation hospital and medical center) just outside Riyadh, Saudi Arabia. Over 300 physicians, researchers, therapists, and nurses from throughout Saudi Arabia were in attendance for this valuable educational experience. Drs. Mark Nash, Edelle Field-Fote, and James Guest travelled from The Miami Project over to Riyadh.

The conference began with Dr. Guest delivering a keynote lecture on “Core Pathophysiology of Spinal Cord Injury and Neuroprotection” followed by a lecture on “The Miami Project to Cure Paralysis, its History, Structure, and Goals.” Later that afternoon, Dr. Field-Fote gave a keynote lecture on “The Role of Neuroplasticity in Recovery After SCI: Methods to Optimize Recovery through Specific Rehabilitation Interventions”, and Dr. Guest gave a “Review of Past and Current Clinical Trials of Therapeutics in SCI: Major Lessons Learned.”

On day 2 of the conference, Dr. Nash began with a keynote lecture addressing “Health and Well-Being Throughout Life With SCI.” Dr. Field-Fote then gave a “Critical Review of Outcome Measures in Clinical Spinal Cord Injury”, and Dr. Guest spoke about “Stem Cell Tourism: What Are the Risks and is There Any Substantive Evidence of a Benefit?” Later that afternoon, Dr. Nash lectured on “Technology Applied to SCI: The Value of Assistive Devices During SCI Recovery and While Living With SCI.”

During the conference there was ceremonial recognition of The Miami Project signing a memorandum of understanding with the Sultan Bin Abdulaziz Humanitarian City to work together on future SCI clinical care and research efforts. Over 21 members of the Saudi royal family were in attendance of the ceremony, led by Prince Khaled bin Sultan, Chairman of the Sultan bin Abdulaziz Al-Saud Foundation.
A couple years ago these battery-powered, external bodysuits designed to artificially help people living with paralysis walk were launched onto the market; henceforth known as bionic exoskeletons. They were cool devices designed by amazing engineers. The question, however, was “what are they good for?”

- Rehabilitation?
- Exercise?
- Mobility device?

Miami Project clinical researchers launched a pilot study to try to answer that question and the results were recently published in a peer-reviewed journal. [Understanding Therapeutic Benefits of Overground Bionic Ambulation: Exploratory Case Series in Persons With Chronic, Complete Spinal Cord Injury](http://dx.doi.org/10.1016/j.apmr.2014.04.026)

Conclusions from this pilot study suggest that walking in an exoskeleton has no rehabilitation or exercise benefits. However, it is good way to improve functional mobility. The really important benefit is the reduction in neuropathic pain, a consequence of SCI that impacts many people and is very difficult to treat. Currently, researchers are conducting another study to evaluate the effect of walking in an exoskeleton on bladder and autonomic dysfunction, and further investigation on the reduction of pain.
American Spinal Injury Association “ASIA”

Leading clinical research organization focusing on spinal cord injury clinical research and care.

The American Spinal Injury Association, more commonly known as “ASIA”, is one of the leading membership organizations focusing on spinal cord injury (SCI) clinical research. Every year they have a scientific meeting, which is a very important avenue by which they share research findings and interact with colleagues from around the world. The 2014 meeting was held in May and many Miami Project faculty were actively involved.

Dr. Kim Anderson-Erisman serves on the Program Committee, which is responsible for creating the scientific format for each annual meeting and reviewing the abstracts submitted for presentation. She also serves on the Membership Committee. Drs. Mark Nash and Eva Widerström-Noga both serve on the Research and Awards Committee, which is responsible for peer reviewing projects that are submitted for funding to ASIA through its grant opportunities.

Dr. W. Dalton Dietrich was invited to give the G. Heiner Sell Lecture this year. He spoke about “Protection and Repair after Spinal cord Injury: Accomplishments and Future Directions”. He is the 32nd renowned scientist and/or clinician to present the prestigious Sell Lectureship.

Dr. Eva Widerström-Noga won the Best Paper Award for the presentation of her research results on “Clinical Sensory Pain Phenotypes After Spinal Cord Injury”. Dr. Kim Anderson-Erisman served as a Moderator for a session on Cardiovascular studies.

Dr. Mark Nash presented two research studies at the meeting, “Circuit Resistance Training Improves Postprandial Glycemic but not Lipid or Inflammatory Responses in Individuals with Paraplegia” and “Fasting Plasma Glucose Values May Significantly Underestimate Prevalence of Dysfunctional Glycemic Regulation in Persons with Spinal Cord Injury”. His post-doctoral fellow, Dr. Greg Bigford, also presented two studies, “Therapeutic Lifestyle Intervention After Paraplegia Significantly Reduces Component Markers of Cardiometabolic Risk” and “Upper Extremity Cardiopulmonary Endurance and Dynamic Strength are Significantly Increased in Paraplegics Following Therapeutic Lifestyle Intervention”. Dr. Jochen Kressler, an Associate Scientist in Dr. Nash’s lab, presented “Body Mass Index is a Poor Indicator of Body Composition in Persons With Spinal Cord Injury”, “Lower Limb Bionic Exoskeleton for Rehabilitation, Exercise or Mobility? Exploratory Case Series in Persons with Chronic, Complete Spinal Cord Injury”, and “Omega-3 Fatty Acid Supplementation (Ω3) has Little Effect on Postprandial Metabolic and Inflammatory Response Markers”.

Next year the annual ASIA meeting will be combined with the International Spinal Cord Society annual meeting and there will be great representation of Miami Project research there as well.
Dr. Mary Bartlett Bunge Among Many Honored at The Greater Miami Chamber of Commerce’s Healthcare Heroes Awards Luncheon

An audience of more than 500 healthcare and business leaders cheered as Mary Bartlett Bunge, Ph.D., Professor of cell biology, neurological surgery and neurology at The Miami Project, won the Health Care Hero Award in the Bio-Medical category at the Greater Miami Chamber of Commerce’s Health Care Heroes Awards Luncheon, held on May 20 in Jungle Island’s Treetop Ballroom.

In addition, Carlos A. Migoya, President and CEO of Jackson Health System, was also a winner, taking home the Health Care Hero Award in the Individuals of Merit category and Miller School Dean Emeritus Bernard J. Fogel, M.D., received the AXA Advisors Lifetime Achievement Award.

The Health Care Heroes Awards recognize individuals, institutions and programs that have had an extraordinary impact on the South Florida health care community, and whose acts of heroism represent dedication to excellence in their area of expertise beyond the scope of their profession.

University of Miami Miller School of Medicine Dean Pascal Goldschmidt nominated Dr. Bunge for the prestigious award.

Bunge has spent the past 24 years of a distinguished career at the Miller School. Her research has focused on Schwann cells, found in the peripheral nervous system, as an important component in repairing damaged spinal cords. New clinical applications include a groundbreaking procedure combining standard nerve grafting with a patient’s own Schwann cells.

“Through the work of Dr. Bunge, millions of people have been given hope that one day there will be a cure for paralysis,” said Goldschmidt. “The advances in the past decade have only been possible through the determination of talented and selfless researchers like Dr. Bunge.”

Bunge called the award “a very humbling experience. I was given an exceptional opportunity to work at The Miami Project,” she said, “but it’s really the people in my lab who deserve this award. They do the work.” Pointing to one of the luncheon tables, she had research associates Vania Almeida, Margaret Bates and Yelena Pressman stand and share the applause.

The KiDZ Neuroscience Center

The KiDZ Neuroscience Center at The Miami Project to Cure Paralysis and the UHealth Sports Medicine Center hosted a concussion care workshop in April for all Miami-Dade County public high schools athletic trainers and athletic directors. The event continued to educate and facilitate the high school concussion management programs and impact testing. The Baseline ImPACT testing program is helping to improve the concussion management of high school athletes. A check was given to the county in order to help in the continuation of the baseline neurocognitive testing each year for all student athletes in the contact sports of football, soccer, baseball, lacrosse, wrestling and softball.

Dr. Mary Bunge with Carlos Migoya

Dr. Hotz with Adam, David and Cheryl Goldstein

Dr. Kester Nedd, Director Neurorehabilitation UM/JMH and Co-Director Concussion Program at UHealth Sports Medicine, Dr. Gillian Hotz, Director KiDZ Neuroscience Center at The Miami Project and Concussion Program at UHealth Sports Medicine, Cheryl Golden, Instructional Supervisor, Greater Miami Athletic Conference, Division of Athletic/Activities, Miami-Dade County Public Schools, and David Goldstein, former student at Ransom Everglades who has suffered from concussions presented a $20,000 check from the Ransom community to cover the countywide cost of ImPACT Testing.
Miami Project Scientists are Awarded a $2 Million NIH Grant to Treat Cognitive Dysfunction after TBI

W. Dalton Dietrich, Ph.D., Scientific Director, The Miami Project to Cure Paralysis and Kinetic Concepts Distinguished Chair in Neurosurgery, and Coleen Atkins, Ph.D., Assistant Professor, Department of Neurological Surgery were awarded a Multiple-PI grant for five years of funding from the National Institutes of Health. This successful competitive renewal is a collaboration between the University of Miami, West Virginia University, and a pharmaceutical company based in Michigan, Tetra Discovery Partners. This project will develop a drug patented by Dr. Mark Gurney, Dalton Dietrich and Coleen Atkins to treat chronic cognitive deficits resulting from traumatic brain injury. Over 3 million traumatic brain injury survivors report disabilities in the months to years after the initial brain trauma. This project will identify the molecules and circuits that are altered in the injured brain that give rise to learning and memory deficits. The drug to be developed has a high translational potential and represents a breakthrough in targeting the specific molecules that are disrupted during memory formation in the chronically injured brain.

NIH Director Features “Unique Method” Used by UM Neuroscientist

NIH Director Francis S. Collins, M.D., Ph.D., is clearly impressed by a unique method used by Xue-Ting Luo, Ph.D., post-doctoral research fellow at The Miami Project to Cure Paralysis, and his mentor Kevin Park, Ph.D., assistant professor of neurological surgery to visualize neurons in an intact brain, which was among the winners of the Federation of American Societies for Experimental Biology’s 2013 BioArt competition.

A video posted along with the article gives viewers a rare close-up of the retinal ganglion cells that carry information from the eye to the brain, where light signals are decoded and translated.

“This acknowledgement from Dr. Collins is incredible, but the credit belongs to Ting, the post-doc in my lab who has done the hard work to harness the technology in our model system,” Park said.

To make the movie, Luo injected a fluorescent dye into the mouse eye, which was taken up by the retinal cells and traced out the nerve pathways from the optic nerve into the brain.

W. Dalton Dietrich, Ph.D., Scientific Director, and Editor-in-Chief, Therapeutic Hypothermia and Temperature Management reports that the journal has been selected for inclusion in MEDLINE. This Journal grew out of the early preclinical and clinical work many conducted over the years at the University of Miami in moderate hypothermia research. The field has gained momentum internationally and targeted temperature management protocols are now being tested and utilized in many human disorders and diseases. The first issue was submitted in 2011 and this was the first attempt at requesting inclusion into MEDLINE. “This is a big step in the maturation of any new journal and critical to its long-term success”, stated Dr. Dietrich. Helen Bramlett, Ph.D. serves as the Managing Editor for the Journal and is critical in the day-to-day responsibilities associated with reviewer selection and other time sensitive decisions.
Meghan O’Connell Blaya, Ph.D. Postdoctoral Associate in the laboratory of Miami Project Scientific Director W. Dalton Dietrich, Ph.D., was awarded the top 2014 Women in Neurotrauma Research Award this year at the 32nd National Neurotrauma Symposium in San Francisco. The award was based on her scientific abstracts and corresponding poster presentations. Her poster was titled *Genetically-Modified Neural Progenitor Cell Transplantation Promotes Neuroprotection, Enhances Hippocampal Neurogenesis, and Improves Cognitive Outcomes after Traumatic Brain Injury*. Her work showed that syngeneic transplantation of neural progenitor cells preserved pericontusional host tissues, increased endogenous hippocampal neurogenesis, and reversed spatial memory deficits after TBI. The findings suggest that transplanting neural progenitor cells in the acute period after brain injury enhances endogenous neuroreparative responses, such as neurogenesis and trophic factor support, which in turn translates to functional recovery at more chronic stages after trauma.

**Three MP Researchers Earn NINDS Fellowships**

The National Institute of Neurological Disorders and Stroke (NINDS) provides National Research Service Award (NRSA) predoctoral training fellowships (F31) to promising students with the potential to become productive, independent investigators to support the career development of neuroscientists and The Miami Project recently was fortunate to receive three of these fellowships. From the lab of Dr. Daniel Liebl, Poincyane Assis-Nascimento and Emmanuel Perez-Martinez received this great honor, and from Dr. Coleen Atkins’ lab Nicole Wilson was tapped for the fellowship.

**Assis-Nascimento** is interested in the molecule signals that regulate blood vessel stabilizing and growth after CNS injury. Blood vessels transport oxygen and nutrition to all CNS tissues and are critical for the health of brain and spinal cord, especially after injury. Poincyane’s research will examine the molecular cues that regulate endothelial cell proliferation and vascular growth. These studies will provide a better understanding of how to protect and restore blood vessels after traumatic CNS injury.

**Perez-Martinez** is interested in examining the contribution of glial cells in the stabilization and formation of synapses. Maintaining and regenerating neuronal connections within the brain and spinal cord are essential for all bodily functions, including sensation, walking and cognition. The largest component of functional losses in the CNS is synaptic damage, thus understanding the molecular mechanisms that regulate synaptic stability and reformation are paramount. His research will examine whether glial cells play important roles in synaptic functions after traumatic injury, and identify specific factors that regulate communication between neuronal processes and glial cells. These studies will not only advance our understanding of synaptic formation, but will establish a therapeutic strategy to protect and regenerate the injured CNS.

**Wilson** is investigating the contribution of phosphodiesterase 4B to inflammation after traumatic brain injury. Although we know from previous work at The Miami Project that inhibition of phosphodiesterase 4 by rolipram is an effective anti-inflammatory treatment for spinal cord injury, recent studies have highlighted the importance of clarifying which phosphodiesterase 4 family (A, B, C or D) is responsible for rolipram’s beneficial effects. Nicole has found that phosphodiesterase 4B in particular is found in inflammatory cells after traumatic brain injury. Her project will determine whether phosphodiesterase 4B in inflammatory cells is important for inflammation and pathology in traumatic brain injury, and whether inhibition of phosphodiesterase 4B specifically is an anti-inflammatory treatment. These studies are in collaboration with Dr. Mark Gurney from Tetra Discovery Partners. Drs. Dietrich, Atkins and Adaikalasamy and Gurney received a patent for a phosphodiesterase 4B inhibitor for traumatic brain injury. Nicole’s studies will push the clinical development of this drug even further.
Twenty-Eighth Annual Great Sports Legends Dinner

Terry Bradshaw, James Worthy, Dave Winfield, Nick Faldo, Bob Costas, Jim Kelly, Kenny Smith and more joined forces to raise funds for The Miami Project’s spinal cord injury research programs.
Celebrities, sports legends, corporate leaders and more joined NFL Hall of Famer Nick Buoniconti, his son Marc, and Event Chair Mark Dalton as they hosted a sold out crowd in celebration of the 28th Annual Great Sports Legends Dinner to benefit The Buoniconti Fund, the fundraising arm of The Miami Project at the University of Miami Miller School of Medicine. Held at New York’s famed Waldorf Astoria, the dinner paid tribute to philanthropic heroes and sports icons that inspire and motivate those affected by spinal cord injuries the event raises important funds for research and the Christine E. Lynn Human Clinical Trials Initiative. Bob Costas, NBC Sports anchor, served as Master of Ceremonies and helped honor this year’s Great Sports Legends: Terry Bradshaw, James Worthy, Dave Winfield, Nick Faldo, Shawn Johnson, Gary Stevens, Antron Brown and Teresa Edwards.

Hall of Fame quarterback Jim Kelly received the 2013 Inspiration Award, and two-time NBA champion player and NBA TV analyst Kenny Smith was honored with the 2013 Buoniconti Fund Award.

A few special donors were so moved by the evening that they made donations on the spot to help fund the important research at The Miami Project. Philanthropist Stewart Rahr donated $2.2 million and Outback Steakhouse Founder Tim Gannon generously gave another $1 million in support of SCI research.

Additional notables in attendance included: NFL Hall of Famer Harry Carson, NHL Hall of Famer Brian Leetch, Grammy Award winning Producer and Musician Emilio Estefan, Olympian Gary Hall, Jr., Friday Night Lights’ Brad Leland, Gossip Girl’s Matthew Settle, NBA Hall of Famer Rick Barry, Three-Time NBA Champion Bruce Bowen, actor Colin Egglesfield from Something Borrowed and The Client List, and former Miami Dolphins quarterback Jay Fielder, and many, many more.

The evening included a live performance by Broadway’s “Jersey Boys”. The exciting live auction offered a unique opportunity to golf with the greatest golfer of all time, Jack Nicklaus, an Iconic New York Package presented by Tiffany & Co., and a Masters Golf experience with guest auctioneer Nick Faldo who added special Masters themed perks to the highest bidder. TNT Basketball Analyst Kenny Smith also surprised the crowd with an opportunity to visit the TNT set and appear on the show during the broadcast.

Sponsors for the evening included: HBO Sports, Tiffany & Co., Diageo, United Airlines, and Barton G.
The Project

Great Sports Legends Dinner

Jim Kelly, Marc Buoniconti, Terry Bradshaw and Nick Buoniconti

Dave Winfield with Bob Costas

Matthew Settle

Tim Gannon and Christine Lynn

Nick Faldo with Mark Dalton

Emilio Estefan and Marc Buoniconti

Matthew Whitman Lazenby with Marc Buoniconti

Dr. Barth Green

Kandy Kramer with Colin Egglesfield

Bob Costas and Jim Kelly
Great Sports Legends Dinner

Shawn Johnson, Marc and Nick Buoniconti
Scott Erickson, Lisa Guerrero and Dave Winfield
Stewart Rahr

Terry and Marc Buoniconti with Kenny Smith
Jim Kelly and Paul DiMare
Nick Faldo and Antron Brown

Colin Egglesfield and Teresa Edwards
Shawn Johnson and Emilio Estefan

Terry Bradshaw with Nick Buoniconti
Dave Winfield with Marc Buoniconti
Gary Stevens, Nick Buoniconti, Terry Bradshaw and James Worthy
A star-studded roster of attendees came out for the world debut of *An Unbreakable Bond*, a film by Emilio Estefan which documents the relationship between NFL Hall of Famer Nick Buoniconti, his son Marc, and their nearly three decade struggle to find a cure for spinal cord injuries. The film made its world debut on Tuesday, March 11th at the 31st edition of the Miami Film Festival (MIFF) at the Olympia Theater at The Gusman Center for the Performing Arts.

Nick Buoniconti and Gloria and Emilio Estefan were joined by NBC News Icon Tom Brokaw, who flew into Miami for the grand debut, introduced the film to a theater full of supporters. After the film, the Estefans, Brokaw and Buoniconti welcomed to the stage NBC’s Legendary Sportscaster Bob Costas, who moderated the question and answer session. Costas made a huge surprise announcement that the Estefans, on behalf of the Gloria Estefan Foundation, would donate $100,000 to The Buoniconti Fund to Cure Paralysis. In addition to the Buoniconti and Estefan family members in attendance, other notables included NFL Hall of Fame coach Don Shula, NFL Hall of Fame quarterback Bob Griese, Polo player and model Ignacio “Nacho” Figueras, Miami Dolphins legend Nat Moore, Model and Television Personality Candela Ferro, Brazilian artist Romero Britto, Television Host Lily Estefan and Miami Dolphins legend Dick Anderson, and many more.

Estefan, a 19-time Grammy award winning producer, directed and produced the documentary which archives the Buonicontis’ lives as they faced paralysis head on. From the beginning in 1985 when Marc was injured, the film follows their journey from the creation of The Miami Project to Cure Paralysis through the present day as they stand at the forefront of paralysis research.
An Unbreakable Bond is narrated by Buoniconti Fund Board Member and Grammy award winner, Gloria Estefan. The film includes appearances by special friends and ardent supporters of The Miami Project including; Academy Award winning actor Tommy Lee Jones, award winning television journalists Tom Brokaw and Bob Costas, NFL Hall of Fame Coach Don Shula, and Golf Hall of Famer Jack Nicklaus. We also hear first-hand accounts from the Buoniconti family as they discuss the devastation that Marc’s injury had on the family and how they teamed up with world-renowned neurosurgeon Dr. Barth Green and developed the fledgling Miami Project, at the University of Miami Miller School of Medicine, into a research effort with international prominence that has changed the way the world looks at paralysis and a cure.

“It’s an honor and a privilege to share with the world this moving story about an incredibly unique bond between a father and his son. Marc and Nick turned their tragedy into hope and inspiration for so many individuals and families who are impacted by paralysis each year. Their story hits close to home for me, as I experienced first-hand the struggles that Gloria endured after her paralyzing bus accident. Thankfully, Gloria was blessed with a miraculous outcome and was able to walk again. The Miami Project gives great hope to so many people and their dedication towards finding a cure for paralysis is so close. My hope is that all families may experience the same miracle mine did,” said Emilio Estefan.

“We have been fortunate to call The Estefans friends for many years, so to work with them on An Unbreakable Bond was a dream come true. They bring such professionalism and class to everything they do and have helped us capture our story on film so we can take our message to the world that paralysis does not have to be forever,” said Miami Project Founder Nick Buoniconti.

Ultimately, this is a story of An Unbreakable Bond between a father and a son. A father and son not accustomed to standing still who believe that all were born to move, and chose to do something about it.
Golf Legend Jack Nicklaus Hosts 12th Annual Buoniconti Fund Celebrity Golf Invitational

Presented By The Tudor Group

Golf icon Jack Nicklaus along with NFL Hall of Famer Nick Buoniconti and his son Marc hosted the 12th Annual Buoniconti Fund Celebrity Golf Invitational Presented by The Tudor Group at Nicklaus’ home club and course, The Bear’s Club in Jupiter, Florida. For 12 years, this event has attracted the world’s top business leaders and celebrities, all working together to find a cure for spinal cord injuries. To date millions have been raised by this event to fund research programs at The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine.

Golfers and celebrities including HBO’s Band of Brothers and Gossip Girl actor Matthew Settle, Bon Jovi drummer Tico Torres, NFL Hall of Famer Harry Carson, former Marlin great Jeff Conine, NFL #1 draft pick in 1995 Ki-Jana Carter, Miami Dolphins receiving legend and current Vice President Nat Moore, Super Bowl MVP Mark Rypien, World Series Champion Pitcher Scott Erickson, Actor from All My Children and Dancing with the Stars Aiden Turner, and many more enjoyed the Celebrity Dinner affair and an exciting day of golf on the prestigious golf course.

Ethan Ruby and Jeremy Schwartz, through their brainchild Poker4Life (P4L), held the 9th Annual Poker4Life tournament at The Tunnel in NYC. Close to 300 players bought in to this spectacular event in what is now one of the best attended and run charity poker events in the NYC area. An additional 150 were in attendance rooting on the players and enjoying the poker camaraderie. This year’s winners again enjoyed prizes that included seats in the 2014 World Series of Poker (WSOP) Main Event that took place this past summer in Las Vegas, Nevada, NYC sports team packages and seats to the 2014 Great Sports Legends Dinner, to name a few. This year’s field included a mix of professional and amateur players from around the country all vying for the coveted 2013 P4L bracelet. Event winner was Michael Sama and 2nd place was Chris Trencher, with each receiving a seat at the WSOP Main Event and Adam Liebman coming in 3rd place. Both players agreed to wear the P4L patch to indicate that they intended to donate a percentage of their Main Event winnings to The Buoniconti Fund.

“Jeremy and I can’t thank our sponsors, players and friends enough for again coming out in force to support Poker4Life and The Buoniconti Fund. Everyone has such a great time and we’re raising significant funds for the important spinal cord injury research programs at The Miami Project to Cure Paralysis. As always, this is the Positive Power of Poker on full display,” said Ethan.

The mission of Poker4Life is to provide a forum for professional, celebrity and amateur poker players to come together and support causes they believe in while playing a game they enjoy. Poker4Life has attracted thousands of poker players and philanthropists with our exclusive charity poker tournaments. Over the last 9 years more than $1,300,000 has been raised through their NYC poker events with The Buoniconti Fund being their charity of choice. A very special thank you to our friends at Jewelry on 5th who have supported this event for many years and always go above and beyond in that support.

Who do you Play For? If you or someone you know would like to use the Positive Power of Poker, visit www.poker4life.org to learn more about how you can get your player patch, and how P4L’s efforts through the poker community can make a difference in the lives of many.
This year our friend Ricky Palermo and his family hosted The 18th Annual Ricky Palermo Spinal Injury Golf Tournament on August 2, 2014. It was again held at Terry Hills Golf Course with 212 golfers participating and an additional 200 joining the event for a dinner that followed at Genesee Community College in Batavia, New York.

This year’s goal of $100,000 was met and that allows the golf tournament to support the SCI research programs at The Miami Project and other local (Batavia, NY) entities helping those in need. The tournament’s 18 year total comes to $1,000,000. Important funds that continue to help people and their families who have suffered the devastation of paralysis and others in need.

Through the generosity of our friends and supporters, the tournament has been able to donate to four different facilities that will be involved in the event of a devastating SCI including United Memorial Medical Center in Batavia, Rochester’s Strong Memorial Hospital, Batavia’s YMCA functional electrical stimulation bike program to help people with challenges stay/get in shape, and The Miami Project to Cure Paralysis’ research programs.

Ricky was honored by the presence of New York State Senator Patrick Gallivan, a childhood friend of the Palermo family, who bestowed upon Ricky the New York State Senate Liberty Award for his efforts these past 18 years. The award is the highest civilian honor that a New Yorker can receive. Similar to the national Congressional Gold Medal, the award is given to individuals who have merited special commendation for exceptional, heroic, or humanitarian acts and achievements on behalf of their fellow New Yorkers.

In 1986 Ricky was one of the first participants to take part in a study that was testing to see if someone with an SCI could ride a FES bike and has been involved with The Miami Project ever since. It also spurred him to start the aforementioned bike program in his hometown YMCA in Batavia New York. In addition to the golf tournament, the Palermos have put on lacrosse, soccer, basketball clinics and comedy shows to raise funds and awareness for the cause.

Jim Palermo, Patty and Joe Fragnito, Ricky Palermo NY Senator Patrick Gallivan and Virginia and Pat Palermo at this year’s event
The University of Miami Sports Hall of Fame (UMSHoF) held the 4th Annual Habitat for Humanity of the Upper Keys/UMSHoF Celebrity Dolphin Fishing Tournament presented by Deep Impact Boats on June 27-28. The event activities were held at Founders Park at Mile Marker 87 and Coconut Cove Resort and Marina at Mile Marker 85 on the Overseas Highway in Islamorada, Florida.

This year’s tournament was hosted by Michael Irvin, a 2007 inductee into the Pro Football Hall of Fame and three-time Super Bowl Champion with the Dallas Cowboys. Irvin was a member of the Miami Hurricanes’ 1987 National Championship team and still holds the UM record for most career receiving touchdowns with 26.

The tournament weekend began Friday evening, June 27th, with a kick-off party and captains’ meeting followed on Saturday by a full day of fishing, awards dinner and live and silent auctions featuring unique sports memorabilia as well as a variety of gift packages. This is the only fishing event of its kind that matches participants with former Miami Hurricanes sports stars for the competition. Cash prizes and trophies were presented to anglers in eight categories. A portion of the tournament proceeds will go to Habitat for Humanity of the Upper Keys, The Buoniconti Fund to Cure Paralysis, and the UMSHoF.
The Woody Foundation held its 3rd Annual Golf Classic on May 1 at the International Links Miami golf course. Nearly 100 golfers, sponsors and volunteers came out to support this great day of golf, community and spinal cord injury research awareness. The Woody Foundation donated $30,000 to the Miami Chapter of The Buoniconti Fund, which has been the beneficiary and partner for this tournament since 2012 and received more than $100,000 from The Woody Foundation to support the ongoing research at The Miami Project to Cure Paralysis.

The Pittsburgh Chapter celebrated the milestone of their 10th Annual Golf Tournament on June 28 at Carmichaels Golf Course with more than 140 golfers, volunteers and sponsors including Tygart Industries and Jeremie Synder Electrical. This annual tournament has raised nearly $100,000 to support The Miami Project to Cure Paralysis.

Nick Buoniconti’s wife Lynn’s son, Justin Weiss, participated in the New York City Triathlon on August 3, 2014. Justin finished 5th in the 25-29 age group and 84th out of 4,000 entrants, including professionals. He finished in 2 hours, 10 minutes and 41 seconds and raised more than $12,000 for The Buoniconti Fund.

Congratulations for such an amazing accomplishment and thank you for your continued support of our cause.
On January 18, the Miami Chapter hosted the 5th Annual Coral Gables Block Party presented by Hillstone Coral Gables and SIG EP Florida Nu Chapter. The event, which raised $20,000, brought more than 300 guests and community partners out for an amazing night under the stars with sumptuous food by Hillstone, craft beer and spirits, Emcee Adam Kuperstein of NBC6, live music, dancing and auction.

Let us know if your community could benefit from a Volunteer Chapter which develops fundraising events and awareness campaigns to help us reach our goal of finding a cure for paralysis. Chapter locations include Baltimore-Washington DC, Boston, Charleston, Chicago, Cleveland, Miami, Nashville, New York City, Orlando, Palm Beach-Broward County, Philadelphia, Pittsburgh, Southeast Michigan and Tampa.

There’s no better time to create SCI awareness in your community! Email bfchapters@med.miami.edu or call (305) 243-3863 to get started. Visit www.thebuonicontifund.com/chapters for the latest events and community outreach and join the Buoniconti Fund Chapters on Facebook.

**Chapters Challenge** is in its fourth year as a successful campaign that encourages our volunteers and supporters participating in local, national and international races to utilize our web-based program to raise funds and awareness on behalf of The Buoniconti Fund and The Miami Project to Cure Paralysis. Race participants can establish their own page, fundraising goals, contact friends and family, track their success, and make donations directly to The Buoniconti Fund. Our goal is to have our supporters walk, run, swim, bike or wheel their way across the finish line!

http://chapterschallenge.thebuonicontifund.com

### CHAPTERS UPCOMING EVENTS

- **October 18-19 ~ Southeast Michigan Chapter ~ Detroit Marathon ‘Run for a Reason’ team ~ Detroit, MI**
- **October 18 ~ Charleston Chapter ~ 8th annual Tailgate Party ~ Charleston, SC**
- **November 8 ~ Tampa Chapter ~ 7th annual Golf Classic ~ Tampa, FL**
- **November 8 ~ Pittsburgh Chapter ~ Wine Dinner ~ Pittsburgh, PA**
- **November 21 ~ Philadelphia Chapter ~ 11th annual Raise a Glass for a Cure ~ Philadelphia, PA**
- **December 4 ~ Chicago Chapter ~ 16th annual Indulgence Night ~ Chicago, IL**
Ralph Wilson
October 17, 1918 - March 25, 2014
Maya Angelou
April 4, 1928 - May 28, 2014
Earl Morral
May 17, 1934 - April 25, 2014
In Memoriam

William G. Sims, Jr.
August 22, 1956 - April 14, 2014
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SAVE THE DATE

30th
GREAT SPORTS LEGENDS
ANNUAL DINNER

to benefit The Buoniconti Fund to Cure Paralysis

THE BUONICONTI FUND TO CURE PARALYSIS
The Fundraising Arm of The Miami Project to Cure Paralysis

TUESDAY, October 6, 2015
5:30 PM / Waldorf Astoria, New York City

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www.thebuonicontifund.com/gsld

*Past legends and honorees featured.
Help Us Find a Cure for Paralysis Today!

The Buoniconti Fund has developed a new tool to help our friends and supporters raise awareness and funds for the critical spinal cord injury research programs at The Miami Project to Cure Paralysis. The Help Cure Paralysis Fundraising Campaign allows you to set up and coordinate your campaign using your own friends and contacts. This customized site will track your progress and send updates and reminders to your friends regarding your efforts. Because of dedicated supporters like you, we continue to make a difference in the lives of people living with spinal cord injuries, and are changing the way the world thinks about paralysis. Together we will find this cure! To learn more about this important tool visit: http://helpcureparalysis.thebuonicontifund.com or email tbendell@miami.edu