



August 17, 2024, Monthly Update

Important Items in this Update:

- 1) Progress on Parkinson's disease and other brain disorders**
- 2) Progress of treatment for severe heart disease**
- 3) Presentation by Dr. Jacobs in Kuwait City, Kuwait on October 4th
**sponsored by the Dar Al Shifa Hospital on the topic of "New Modalities
for Treatment of Parkinson's Disease"****

1) Progress on Parkinson's disease and other brain disorders

On August 18, 2024, our Cohort #27 to treat Parkinson's disease will start in the British Virgin Islands. We now have some more Parkinson's disease test subjects who are reaching their two-year anniversary in the medical research studies.

About a year ago, we advanced to a new dosing protocol, which we call protocol 17. This protocol extends the continued dosing of our test subjects with FGF-1. I believe without question we are seeing enhanced recovery with the continued dosing of FGF-1. We have now dosed 180 Parkinson's patients and except for one patient who reported a mild headache after dosing, we have had no reported

adverse events. The enhanced improvements in motor skills and mental skills have varied with each patient. As you can read from our updates, Vika gets emails from our patients, with some having shown amazing improvements, others less improvement. The test subjects who had made the most improvements after they received FGF-1 are the ones who have then lessened their intake of other Parkinson's disease medications, such as levodopa. They have had the most impressive improvement results, since everyone knows that Parkinson's disease medicines tend to have serious side effects.

While it is gratifying that we are seeing some wonderful improvements, we are still trying to understand what the best dosing is to achieve the best outcome. In the heart clinical trials, we saw one round of a few injections into the heart muscle and new blood vessels grew and provided fresh blood to ischemic areas. Six weeks after the injection of the FGF-1 into the heart, the patients had a rejuvenated functional heart again. In the brain, the dosing is like having a water hose running into the Arizona desert, yes, good things are happening, but very slowly. We are studying our patients and thinking about how to enhance their recoveries. The improvement in motor skills, mental skills, the improvement in memories and enhanced control of body functions are all good, however, we want better outcomes for our people, and if possible, quicker improvements.

Also, keep in mind three years ago, few people believed that FGF-1 taken up the nose could stop the decline from Parkinson's disease and then be able to reverse it and that people could start to recover from this horrible disease. In the last two years, we have human data which shows we could be on the right pathway to treating Parkinson's disease. Two years ago, 100% of neurologists said that what

we are doing is crazy or worse. Today, some neurologists have seen their patients recovering, and they are watching us now with an open mind. In the last two years, we have been invited by prestigious hospitals in Saudi Arabia, Dubai, and now Kuwait to present our medical evidence to their communities on our treatment for Parkinson's disease and other brain disorders. The more evidence we generate that FGF-1 can treat and perhaps reverse Parkinson's disease, the better off everyone is. My hope is once we find the best dosage, we can start an FDA Phase I trial in the United States to advance us getting this medicine to the millions of people in the world who need it. There is no doubt in my mind that the medical test subjects we have had to date are helping us find a viable treatment for Parkinson's disease, and for that, we thank each of you!

2) Progress of treatment for severe heart disease

We are making progress on treating patients with severe heart disease in The Bahamas. We have obtained clearance in The Bahamas to dose patients with FGF-1 to treat their severe heart disease. Now we are working with our partner in The Bahamas, The Bahamas Heart Centre, on the operational logistics. Dr. Jacobs, our President of Zhittya Genesis Medicine, has overseen this process before in USA FDA Phase I and Phase II clinical trials, so I do not anticipate any major issues. It just takes time and effort on how to access the condition of the patient, how to treat them, how long they should stay in the hospital, etc.

While we are dealing with the task of how to deliver the FGF-1 to the heart patients, we have started a small awareness campaign. The initial responses have exceeded my most optimistic expectations. With our first human clinical trial in the United States, ABC Nightly News came and did a news broadcast where you

can see the heart before and after the FGF-1 drug treatment:

https://youtu.be/lPtv_0LWK4k

When that ABC News Story ran, we received thousands of inquiries from people with severe heart disease who wanted that treatment. As of August 5, 2024, we have surpassed over 100,000 views of that YouTube presentation. These are people who wanted our treatment to extend their lives. Now we are again confirming the medical need is great, and the patients want it. Heart disease will be responsible for 1/3rd of all deaths of adults in the world this year. An estimated 19 million people will die from heart disease this year and I believe our medicine, which can biologically grow new blood vessels and save their lives, is the only viable treatment. In the United States, it is reported that over 800,000 people will die of heart disease this year. I am always amazed when I meet a person, who tells me their heart disease is being taken care of by a bypass or balloon angioplasty, then I ask, **“If it is being well-treated why are there 19 million heart disease deaths this year killing over 33% of all adults?”**

I believe heart disease is an unmet medical need which only our medicine can treat. Brain disorders such as Parkinson’s disease, stroke, dementia, Alzheimer’s disease, etc., are all horrible diseases, but those diseases can last a long time (many years) and seldom result in a quick death. If you know you have severe heart disease, you know your life could end in a few hours. We are getting a great response, and I hope we will be treating heart patients in The Bahamas within a few months. I also hope we will be able to file our Investigational New Drug (IND) application with the USA FDA next year to start a Phase II for accelerated approval in the United States. People are dying and are suffering because of the delays in

getting this medicine approved. If you are interested in our heart disease research program in The Bahamas, feel free to respond to this email with your interest.

3) Presentation by Dr. Jacobs in Kuwait City, Kuwait on October 4th sponsored by the Dar Al Shifa Hospital on the topic of “New Modalities for the Treatment of Parkinson’s Disease”

Dr. Jacobs will be making his third trip to the Arab Gulf in the last two years to make a presentation on our treatment for Parkinson’s disease at one of the largest private hospitals in Kuwait. When I was an Investment Banker (1968–1998), I made many trips to Kuwait starting in the late 1970s to raise investment capital for high technology ventures. Zhittya has many friends in Kuwait and some important shareholders there who support us. Kuwait is very wealthy since it has one of the largest oil reserves in the world and for many decades has sold billions of dollars’ worth of oil every year. Kuwait's 2023 population was 4.82 million people, of which 1.53 million were native Kuwaitis and 3.29 million were expatriates. Of the 1.53 million Kuwaitis, when you remove children and those citizens not in commerce, you have a few people handling a remarkable amount of wealth.

Vika and I will be accompanying Dr. Jacobs to Kuwait, and we will arrive on September 26th and remain there until October 8th. This should provide us time to meet with and talk to many people there. We have been exploring setting up a clinic in Kuwait to treat medical tourists from India. The World Health Organization (WHO) estimates the Indian subcontinent has over 60 million people suffering from severe heart disease, of which I believe about 85% are suffering from small vessel heart disease, for which I believe our medicine is the only

treatment in the world. If only the richest 1% of that 60 million traveled to Kuwait to be treated, that would be 600,000 people. That is a massive marketplace opportunity for Zhittya!

We will be sending out invitations to meet with us while we are in Kuwait.

I am also hopeful that during that trip we will complete the Pre-IPO placement we are working on now.

The Pre-IPO placement we first discussed at the FreedomFest is proceeding well, and I believe whatever investments are still open at the end of September we can finish off in Kuwait.

Investment Opportunity: For those individuals which a Pre-IPO placement would be suitable, we are seeking to privately place some common shares before the IPO to fund some special operations which have developed over the last 60 days.

Our projects are advancing rapidly, including studies in the heart, the brain, the lungs, the legs and more. For those persons who are suitable for an investment in Pre-IPO shares, please contact: Mr. Bart Vossen at: bhvossen.rmena@gmail.com

Vika Montano's Patients' Comments Section: Every month, I receive emails and phone calls from our test subjects. I select a few so you can read what those who have joined our Medical Research Studies are reporting to us.

Patient 1)

I'm doing well. My voice has improved noticeably, and my balance and energy.

Looking forward to more healing.

Patient 2)

I'm doing really well right now. Getting busier every day, gardening, cooking and enjoying my family.

Love and hugs

X

Patient 3)

Dear Dan & Team Zhitty,

I thought it appropriate to let you know that this last 2 times I used the nasal spray, (or the Juice as you Zhitty guys call it) **WOW, what a difference I saw!**

After the 2nd day I noticed a drop in the need for my primary Carbidopa-Levodopa Medication that I use, **Rytary**. As I'm sure you know, Rytary is time release capsule that lasts me approx. 2 hours 45 min – 3 hours 15 min before I crash, so to speak. **(So about 3 hrs.)** So, on day 2, during my 3rd dose of the day, I went from 3 pills every 3 hrs to 2 pills every 4–5 hours and by the 4th day, BAM I went from **THREE** 48.75-195 mg pills, every three hours to initial dosage of 3 pills, then only 2 pills every 4.5-5 hours all day. And my last dose was about 7:00 PM, my meds lasted all night until the next morning! **And that was a Monster HR!!!**

Unbelievable, Wow what an upgrade!!! It may not seem like much, but it's amazing what a small change like this can do for you, and how much better it makes your quality of life. To be honest, until this happened, I didn't think I saw any changes. I personally made a change in my dosing of my Rytary from just taking 3 pills every 3 hours based on the clock, to spreading it out a bit more and taking the Rytary over a min of 15 mins, ideally, 30 mins is, divided into thirds.

When I take it this way, I just feel better and I can listen to my body better, as opposed to the Clock. (*Which is often a bit off and helps create medication build-up*)

On this day, I was leaving for the gym at noon until 1:00 for a VERY demanding group class I take. I took my 1st dose of Rytary @ 11:30. My 2nd dose @11:45 and I got very busy, felt great and my body wasn't asking for the 3rd dose, so I forgot to take it at 12:00 when I should have. ***And when I got home about 1:30, I sat at my desk, looked down and there was my 3rd dose! Wozza and I never missed it. So, I waited until my meds ran out and it took almost 5 hours with just 2 pills! WONDERFUL! Absolutely Wonderful!!***

As GREAT as it was, just a few days later, without the nasal juice, my body reverted back to its old dosing schedule :<(I am back to 3 pills every 3 hours starting about a month ago. (so that lasted about 6–7 days) And I just finished the last of my juice 1 week ago, with essentially the same results, but for the 1st day off of the juice, my body was craving a higher dose of the Rytary, then my previous standard. For a day it was craving 4 pills every 3 hours, but I'm only giving it 3 ½ through lunch, then back to 3 pills every 3 hours...

So, I am finally seeing noticeable improvement and change greater than 1%-2% and would like nothing more than to lessen my need for Rytary **(It's REALLY Expensive-about \$2,000 a month)** but, I'm now out of nasal spray.

Sincerely,

Larry X

Patient #4)

X seems to be making improvements at a faster rate. He only fell a couple of times since the 1st dosing session. His cognitive seems improved and he has started a few small projects on his own.

We will always be thankful for the opportunity to be a part of this research.

Thankful also for you Vika.

Patient #5)

Good Morning Vika,

I continue to have excellent results and will keep you apprised of developments as they occur. As I told Mr. Montano in our conversation, my neurologist is going to retire at the end of the year. After the examination he performed at the end of June, he seemed genuinely astonished at the results. He declared I had no further physical symptoms of Parkinson's except for loss of balance and poor gait. He also said the DBS is causing most of my problems. More on this saga later...

With Best Regards,

Joe

Cross Border Medical Tourism

Cross Border Medical Tourism services is for those people who want to be considered for Zhittya's future clinical trials or its current Medical Research Studies. Cross Border's focus is to fill all available slots in the Medical Research Studies in the British Virgin Islands and The Bahamas, while we wait for other clinics to come online.

Cross Border is working on filling the available slots for the next BVI Medical Research Studies (intranasal FGF-1 for Parkinson's disease) on the following dates:

Cohort #27: August 19 – 24, 2024

Cohort #28: September 5 – 10, 2024

Cohort #29: October 22 – 27, 2024

Cohort #30: November 12 – 17, 2024

I am showing cohorts further out in time since we are filling up faster and have fewer spots open each month.

Please contact Sam Cross at Cross Border Medical if you wish to be considered for the BVI cohorts or slots in The Bahamas. Sam's email address is:

sam.crossbordermedical@gmail.com.

In addition, if you are interested in participating in the brain scan studies which will take place at Washington University in St. Louis, please let Sam know. There are a finite number of slots for the imaging studies. These studies will look at brain blood flow before and after treatment with FGF-1. There has been no reported pain associated with the MRI scan.

Upcoming events:

September 26 – October 8, 2024, in Kuwait City, Kuwait we have meetings.

October 5: **Presentation by Dr. Jacobs in Kuwait City on October 4th sponsored by the Dar Al Shifa Hospital on the topic of "New Modalities for Treatment of Parkinson's Disease"** Dr. Jacobs will be presenting the medical data on our FGF-1 medicine to treat human test subjects with Parkinson's disease. The event will be

in the auditorium of the hospital and several hundred guests are expected.

During the visit, I expect we will have meetings with businesspeople, possible patients, and possible investors. If you wish a meeting with us while we are in Kuwait, please email me at: Dan333@aol.com

Dr. Jack Jacobs

As Dan mentioned above, heart disease is responsible for 1/3rd of all adult deaths in the world. This year, almost 20 million people will die from heart disease, and we believe our drug, FGF-1, can be a very attractive treatment through its ability to stimulate the growth of new coronary blood vessels in the heart. As we have recently received approval to treat heart patients in The Bahamas, I thought I would review some of the previous results seen with this medical indication.

In previous studies, including two separate studies in Germany and two in the United States (Phase I and II clinical trials), over 70 patients received intramyocardial injections of FGF-1 into their hearts. Of note, no significant severe adverse events attributable to FGF-1 were seen in any of these patients and good efficacy (exercise performance) was seen.

A. Human Studies in Germany

Two clinical studies were performed in Germany with FGF-1 in patients with coronary heart disease. In the first clinical study, FGF-1 was injected intramyocardially into 20 patients with coronary artery disease. These patients were also receiving a coronary bypass procedure on another affected artery. A control group of 20 patients received bypass surgery alone. Evaluation of these patients, at three months and three years' post-treatment, found no adverse

events from the growth factor injection. In patients receiving FGF-1, there was an approximately three-fold increase in vascular density in the treated myocardium compared to the control group. Localized angiogenesis in the FGF-1 treated myocardium persisted over 3 years, and an improvement in myocardial perfusion and function was demonstrated by an increase in capillary density and working capacity, and a reduction in use of anti-anginal drugs.

In a second clinical study performed in Germany, 20 patients with coronary heart disease received FGF-1 as the sole therapy. The results of this second clinical trial demonstrated that 80% of patients showed a significant improvement in their treadmill exercise test, and that perfusion of the heart under stress showed a 5-fold increase in the SPECT perfusion score. Importantly, no significant adverse safety effects of the therapy were noted, and all patients had an improvement in their dominant clinical symptom, angina or chest pain. During the stress exercise test, angina was either completely absent, or began at much higher levels of exertion. The results of this second clinical trial confirm and extend the results of the first clinical trial that FGF-1 is a safe, efficacious and localized monotherapy for the treatment of coronary artery disease.

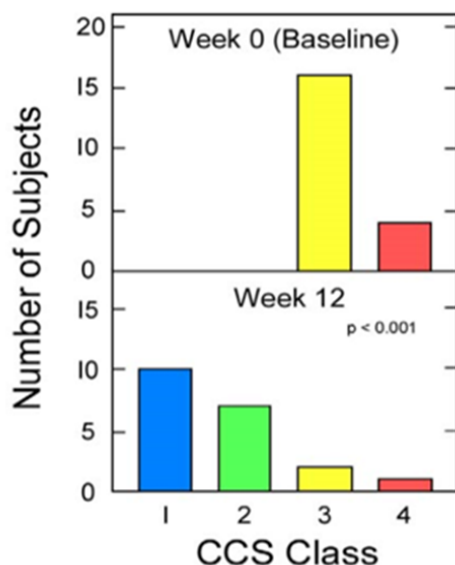
B. US Studies (Phase I and II)

In addition to the two clinical studies performed in Germany as described above, a Phase I clinical trial was performed in the US where human recombinant FGF-1 was administered by intramyocardial injection into subjects with severe coronary heart disease. In this completed Phase I trial, 21 subjects received two concurrent intramyocardial injections of FGF-1, including four subjects at a total dose of 2 µg/kg, eight subjects at a total dose of 6 µg/kg, and nine subjects at a total dose

of 20 µg/kg respectively. The results of this trial demonstrated that FGF-1 was a safe and well-tolerated treatment for advanced coronary heart disease. No significant drug-related adverse events were noted, and the treatment produced statistically significant improvement in two main efficacy endpoints, including treadmill exercise performance and CCS angina scores. In addition, pharmacokinetic parameters established the relatively rapid clearance rate of FGF-1 from the body (4–6 hours) following intramyocardial injection.

Although this phase I trial had as its primary endpoint the safety and tolerability of the intramyocardial injections of FGF-1, additional endpoints included collecting and analyzing various efficacy readouts. Figure 1 below gives data on angina scores derived from the Canadian Cardiovascular Society's (CCS) which ranks angina in 4 classes, with class 4 being the most severe form of angina. As shown in the figure below, there was a significant improvement in angina scores across the patient population.

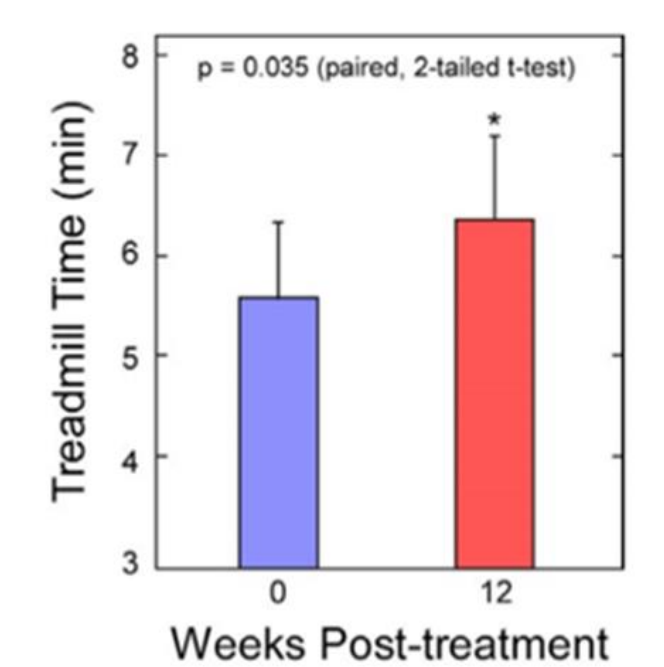
Figure 1: Classification of angina based on the CCS Questionnaire at baseline and 12 weeks after treatment with FGF-1



In addition to angina classification, another efficacy endpoint collected in this trial was to examine the subject's performance in exercise treadmill testing before and after treatment with FGF-1.

The figure below shows the difference in subjects' exercise treadmill times from baseline to 12 weeks after being treated with FGF-1, with a statistically significant improvement following treatment.

Figure 2: Exercise treadmill times at baseline and 12 weeks after FGF-1 treatment



In a U.S. Phase II clinical trial which was to have enrolled 120 patients with severe heart disease, the trial was halted (for Sponsor financial reasons) after approximately 10 patients received the FGF-1 treatment. However, the safety and efficacy data from those 10 patients mirrored the excellent safety and efficacy results observed in the U.S. Phase I study.

Conclusion by Dan Montano

I am very excited with our progress and success with our medicine to treat the major causes of death and suffering in the world. Medical discovery is a slow process of small steps forward and then watching and observing if you made a mistake, or you made improvements. For the FGF-1 treatment for the heart, I am pleased to say that in all the human experiments done over the last 29 years, the medicine has shown to be safe and dramatic improvements in heart function were seen. I look forward to being able to treat more heart patients and learn more while we extend their lives.

After two years, the brain is still a mystery. We have seen material improvement in test subjects, however, why does one patient at 6 months improve 80% on their motor skills and another only 10%. Why is a patient struggling with short-term memory and then, 12 months after dosing, suddenly remembers many, many things one day? Why does it seem changes occur in waves, good and then not good, up and down? What is the best dosage, and what is the best duration of dosing? In two years, we have made outstanding progress, however we have not figured out everything we need to know yet. I guess if it was easy, someone else would have done this.

Every month we obtain more evidence we are on the right path; however, we are not where I want to be. The road to recovery in the heart is measured in a few months. The brain is definitely more difficult. We have seen dramatic improvement in motor skills. We have witnessed enhanced mental functions, and yet, we still have not achieved full recovery. Maybe we need to dose longer, or with higher doses, or something else. Every week, one of our test subjects tells us

to give them more FGF-1 so they can heal faster. I will take the chance, they say. We say NO! We must advance the treatment in a safe and rational process to treat all of our test subjects the same, so we know what works and what does not work. We have not had any material adverse events. We have patients who needed a walker when they arrived in the BVI. A year later, they are walking semi-normal, but not normal yet. Patients who experience terrible nightmares are now sleeping through the night (and so is their spouse). Maybe the journey to recovery is longer than we thought, however since we are the only ones showing any real progress in treating Parkinson's disease, so, keep the faith!

Bless you all!

Dan Montano, CEO

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