TB-006- a new treatment for Alzheimer's Transcript

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Opening Anecdote and Podcast Introduction

I said, give me a treatment, which is a, um, which is 25 vials in a box, which I can actually show to the people here. Cause I have one here. This here is one treatment.

Now I'm, I hold the box like this and take one vial out. This is a vial of medicine right there and there are 25 vials. So they gave me a box. I went to my mom who lives in Los Angeles and I treated her.

And three days later, my mother, who was almost babbling incoherently, said she felt like a cloud had lifted out of her head. Hey there. Welcome to the Recharged Biomedical Podcast.

I'm Dr. Edward Park, and if you're curious about regenerative medicine, you've come to the right place. We're diving into the latest breakthroughs in telomeres activation, stem cell exosomes, and all the cutting edge science that's shaping the future of healing and longevity.

Let's get started. So welcome to another episode of the Recharged Biomedical Podcast. I'm your host, Dr. Ed Mark, and today we're very lucky to be joined by Dr.

William Gale. Dr. Gale, thank you for joining us. Sure. I'm glad to be here. Thanks for having me. So he's got a patient he has to attend to, so he might have to bug out soon.

But I met Dr. Gale when he was giving a lecture. One of his many lectures is a key opinion leader for True Binding Corporation. And so what they're doing is treating neurodegenerative disease, specifically Alzheimer's mainly, With an antibody called TB true binding zero zero six.

Can you tell us how you got involved with that? Sure. It's a pretty interesting story about 2010 I was doing mainly aesthetic dermatology And I started my first meds bond the year 2000, but that was 2010.

And I saw a conference called stem cells and aesthetic medicine. And I thought, wow, this would be great. Uh, so I took that course and it allowed me to meet people who were PhD scientists.

Dr. Gale's Background and TrueBinding Connection

And I started doing research for a couple of biotech companies using stem cells and actually getting stem cells from people's fat. This is like 2012 through 15 and using what we call stromal vascular fraction.

And during one of the meetings that I had with a group of doctors who were doing research with stem cells, I met a fellow who eventually became the head of the expanded access program for true binding.

Now he and I became friends in about 2015 or somewhere around then, and he found out about true binding and he lives outside of San Jose in a town called Los Gatos, California.

The true binding headquarters is located only about 15, 20 miles from where he lived. So he called me and he said, hey, Bill, you need to come to the San Francisco airport.

I'll pick you up because you have to see the data that this company has on treating dementia with their drug called TB-006. Now he knew my father died of Lewy bodies dementia and he knew my mother had dementia.

So, I was very interested, and I flew to San Francisco. He took me to the facility. I met the people at TrueBinding, the CEO. I met the CFO. I met the chief scientist.

I wanted to make sure that the facility was on the up and up. In other words, I don't ever use anything on anyone unless I see the facility. I meet the people who work there.

I wanted to meet the technicians in the lab. I even checked out their cafeteria to make sure they treat their employees well. And I said, well, everything was brand new.

The stainless steel equipment was sparkling. It looked like you could eat off the floor. Everything looks great. I had a presentation given to me. The data was amazing.

And I said, well, the proof will be in. the actual to use the word putting the proofs in the pudding. But I said, give me a treatment, which is a, um, which is 25 vials in a box, which I can actually show to the people here.

Cause I have one here. This here is one treatment. Now I'm, I hold the box like this and take one vial out. This is a vial of medicine right there and there are 25 vials.

So they gave me a box. I went to my mom who lives in Los Angeles. And I treated her and three days later, my mother who was almost babbling incoherently said she felt like a cloud had lifted out of her head.

And I saw her on the couch using the remote controls and she had forgotten how to use the remote controls to change the TV channels. And she was incredibly better.

I would say a month later I treated her again and she was even better. And now my mother is like someone, any normal person that you can have a conversation with.

So it's really incredible. No, I mean, I think that's great that you did it on your own family and now you're prescribing it. So let's just back up a little because not everybody knows what we're talking about.

Let me give a little context here. So as far as you correct me anytime I'm wrong, but as far as I know, TB 006 is a humanized antibody against Galactin 3. And what that means is that it's got some mouse parts, but it's mainly human.

So it doesn't react a lot with your immune system. So it's a protocol that was developed through the FDA. In other words, they did safety testing, some efficacy testing, but it's not FDA approved yet.

It's in the EA or expanded access. Which are the consumer means that they need to pay out of pocket, but it's not like it's FDA unapproved. It's in a gray area.

So what is keeping it from being FDA approved? I'll expand slightly on that company completed a phase one. Trial which means that the drug is safe. Yes.

Okay, then they started phase two and phase two can be divided into two parts a and B B is really just getting the dosage correct for whatever client like if you wanted to use it in a child or but weighs 50 to 100 pounds, it's going to be different than an adult like myself, the dosage.

So they haven't completed phase two, but they did phase two A, which phase two means, does the drug work? So we know that the FDA knows that the drug is safe and that it actually works.

So that's that's your face to a now get the dosage right you finish face to be and then you move on to phase 3 when people ask me what's holding it up.

The answer is usually about 350 million dollars sharp is it's yeah it takes a lot of money to continue on to phase 3 but.

TB-006 Expanded Access and Treatment Protocol

What the company has done is applied to the FDA to get approval to use the drug while the study has been halted, while they're raising money to complete phase three.

So for the person out there listening to us, they have a family member that's affected. Somehow they have what is it like 20 to 40 thousand dollars to shell out?

So it's a protocol what like once a month for how many months well, I'm the first Clinician at the expanded access program, which is also known as compassionate use so there are people that would like to have access to the medication even though the trial is closed, and that's why it's called expanded access to those people.

So each person has an individual application that has to go to what's called an IRB, institutional review, and to the FDA and approve each individual to have access to the drug.

So it's very much within a data collecting FDA schema still. So, it's not like I just write a check and I'm getting my diffusion? No, every person has to be applied for individually.

But now, over the years, you were the first. Right, I was the first. Now, how many people do you estimate are doctors? I hear there's about somewhere around 170. Yeah, it's really expanded over the last two years.

Yeah, it's really gone up. I've been lecturing for true binding for three years now. So, over those years, people have seen me lecture, they've learned about it, they want to be a doctor or clinician that participates in the expanded access program and then treats clients.

So, I'm going to tell you exactly what it costs to the patient It's $6,300 per treatment. Our initial protocol three years ago was to treat each client once a month for four months in a row, and then we would see how is that client doing.

In my opinion and my experience and having treated more people than anyone, it depends upon the severity of the dementia when you start so that if your dementia is moderate to severe, you're going to need to have more treatments than someone who has mild dementia.

Now, true binding will tell you that you need a treatment once a month. But I have found out that after the first four, I'll give you a very good example.

I have a patient with Lewy bodies dementia who didn't need a treatment for over a year and a half. And then he started to have nightmares come back and a little bit of hallucinating, which comes along with Lewy bodies, along with Parkinson's type syndrome, Lewy bodies includes that.

And he noticed the nightmares coming back. So he came back a year and a half later. Sure. I also have severe dementia on someone who has Alzheimer's, who has had strokes, who had anoxic encephalopathy secondary to emergency surgery.

He needed, didn't get enough oxygen to his brain. So almost three strikes. Now he needs a treatment once every month. If he goes more than a month, he starts to decline.

Now my mother, who I talked about, who is between, I'd say moderate to severe, but really close to moderate dementia, she needs a treatment every other month to stay where she is.

So this is not a cure. Let me get this straight. So let me just dumb it down for the listeners. So anecdotally, This is an FDA approved under expanded access.

So once the patient gets approved, they can actually, if they move, they can have another doctor as long as they're doing the same protocol under the FDA Aegis.

Absolutely. Which happens all the time. So in your experience, it's not a cure, but it does in many cases, if not most, improve symptomatology through mechanisms which we'll get into.

But it is something that is expensive and that last 350 million, I guess the companies that have done the historically failed, you know, Alzheimer's drugs, they have no interest in adopting this because it cannibalizes their revenue stream.

But isn't there anybody that might want to step in and push this over the goal? Well, they have been raising money and actually started a Parkinson's trial and an adult autism trial.

And they're starting to do the trials in other countries. So they are raising money. I can't tell you being on the outside how much money they've raised, but they are raising.

Okay. So you show us a box of 25 miles. So that's like, is it room temperature stable? No, we keep it in the refrigerator, and as long as you keep it in the fridge, the box, which I was holding here, is good for a few years.

Great, great. So it's an IV. It's an ID or infusion. No infusion. It goes into, I use a bag of 500 milliliter normal saline. And so now people will say, um, you know, that IgG, which I assume it's IgG doesn't really cross the blood brain barrier that well.

Do you do anything like mannitol or low intensity focused ultrasound or anything? Oh, wouldn't that be great? It's just not part of the protocol that's been applied to the FDA.

There, there are people. that have the ability to increase the amount of drug through the blood-brain barrier. That's not part of the protocol that we are doing right now.

My colleague Shelly Jordan has been doing that a lot. Exactly. Well, let's shift gears a little bit. You mentioned Parkinson's now, so let me just dumb it down.

For people that don't know, decades of research and drug development has gone into the idea that Alzheimer's is a disease of the amyloid alpha beta and then there's talcangles inside the cells, but if you really kind of ask yourself what caused Alzheimer's?

How the Therapy Works and Clinical Experience

The answer is we don't know. It's probably multifactorial. It's not all genetic. What we can say for certain is that if you have two mutated ApoE4s, then your inflammatory type tends to give you a higher risk lifetime.

We know that poor sleep, you know, they taught us in med school that old people don't need sleep. That's probably not true. During sleep, the glymphatic system rinses away a lot of the trash.

So, but it's also a vascular disease. Like, I don't know if you think that people are conflating or wrong about COVID, but some people have small vessel disease.

Maybe it's contributing to some vasculopathy and reactivation of COVID immune systems, but it's probably nutritional. Now these people are coming out with those mitochondrial theories, so it's a lot of things.

It's multifactorial, you're absolutely right. But you don't have a great animal model. They have these kind of mouse models where they knock out the genes involved with pre-amyloid and and what have you and that's how the proof of concept was done for TB 001. So we know that basically the premise is that Galactin 3 is this protein you make and it helps to form these tangles which gums up the system and activates the microglia or the immune system and it causes this mess.

So your, your experience as a clinician, as a scientist is that if you can bind up this Galactin three, that's less of a mess and the brain washes out and the function is at least better for awhile.

Is that roughly the case? Well, I would say a hundred percent true what you said. And I would. Say that because it seems that all neurodegenerative disorders improve from this drug that it is one secondary to inflammation and

once those microglial cells start going back to work and reduce inflammation, which collected three seems to help them.

I'm sorry, that TB-006, which binds the elected three, seems to help those microglial cells get back to work. That seems to be a big part of reducing inflammation, which gives people back their function.

My mother, in fact, is microcirculatory. That's her problem. So let's pivot because I was walking by the booth this year at A4M and I saw Sharon's thing, IntelliX DNA.

Now, I gave him a lecture two years ago. I trained them in exosome clinical use. And when I talked to her a couple of years ago, she was like, yeah, we've been doing the TV zero to six, but there are some non-responders.

So I noticed that you've incorporated genomics into it. Now explain to us, I know that 6300 includes all the lab testing. I don't know if it includes the IntelliX DNA.

It does not include the intellect's DNA. But tell me if you think the premise is correct that some people with variants of Galaxin 3 will be less responsive.

There's supposedly 5% of the people have a mutated Galactin 3 protein that will not respond to TB-006. I personally have not had a non-respondent. Okay, so it's not as common as she was thinking.

Yeah, but I've heard That of all the people treated there were a few non-respondents who tested to be non-respondents. So typically the infusion is what like an hour?

Untoward reactions, can they get fevers or is that relatively uncommon? We've never had anybody have an adverse reaction or even a side effect. The worst that's happened is Is, uh, some redness at the IV side of someone.

Do you pre-medicate with the antihistamine or a steroid or anything? No, no. And, and no one's, no one's had a reaction. I heard in a, in a phase one or it could have been a phase two way many years ago that someone did have a little bit of.

blood on an MRI, but it was deemed not secondary to TB 006, and they were asymptomatic. Also, the Parkinson's has another bad protein called alpha-synuclein.

Have you also used it in cases of advanced Parkinson's? Yes. And we've seen great results. We've, we've seen, uh, not me personally, but I know a couple of doctors have seen tremors disappear during the IV infusion and seeing that people walk in with a shuffling gait and walk out with a much improved close to normal gait.

Wow. But really incredible. I, I personally do have a client who has Parkinson's also of course, uh, dementia with the Parkinson's. who went from a mini mental status score from about 18 or 19 to 29 and walks well and says that he's no longer falling anymore.

Yeah, I mean, listen, I mean, I listen to you guys on the stage and you know, we hear some good anecdotes from patients. So I do think there's promise for this, you know, a lot of people out there probably can't afford it.

But for those that can, obviously, you are the original, you have the most experience based out of Manhattan. But if they're more difficult for them to travel, does TrueBinding website have a list of referral doctors that are in the FDA?

Broader Uses, Costs, and Patient Access

That has just started that you can go to a website, a TB provider website and put in a zip code and see what doctors and actually it even shows, I believe it shows the amount of clients that that doctor has or how many treatments that doctor has done.

Yeah. Someone told me they, they got in touch with me because they saw that I had treated, you know, like I'll just say many, many more than the other people that were located.

in Manhattan, New York City. Yeah. No, I think it's all good. I mean, hopefully you'll be able to help a lot of people with a lot of neurodegenerative things.

So for those that can't afford it right now, I know that they can be tested for APOE4 or whatever, but what are some general free things that people can do in terms of diet, nutrition, sleep, whatever, exercise?

I tell everyone, if you can, avoid gluten, right? reduce your sugar intake, and even dairy seems to influence. Those are all very inclinogenic, yeah, for sure.

Exactly, right. Because let's remember, the lectin 3 protein is a pro-inflammatory protein, and it's involved not in just neurodegenerative disorders.

One of the slides I show in our lecture is I show all the different organs, lectin 3 is involved in inflammation, which is heart failure, lung, liver, kidney failure, arthritis, asthma, irritable bowel.

So just about any inflammatory disorder, Galectin 3 seems to be elevated in. So you might see systemic effects. Have you ever seen incidental improvement in like, I just had a consult about cardiac amyloidosis.

Have you ever seen that be improved? Yes. Yes. In fact, We've seen cardiac functions, especially people with hypertension. We've seen that improve. We've seen people get off medications.

We've seen diabetics improve and lower their medications. So I've even seen one person said that he's not peeing as frequently at night because of his prosthetic hypertrophy.

So we do see inflammation reduce throughout the entire body, including kidney function. I just treated a fellow from Australia. And he said, oh, I'm peeing like a fire hose now.

I'm like, OK. So yeah, I think like you know about Exosomes, obviously you have your own cosmetic brand. I think that's also one way to get into the anti-inflammatory.

But yeah, I think it's really interesting and promising. A lot of people may be despondent about the cost, but maybe there's a path. I'd say that's the largest hurdle is the cost.

Yeah. Yeah. But it really is. I think of it as a game changer because is the only drug in the history of our lifetimes to actually reverse symptoms. We're not just halting progression.

Absolutely, no. Halting progression is a pretty low bar, but yeah, my good friend..

Closing Remarks and Podcast Outro

. Well, that has been the bar. I know, but my good friend Cat Tubes, who I'm sure you know, she spent decades trying to find the magic bullet, and it turns out it's much more complicated than that.

So I see your nurse hovering in the back, so we'll let you go. But if they want to contact with you, you're the Gale Center? I'm the Gale Center and I'm also drgael.com.

And on Instagram, I'm Doc Manhattan NYC, D-O-C Manhattan NYC. But this is a game changer, which is why I got into it. And I have personally seen it change family's lives and of course the client's lives too.

So it really is amazing. I hope you can help the lady waiting or the person waiting. And thank you for your time and they'll get in touch with you at the Gale Center.

Okay. Okay. Great. Thank you. I'll see you soon. Okay. Bye. Thanks for tuning in to the Recharge Biomedical Podcast. If today's episode got you thinking, you'll love my book, Exosomes, Songs of Healing.

It's packed with cool analogies, full color illustrations, and all the science you'll need to understand how exosomes are changing the game in aging and regenerative medicine.

You can grab it in paperback, ebook, or audiobook, whatever works for you. Now head over to www.rechargebiomedical.com to check it out. And don't forget to like and subscribe so you never miss another episode.

See you next time.