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Q&A with Jeffery A. Meckler, CEO and Vice Chairman of Intec Pharma Inc. now in Phase 3 Clinical Trials for Parkinson's Disease with their Accordion Pill™ Technology a revolutionary Drug Delivery System that will allow L-DOPA to Remain in the Stomach for 8-12 Hours

Jeffery A. Meckler
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CEOCFO: ***Mr. Meckler, Intec Pharma is advancing its unique drug delivery system with your Accordion Pill™ technology. How does it work? Why is it superior to what might be available today?***
Mr. Meckler: Our drug delivery technology is called the Accordion Pill. Simply stated, it is drug applied onto films and folded to fit in a capsule. When you take the pill, the capsule dissolves and the film opens up like an accordion in your stomach, providing gastric retention – meaning it remains in the stomach for 8-12 hours. During that time, the drug slowly eludes off the film or is released from the film. This is a benefit for certain compounds that are very sensitive to the way the body absorbs the drug, such that it is advantageous to give a little bit of drug consistently over time. It is a bit like an IV infusion, where you are giving the drug in a drip-drip-drip fashion and the patient receives a little bit of drug over hours. When you take an ordinary oral drug, the pill dissolves in your stomach and "boom" - all the drug is immediately released. Oftentimes that works as the drug stays active for a long period of time and can flow through the body. However, there are scenarios where a drug is only active in the body for a short period of time or it may only be absorbed in a very narrow part of the gastrointestinal tract. In those cases, drugs that are released slowly in the stomach, more like an IV, provide a therapeutic benefit. This benefit is one that can change the actual way the body reacts and receives the optimal therapeutic effect of the drug.

CEOCFO: ***Would you tell us a little bit about the film, what it is, how it works? Has something similar been tried?***
Mr. Meckler: Drug-on-film technology has been around for a number of years. For most people, the first thing they think of is Listerine pocketpaks. These are sublingual, immediate dissolving films. Films are also used extensively in patches, where a drug is loaded onto a patch that is then adhered to the skin where it slowly provides drug over time.

For years, we have had technology like this. What Intec has done is to take that technology to the next level by loading the film with drug that is then released in the stomach over 8-12 hours. The core technology of these films is a technology that has been around for years. The analogy I give is to think about the ship in the bottle. The tough part is getting the ship in the bottle because it is bigger than the hole in the bottle's neck. Therefore, in delivering drugs in the way that we do, by folding the film up, it then becomes small enough to put into a capsule that you can swallow. The capsule dissolves, then the film fans out and its enlarged size prevents it from passing through to the GI tract, allowing it to stay in the stomach for long periods of time. That is the new trick. However, the actual components of the film and the technology of loading drugs onto films have been around for years.

CEOCFO: ***Is it well accepted in the medical community?***
Mr. Meckler: Yes, it is.

CEOCFO: ***Your Phase III program is for Parkinson's disease? Why has that been the lead program and is the technology applicable for other applications? What is in the pipeline for you?***
Mr. Meckler: Parkinson's disease is a neurodegenerative disease. We still do not have a cure for Parkinson's disease and our Accordion Pill technology is a treatment not a cure for Parkinson's. The gold standard treatment for Parkinson's disease for the last fifty years is L-DOPA or Levodopa. This drug is a precursor for dopamine in the brain. For the majority of Parkinson's patients, the issue is the production and reception of dopamine in a certain part of the brain. Levodopa goes into the brain and is converted to dopamine, allowing the brain to function well again. The problem or the challenge with Levodopa has been that it has a very short half-life. Consequently, it only remains for a short amount of time in the body once it is released. Further complicating its therapeutic effect is that Levodopa is only absorbed in the upper duodenum or the part of the upper gastrointestinal tract that connects to the stomach. Therefore, the drug does not last very long and is only absorbed right in the region outside the stomach.

This creates the clinical challenge of how to give Levodopa in a way that you can achieve a steady state of the drug in the blood plasma. The solution, to date, has primarily been through prescribing Levodopa to be dosed several times a day with multiple pills per dose. In advanced Parkinson's disease patients it is not uncommon to take six or seven courses of therapy each day, taking multiple pills at each course of therapy. Physicians are trying to emulate an infusion like delivery of Levodopa with these multiple doses. For example, patients will take a couple of pills when they first wake up and maybe a couple more at ten o'clock with coffee. They will take another dose at lunch. Throughout the day they are always taking pills in an effort to constantly achieve the right Levodopa levels. Not surprisingly, drug delivery companies have been trying to find better ways to deliver Levodopa for years. A variety of extended release Levodopa technologies have been developed, whereby the drug is dissolved over multiple hours. The challenge has been that once the stomach evacuates the drug, which is 2-3 hours after ingestion, it passes by the region where the drug is absorbed. As a result, the benefit is limited and the best current therapy on the market still requires the patient to be dosed up to five times a day compared with approximately seven times a day with generic Levodopa. So, the benefit in terms of both efficacy and pill burden is minimal.

With our technology, Levodopa is released off the film and the Accordion Pill™ is in the stomach for 8-12 hours making this a particularly ideal candidate for our Accordion Pill platform. As to what else we can use the platform for, the Accordion Pill can be applied to any number of other drugs. We are currently working on a cannabinoid program where we are evaluating Cannabidiol (CBD) and 9-Tetrahydrocannabinol (THC) and the combination of both in Accordion Pills. These are drugs that are now getting a lot of press regarding their therapeutic potential, but they are difficult to absorb given their poor solubility and they are very often misused. With the Accordion Pill, we believe we have a better way to deliver the cannabinoids very steadily, which is expected to provide enhanced therapeutic effect while reducing some of the psychotropic adverse side effects. For the cannabinoid program, we are looking at a variety of pain indications where providing a nice, steady dose of drug will provide pain relief over time. We will be going into the clinic with our THC formulation later this year and will follow that with our CBD and combination studies in the early part of next year. We are also working on a program with Novartis to develop an Accordion Pill to more optimally deliver one of their proprietary compounds.

CEOCFO: ***With the Phase III in Parkinson's disease the endpoint is only one hour of improved OFF time, how important is that difference?***

Mr. Meckler: That is a great question. If you look at current patients' medical regimens, they are taking multiple doses with multiple pills each day – oftentimes up to 20+ pills per day. In our Phase 3 program, patients take one Accordion Pill-Carbidopa/Levodopa (AP-CD/LD) either two times or three times a day. Potentially, you will take your Parkinson's medication with each meal. This simplifies the regimen. It also should improve the Levodopa-induced motor fluctuations and complications in these advanced Parkinson's disease patients. It is not just improving OFF time. It is also providing improved ON time without troublesome dyskinesia, which is abnormal, uncontrolled or involuntary movement. The result is much better control for the Parkinson's disease patient.

The primary endpoint of our Phase 3 study is the change from baseline to study endpoint in the percentage of daily OFF time during waking hours and our study is 90% powered to show a one-hour reduction, which would be a statistically significant reduction in OFF time. That said, we are looking at other parameters in addition to reduction in OFF time, such as easier compliance, better pharmacokinetics, enhanced reduction or control of dyskinesia and reduced pill burden. We look at the totality of those data as the parameters for commercial success. One of the things we are now spending a lot of time on is the commercial assessment work. The majority of Parkinson's patients are not adhering to their therapy and because they are not compliant, they have increased medical complications and healthcare costs. The easiest example to consider is when a Parkinson's patient is not in good control of their motor functions, they can fall. Most of these patients are older patients whose falls result in either hospital visits, hospital stays or even other complications such as broken bones or head injuries. What we are seeking to do with the Accordion Pill is to manage the drug's delivery as closely within the therapeutic window. If we can do this, we can reduce a number of these other complications associated with the disease. Collectively, this is really important for the overall care of the patient.

When you consider that a typical advanced Parkinson's patient has approximately five hours of OFF time and approximately one to two hours of dyskinesia each day, that means they have six to seven hours when they are not functioning well. Therefore, the goal is reducing the OFF time, reducing the motor complications and reducing the dyskinesia. Earlier studies of our AP-CD/LD have shown that we can achieve this. Over the course of the next year, as we do more work, we believe we will be able to highlight an even greater commercial opportunity. For us, it is important to get people to move away from the concept of "is it an hour, is it an hour and a half of OFF time improvement?" and to look much more broadly at how we are improving the patient experience and adding to patients' productivity while reducing cost and other complications that arise from this disease.

CEOCFO: ***What surprised you? What have you learned as you reached Phase III with the Accordion Pill in Parkinson's disease?***
Mr. Meckler: The thing that surprised me the most is how broadly impactful Parkinson's disease is around the globe. When you read the literature, there are just over one million patients in the U.S. who have Parkinson's disease. With a U.S. population of approximately 350 million people it doesn't seem like that big a number. However, when you start working with Parkinson's patients you realize its impact to society because it is not just the effect on patients; it is the impact on the families and caregivers too. Literally every time we present our technology, we meet someone who is impacted by Parkinson's disease -- whether it is an investor, a patient or someone with a loved one that has the disease. For example, we rang the bell at NASDAQ earlier this year and the executive who oversees those events told us his mother-in-law has Parkinson's disease. So, the widespread impact of the disease was one of the biggest surprises. Another surprise was the lack of new drugs to market for Parkinson's disease. Consequently, there hasn't been a lot of industry-led physician education and outreach in the Parkinson's field. The Michael J. Fox Foundation has done a tremendous job shedding a light on how we look at new therapies and in supporting the development of new therapies to improve the lives of Parkinson's disease patients. However, if you look at what has been generated in terms of new curative therapies and new knowledge about underlying causes of Parkinson's, there has not been as much as there has been in cancer or hepatitis, areas where we have developed cures within the last twenty years.

CEOCFO: ***As you are looking at additional types of drugs do you anticipate more partnerships similar to Novartis or will you be working on some of this on your own?***
Mr. Meckler: Our business model is to have partnerships such as the Novartis agreement with other large pharma companies that have both proprietary and novel compounds that would benefit from our delivery platform. In addition, we will continue to develop our own pipeline. Our internally developed programs will focus on known drugs that could benefit from gastric retention. For example, CBD, THC and Levodopa have been around for years. They are well characterized and well understood compounds. It is the gastric retention and enhanced delivery of the drug that creates the therapeutic benefit. I worked at Pfizer in the 1990s and I like to use the example of Pfizer's Procardia XL product launch. Procardia XL was a hypertension drug and the XL stood for its sustained release delivery system. Once we started delivering that drug in a much steadier state, it totally changed the therapeutic benefit. That

was Pfizer's first billion-dollar drug! I think it is a good example of what our business could be -- enhancing compounds where we know the molecules, and by delivering them slowly in the stomach over time we significantly improve the therapeutic benefit. Those are the areas that we want to advance.

CEOCFO: ***You joined Intec just about a year ago. What drew you to Intec and how has the company changed under your leadership? How will it continue to grow?***
Mr. Meckler: The excitement and what drew me to Intec is two-fold. One was the fact that Intec has an interesting new technology that is truly innovative and has the potential to improve the baseline therapy for advanced Parkinson's disease patients. The second draw was that Intec is at a point of transition as it nears the completion of a pivotal Phase 3 development program. To have the opportunity in one's career to clinically develop and get a drug approved is rare, so this was appealing for me. At Intec, we are working on a Phase 3 development program. For me, the big rush or excitement is that we are going to be able to bring a new therapy to market that will have a huge benefit for Parkinson's disease patients and I will be able to look back and say, "I got to help in bringing this drug to market." It is funny because we recently had our Rosh Hashanah employee luncheon in Jerusalem and we were discussing how you look back over the last year and you look forward into the New Year, and by next Rosh Hashanah we will have our data and will hopefully be well on our way to getting this drug to Parkinson's disease patients.

The last year has seen tremendous change for Intec and we have made great strides toward achieving both our clinical and corporate objectives. We raised approximately $100 million dollars, have built out both our clinical and commercial-scale manufacturing capabilities and are nearing completion of enrollment of our key Phase 3 clinical development program in Parkinson's disease. Earlier this year, we also signed a deal with Novartis to develop an Accordion Pill with one of their proprietary compounds. Clearly, we've made a lot of progress over the past year or so.

I am confident the next year will be another important transitional year for Intec as we complete our Phase 3 trial of AP-CD/LD in Parkinson's disease and report the topline data from that pivotal trial in the middle of 2019. I believe this will reset the company's positioning because we will no longer be a company with a technology and an idea. We will have the data to validate that AP-CD/LD can improve the lives of advanced Parkinson's disease patients. The Parkinson's disease program really is the best proof-of-concept for the Accordion Pill platform going forward. Once we get the data next year there will be many more opportunities to expand the platform through potential partnerships, such as with Novartis, and through our own development efforts. Next year we will advance multiple new clinical programs. Through our cannabis development program, we plan to advance CBD, THC and the combination into Phase 1 pharmacokinetic clinical studies. In addition, we hope to extend our partnership with Novartis to the next stage of development and to secure additional partnerships with other large biopharma companies.

These are very exciting times at Intec. Over the coming year, we will advance our build-out to the next phase and take Intec from a small

Israeli development company to a much larger, multi-faceted drug delivery and therapeutic company.