Introduction to the Parkinson's Solutions Summit

Hello. I'm Dr. Ken Sharlin. I am very, very excited to welcome my speaker for today, Dr. Peter Everts. You are listening to or viewing the Parkinson's Solutions Summit where we are interviewing many innovators in the field of Parkinson's medicine, regenerative medicine, which is the theme for today.

My interviewees are topnotch researchers. They are clinicians at the most premier research institutions in the country. They are working within the holistic medicine space to bring you lifestyle medicine strategies to change the trajectory of Parkinson's disease as we know it.

And we are, of course, bringing you also the latest information on treatments that you can go to your doctor today and talk about. So with that brief introduction, I am truly excited to welcome Dr. Peter Everts.

Dr. Everts is the Chief Scientific Officer of EmCyte Corporation in Fort Myers, Florida. He is also the program director for the Gulf Coast Biologics Institute.

Also in Fort Myers, a fellow of the Royal Society of Medicine in London, UK, and more recently appointed professor at the Max Planck University in São Paulo Brasil.

He is truly an innovative researcher, a leader in the field of regenerative auto biological medicine with extensive teaching and educational program development experience.

And I might add on a personal note, Dr. Everts has been a mentor to me and truly taught me what I need to be doing when I approach this subject as a neurologist.

Thank you so much, Dr. Everts, for joining us. It's a great pleasure Dr. Sharlin, I came to be with you here on this very, very important subject.

Dr. Everts' Background in Regenerative Medicine

And so I'm truly excited to be part of your team and really look forward to our conversation. Thank you. Dr. Everts, could we start just by hearing a little bit about your journey, how you came to be interested in this subject and the kind of work that you do today?

How much time do we have? Well, I just started my journey in regenerative medicine, as we call it, in 1989. And in those days I was a clinical perfusion is taking care of the function of the lungs.

And patients were operated on their hearts and very quickly and was connected to anything that has to do with glass and blood products. And taking that as a starting point, I learned to appreciate in the early nineties how powerful our own tissues can be in healing disorders.

For example, patients who were severely compromised because of their disease. And we were able to do a lot of reparative processes in these patients using their own blood, using their own bone marrow, and just to make very safely products that can be brought directly into the area where the repair needs to be done in a completely biological way.

So we started a journey and 89 days we moved on and did a lot of publications going wrong in 2007, University of Utrecht in the Netherlands, and I continue to work getting more specific in the use of what we call platelet rich plasma therapies.

Most of you would note it well, maybe more easily than bone marrow stem cells, or find the right stem cells. From

there on, I was asked to take a job in the United States, which I happily took where I could to all fulfill my dream.

And that is be in the forefront and developing and finding ways to cure, well, maybe sometimes the impossible and by using again, a patient's own tissues and fluids to induce tissue repair.

So was very excited when the cajoling approached me couple of years ago to have a very brief discussion and remember, like the day of yesterday when we met at their office in Florida and we had a well, very light starting point of a discussion and it ended up in a lot of interest in.

While hearing Dr. Sharlin thoughts on how potentiallya lot of neurological diseases could be treated using patient's own fluids and tissues. So here we are now discussing yesterday what we will potentially have in mind and why it is that we believe that the therapies that we will set forward to develop are safe therapies for patients and maybe creating all the different line of WOW therapy applications in the near future.

Absolutely. So, Dr. Everts, I wanted to start kind of basic for folks. We could lay the foundation. And to be clear, if I can distill out a point or two that you've made, what we are talking about today are by a logical therapies, tissue therapies, not drugs, which are regulated under a completely different guideline by the FDA. So with Oh, no, not at all, please.

No, that's a that's a very, very important point. And like I said, biological products from your own, that would mean what we call ontologies therapies and ontology therapies would be there is no water involved from a drug made by a pharmaceutical company.

There is no intervening activity between your patient and just yourself. So we work completely within one of the guidelines of the United States FDA, and they need to be very strict and they are very strict in the guidelines they set forward where physicians need to be very compliant and what they can and most of the times what they cannot do.

So we feel very comfortable in working with patients own tissues to make a concentrated version of that and have more and more, more what I would like to call it a precision personal medicine approach where there's no other intervention done than connect with your body's tissues.

What Biological Therapies Are and How They Differ from Drugs

And inside the treatment room, a device which you can see where it's well, you find the product is being produced before it's being given back to your body and with the intent to well, to start healing mechanisms in place.

So it's a very, very strict protocol. As a patient, you can see exactly what's happening. You will be informed at all times. And we learned well over the years.

Right. It's not something this is a new therapy. No, we have been around in these therapies since the early 1980s, and it became clear that more physicians, more patients should have access to these kind of therapies based on the powerful potential of your own healing factors, whether these are well, so called stem cells originating from your bone marrow tissue or from from your peripheral blood, if it would be another tissue.

And we learned that over the years. So I was pretty excited when the well, neurological field starts to open up with our well, physicians. We started to develop a biological mindset.

In other words, the recognition for specific products like particular stem cells from bone marrow, how they potentially can be used. So now we need to stick with with the guidelines that that that's what we are doing.

And we just use the powers of your natural healing cells to be very much directed to the area where these cells are going to work. Yes. So when we use the term stem cell, there's kind of a lot of mysticism associated with that word or those, you know, stem cell, two words.

And it's been my experience that the broad belief and we use that term, that we're talking about cells that enter a specific tissue space, whether that's the brain area, the cranium, whether that's the heart or maybe a joint, which you I know you do a lot of work in the ortho biologic area that somehow these cells differentiate and become the cells that are missing, gone or have died.

And of course, you know that in Parkinson's disease, one of the cardinal features is the loss of dopamine producing cells in the striatum of the brain.

And so, you know, the hope, of course, in Parkinson's is somehow we can introduce cells into that area and actually regenerate that part of the brain.

Now, back in the 1980s, when I was at Emory University, Dr. Ray White, who went on to become president of the University of Alabama Medical, well, I think the entire system.

But at the time, he was actually using embryonic stem cells that were stereotactic surgically introduced specifically into the area of the brain affected in Parkinson's.

There's to my knowledge and correct me if I'm wrong, there's not a lot of embryonic stem cell research going on anymore in the United States, but a lot of the interest has turned to what are called induced pluripotent stem cells, where cells can be reprogramed through their DNA to become the cells that we want them to become.

But when we're talking about mesenchymal stem cells, we're really talking about something a little bit different. And I think you've touched on this when you used the word natural or the phrase natural healing process.

Could you help clarify that a little bit more? Yeah, let's yeah, let's try to keep this on the stand. Well, you're absolutely right. The word umbilical stem cells, it says it.

It's not from you as a patient, it's from a donor. It's in a biblical cord. That wall came from a mom giving birth to a child. That umbilical cord undergoes a lot of process.

It's not a words. It's out of your control. It's out of your sight. And the thing that really struck me when these kind of products like water, the jelly stem cells and biblical cord stem cells we know entered the market very briefly before the FDA put a halt to these to these products, so to speak, as being about it.

You need to develop a cord. You need to find a way to get these stem cells out of there. And then they need to go to a lab and they need to be sterilized.

So in other words, you're going to sterilize stem cells and then have them in a vial ready for injection. Everybody can understand that when we sterilize thing, it's with the idea to kill potential bacteria or contaminants.

So we're going to kill these stem cells. And for those reasons, they have been, well, poorly studied. And I don't think based on the guidelines, there is an interest in where the interest really is, is in your own tissue, in your own bone marrow.

Stem Cells, Inflammation, and Neurodegeneration

There are stem cells in there, different kind of stem cells. They have different functions and like you mentioned, looked the child. And initially we thought and we still think that these stem cell skin cells renew.

So these stem cells are capable of a self-renewal process. So they're able to make more of these stem cells. And from there on, they will induce the potential of developing different kind of tissues where they have been brought within contact.

So in other words, if a mesenchymal stem cell, the mother of all cells, as a lot of people would like to call them, are brought into an environment which is outside of the bone metro area.

And these cells have what we call plasticity. They're able to take on that tissue, construct these tissue definitions and do that area reparative processes.

That's how we got started. If I may, just for one more minute, Dr. Charlene. What we learned over the last couple of years is even maybe, maybe more is important in neuro degenerative diseases, and that is that these and sees these mesenchymal stem cells, the mother of all cells are capable of controlling an environment that is in flames.

So these cells have been found, but only three or four years ago. How they can alter the environment that's into a chronic inflammatory state. And that's going to be very important for a lot of diseases, whether it's neuro degenerative diseases, neuroinflammation and chronic inflammation.

So these cells are able to confirm a well tissue that's chronically inflamed to a normal understanding where normal dynamics or normal activity, so to speak.

And that's going to be even more as important as what we think right now. And then we'll just do the repair mechanisms in diseases, brain tissue. Wow.

So we have participating and or facilitating the healing process. We have an anti inflammatory role and then there is kind of a complicated word or concept that we recognize in these neurodegenerative disorders, whether it's Parkinson's, Alzheimer's or ALS, which is apoptosis or programed cell death.

And it's my understanding that in the biological arena that these cells may also be anti a pot tonic. Is that your understanding? Is Absolutely. And what they do is one of the typical features for your own stem cells is they will attract more cells.

So they will attract more cells to the environment where we have a concentration of these cells. And it's a process which we call homing and having these stem cells available.

And the literature really looks to us as the best way to get them into the brain would be to the intracellular route. I know there have been studies done looking at intravenous and drug serial because you need to get these cells from your bone marrow.

When you process them in your syringe, you need to get them to that area where you would like them to work right. And the area the best around to the liver as of now, do we know where would be the intra declaro?

It's safe. We have a lot of safety studies are available, so there is no myths there that this is all experimental. No, the interesting go around for delivering of what we call these biological your own biological tissues is a safe right.

And the big, big advantage is there is no barrier. Right. So any other drugs from the intra arterial intravenous way and they need to cross that blood brain barrier and with the tissue around, it's in direct injection of these stem cells into the serous spinal fluid and is being delivered directly where it needs to be.

So they are ready to work without having the potential that the blood brain barrier might be in its way before they can act and they can do their job in a little bit.

Excuse me. Does that answer your question a little bit? I think so. Where I think we're going to a wonderful direction. Absolutely. I hope folks are getting a lot out of this discussion.

So we're talking about how we say in theory and I think it's important understand that this entire discussion is not about an FDA approved treatment. So we don't say, well, stem cells are approved for the treatment of Parkinson's, of Alzheimer's.

We're sort of closer with ALS and have some evidence of different types of stem cell treatments for multiple sclerosis. That's that's not to say that there haven't been publications, some of which are from outside of the United States, where there is more momentum or interest in our research in the clinical applications of stem cells.

But for example, there is a company called Brainstorm Cell Therapeutics that has a product they called Neuron, and you are O. W. N or M. S.. A. F. As sort of a generic name means that camel stem cell neurotrophic factor.

Now these cells are manufactured or manipulated to a degree, so they have been turned into a drug, a biologic substance. So they fall under a different FDA guideline, but instead they are extracted.

They are initially they come from the extraction of your own bone marrow, which is then presumably centrifuged, and so that the mesenchymal stem cells can be separated from the other bone marrow cells.

Then they are sent off to a laboratory where those cells are processed in a medium. We don't really know at that meeting Amir's because that's part of their proprietary process and then returned to the clinic site, the treatment site where the cells are introduced directly into the spinal fluid through a standard lumbar puncture, the lower back.

We're in an area called the lumbar cistern, which is away from the spinal cord. So there's no possibility of spinal cord injury.

Delivery Methods and the Role of the Blood-Brain Barrier

And the idea is that they are already behaving in such a way that they know what environment they are in and they sort of sort of act like, you know, homing pigeons of of sort where they're going to find their way to the area of injury and inflammation and start their repair process.

Now, they are in discussions with the FDA for the treatment specifically of A. L. S.. They have reported on phase two results. These are this is not quite as advanced a clinical trial as the one that would lead to FDA approval.

But and that's a phase three, by the way, but nevertheless have reported at a major European meeting on improving progressive multiple sclerosis. So there certainly is some optimism around the use of this type of cell, albeit manipulated cell changed cell before it's introduced into the patient.

But all this leads me to an interesting discussion based on the literature that raises the question whether or not it is even necessary potentially to manipulate these cells ahead of introducing them into the spinal fluid space.

Would you agree with that? I completely agree with it. I still always close my eyes when I speak with physicians and patients about the potential of what we call these pathologies, your own, well, healing factors, so to speak.

They are in an environment for a certain reason bone marrow and masses are in the bone marrow cavity and they're not the only cells there that are many more cells and they have a close relationship to each other.

Minutes of blood, platelets where there is particular white blood cells, they all are related. It's one big family. So when you start to manipulate and you going to culture what we call culture and fluids to it and whatever you want to make to it, it's going to change the behavior of your mesenchymal stem cells or you want to protect stem cells.

And we still have to see whether that's going to be the future. And because we manipulate more than minimal only what we are doing. So look, starting with you and doing with extracting bone marrow from the patient, have it easier.

It extracted pretty fast, grit it in a centrifuge, which is no more than a device that's going to concentrate the number of cells with smaller portions so you can injected easily without any complications.

But that environment didn't change. We still have the other cells in there, as there were in the bone marrow environment. We take these cells, we do not change their relationship.

So the way they function, even in the peripheral blood and that exchange from bone marrow cavity to bristle blood is a continuous ongoing process. 24 seven And that's why we heal.

We heal because we do not change our environment. And I think it's going to be pretty warm, a pretty, pretty long road to see how the impact of all these small, more than minimal manipulative products alter me going to compete with your own tissues and your own concentrated products, whatever, from a safety perspective or from an efficacy perspective going to be in the same in the same direction?

Let be let be and we don't want to go there right now would be the cost for these kind of procedures and the oversight that's needed to do these therapies very successfully.

Yes. So the cells can, when they find their way to this area of injury and inflammation and they sort of say, oh, I know where I am, and they begin to they use their own genetic information to turn on the appropriate proteins, basically DNA, RNA and so forth, to secrete growth factors that are appropriate for that specific micro environment, whether it's the brain, whether it's joints, whether you know, other applications, which I'd love to hear about.

And we think we hope that these cells can then participate from a more therapeutic perspective in this process of healing.

Current Research, FDA Context, and Clinical Evidence

They may not be certainly the panacea where all we need to do is introduce stem cells and sit back and wait for the magic to happen here at Shoreline Health in Neurology.

We certainly believe in other principles that need to be applied in sort of a multivariate or multifactorial approach in which, you know, diet, exercise, mind work, etc., quality, sleep, you know, all of that is very, very important.

And and in some cases, you know, I always say that this is an integrative practice and that in particular, when we look at Parkinson's disease, where even at the time just of diagnosis, it said that the person has lost 80% of their dopamine producing cells, we really may need to introduce some dopamine, if you will exaggerate.

It's exogenous. LEE Meaning give that person some, leave a dopa carbidopa so that they can actually move and then do the things that need to be done. So it's truly there are many tools in the toolbox that are being applied at one time, not just one, but it certainly is a very promising approach.

And while the application in neurology may be still in its relative infancy, you're involved in quite a bit of work with the orthopedic space, and that really tells us much more about the potential broadly of what these cells may be able to do.

I wondered if you could share a little bit about the type of work that you do on a daily or near-daily basis? Yeah, yeah, absolutely right. I tell physicians and patients, listen, if if you have an injury, you are, let's say a runner and you injure you Achilles tendon and it starts to play out that while you have little micro fractures and all of a sudden get inflamed, it is going to get worse and worse and all of a sudden it's going to rupture.

Pulling stem cells in that area will do only part of the job. It's like you mentioned, it is the entire package of care that ultimately is going to make the final healing as a complete resolution.

And that's where we'll you will have an integrative medicine as part of well, a very, very advanced biological therapy is going to be very, very beneficial.

So working from those two angles is going to give you maximum resolve. And that's what we see in the biology as well. Or the biology is no more than using the bone marrow stem cells, fat stem cells, Europe to treat a lot of all degenerative diseases and very simple one and most known to your patients would be osteoarthritis.

Right. And you can change the environment in the knee that's causing you all the discomfort, right. Where it's pain, words and swelling and you don't want to have a knee replacement.

Right. You want to see whether your own tissues, a personalized, precise medicine can alter the environment that's

causing damage. So in other words, if we inject and what we do on a daily basis and very safely is we do this same technique, we use the same centrifuge, we use the same products, you make actually the same product.

And we injected in a need. And we have many, many studies indicating safety of doing that procedure from harvesting to concentration for injection. But even more important for patient is what it does to be what we call the local microenvironment.

You need tissue. And that's again, where the stem cells surprise us on a daily basis. What they do to wall to well get rid of defining inflammation and inflammation is gone and a lot of it is Spain is born and that's where the reparative processes really kick in.

So it's anti inflammation. It's avoiding over a heap of doses and it's angiogenesis and all of the reparative processes we see and many publications have arisen from from that area where it's fine when it's a Niehaus you are tried this and well, we are positive without making mold very big claims at the moment, but we are positive that the same potential that mesenchymal stem cells or even other stem cells are really bone marrow, which we all we didn't talk about so far. But these stem cells can do the same function in a different microenvironment like, like in the brain.

And it only gets to the point, what I call precision medicine, it's all getting to the point is how do I get my product? I mean, if you are not able to do a proper collection of bone marrow tissue, well, you might not have the ideal product.

So delivering in the broadest well, pretty clear. So I'm convinced that with the potential that we see on a daily basis for many decades right now, that will, if we continue monitoring, we continue to do the good monitoring of patients with and supplemental care as well.

I'm hopeful, hopeful. And I want to be very careful and only create any expectations. I want to be very hopeful that these mesenchymal cells and other cells in that environment well going to have this same potential effect than what we see into orthopedic pathologies.

Excellent.

Orthopedic Applications and Microenvironment Repair

Now, as we move toward to talking specifically about site, which I very much want to do and how the products that your company is trademarked for and why that might be different than other approaches.

A lot of folks who have explored this space are familiar with the fact that bone marrow is not the only tissue space where these cells can be found. And it's my understanding, in fact, that there are quite there are quite a few of these cells in body fat and at one time it was very common to extract body fat and separate these cells.

But just to clarify again that we were talking about operating within the regulatory environment of the United States of America, that at this time extraction of fat and separating mesenchymal stem cells from other from adipose cells would be considered manipulation of tissue and therefore frowned upon by the FDA.

Perhaps one day we can return to that. But right now we're exclusively talking about bone marrow. And as Dr. Everts has said, that not only do we have these mscs in the bone marrow, but we have other cells that participate in the repair process.

So how Dr. Everts, do we get to those cells in the first place? And the fat cells, you. Know, the bone marrow cells? Can you talk a little bit about the Aspire?

Okay. What process brain cells? Um, yeah. So again, I'm very lucky. I was very excited when I was asked by the owner of the company, Mr. Patrick Benning, any CEO to join the company.

And I did it with Will full confidence to wall to step into an adventure moving from Europe to the U. S. and based on the fact that EmCyte Corp is a company that always has been producing products based on science and the data that have been generated with clinical trials always benefited while developing new products and developing new products that would withstand what would be expected from physicians.

Now, biological products like plasma and bone marrow concentrates how they well going to be a better product tomorrow than yesterday and how we can will change the environment and be more effective for patients without losing any safety aspects.

So again, we at Amazon Corporation, we are now looking at a fourth generation of well known titration devices and very recently the company also developed what we call a bone marrow extraction needle.

As you can imagine, we need to get the bone marrow tissue from a very dedicated place in the body before we have any product that can be used. But he was a physician, right?

And we know the body has multiple sites that have what we call the bone marrow. And the literature told us there is one very special place where we can have quickly access in a safe way and then would be in your earlier crash on the back of you idiot breast.

And Mario's being numbed when it's numb. Ultrasound will guide you to the proper direction as to where that cavity is. And then with the productivity vehicle.

Yes. Fire and bone marrow harvesting system. It's a unique device. Looking at the past again, what did we learn? And we learned we do not want to have too many red blood cells in our final product.

So one of the things that we added to that new system is how can we avoid a lot of influx from red blood cells and very simple and close off your well, the distal tip of your respiration needle.

So when you go in, you want to collect marrow tissue that's rich in mesenchymal cells together with a couple of cells close to the mesenchymal stem cells with red blood cells.

They do not take part in any reparative, their only function in the body. And as long as we are just bringing oxygen to an area and remove carbon dioxide so that that's a function of the red blood cells and they do not have any reparative function, I wouldn't allow that.

Bone Marrow Harvesting and EmCyte's Approach

I know what I am and I look at literature pretty carefully, but so yeah, we we looked at developing a needle that when you introduce it in a patient, when you collect your bone marrow tissue and that it has there has of emphases in your what we called bone marrow spread and from there on is brought into a dedicated container also from from inside and super physiologic those tells you we need to concentrate these cells and more cells we have all the more profound function of the embassy is going to be and inside choose to have a product in place where we do two spin cycles.

It won't be the frozen separation of tissue in developing AML layer where these cells are concentrated, we get rid of the layer that has no cells and then the plasma component of it.

And then we do a second cycle where we going to concentrate these cells. And that's why we are successful both with a different way than traditional collection of bone marrow tissue and followed up directly by a procedure that really is capable of concentrating while the cells from the marrow before while you extracting and to be used in the patient.

Excellent. Dr. Everts this has been and outstanding discussion when to reassure folks who are watching this that there are elements here that are complicated.

We've done our best to explain is as best as we can, the process. This is something that is done in a handful of centers around the country. It's not something you can just go to your local neurologist and have her give you more orthopedics or orthopedic surgeons and other practitioners who are involved in the use of this technology for joints and tendons and so forth.

But in the neurology space, far fewer it at Sharlin Health, this is about a 90 minute procedure altogether, although there is a period of observational recovery that follows and our our patients have done quite well in terms of tolerating the procedure and seeing outcomes that help to stabilize the downward spiral of some of these diseases, particularly ALS.

But we've seen some motor control improvements in Parkinson's patients as well, and perhaps we'll do a mini talk later on so folks can really get a good visual of what that process looks like.

But in the meantime, Dr. Everts, could you tell us for those who want to find out more about the work that you're doing in Fort Myers, Florida, including a handful of clinicians who may be watching this, who may perhaps want to get trained, can you tell us a little more how to access you and EmCyte?

Yeah, the website is very simple. It's www.emcyte.

Closing Remarks and Contact Information

com advanced the manufacturer of these while highly designed products. Apart from that, we have a an occasional center that's www.gulfcoastbiologics.com if not the gulf with the Singapore goals and the Gulf of Mexico.

So yeah, we really consider it of the utmost importance is to train physicians at the high at the highest level possible based on the evidence that has been gathered by well by the scientific and clinical community.

So no more I'm happy and if you have any questions, you can contact me at peter@emcyte.com. And we're happy to answer any of your questions. Again, it's been truly an honor, Dr. Everts, to get to know you personally, to have been educated by you and your company has provided tremendous support to our regenerative medicine efforts here at Sharlin Health and just know if you are a clinician that you can expect equally impressive support if you are interested in sort of entering this space with your clinical skills to help your patients.

But in the meantime, thank you so much for joining us. I hope folks stay tuned for other outside landing interviews to come in the Parkinson's Solutions Summit.

Thank you so much for the invitation. And again, I applaud you for your vision and, well, having that biological mindset, how well patients own tissues, so to speak, potentially can contribute to reparative processes.

Thank you so much for I for working with you and we wish you all the best. Thank Dr. Everts.