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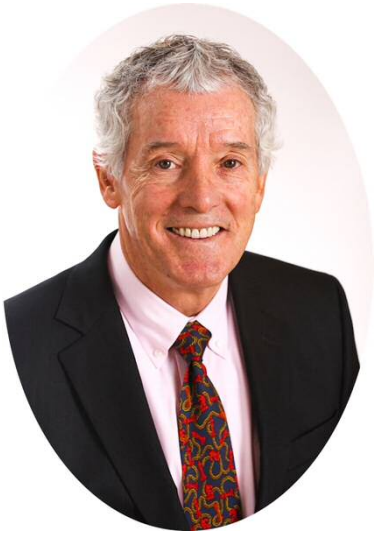
Platinum-Based Chemotherapies



Robert E. Fallon
CEO

CEOCFO: ***Mr. Fallon, what attracted you to Phosplatin?***
Mr. Fallon: It was really an association that I had with Ohio University, which held the rights to the drug. I was a trustee of the Ohio University Foundation and became familiar with the inventor, who was at the time the vice president in charge of research at Ohio University. I followed his research for quite some time and became interested in trying to help the compound see some commercial opportunity. I did some investigation through friends in the biotech and Venture Capital communities, and some oncologists on understanding the chemotherapeutic environment and opportunities in new drug development in terms of the platinum class of drugs. I became quite interested intellectually in this exercise because I kept trying to prove the negative, but I was not able to. I was working with another colleague at the time, Matthew Price, who became a founding partner with me, and we did a lot of early stage work in terms of assessing the strength of the IP patent suite, and even looking into the chemistry manufacturing and controls. It all hung together well, so we set up the company, licensed in the rights from Ohio University late in 2010 and essentially have been on our way to clinical trials ever since then, which trials we have recently begun.

CEOCFO: ***What is the new concept?***
Mr. Fallon: It is a platinum chemotherapy, and in oncology and chemotherapy, the platinums are the largest class of chemotherapy drugs. The platinum class has three drugs that are still in use today: cisplatin, carboplatin and oxaliplatin. They are used for different indications and different purposes, but they are all very well known within oncology therapeutic circles and very well respected for their activity and efficacy. But these drugs have problems with certain toxicities and forms of drug resistance. Our drug is a platinum, but it is a novel platinum because it is very different from the earlier generations. It has different electrochemistry and a very different profile in terms of pharmacokinetics and stability in plasma. Primarily, it has a much more impressive safety profile. It does not engender the neurotoxicity or the nephrotoxicity that tends to plague the earlier generations. Its novel mechanism of action also tends to guide it away from the forms of drug resistance that are common within the class. These properties together make for a compelling new therapy.

CEOCFO: ***What is happening in the body that is not giving that toxic effect?***
Mr. Fallon: It is hard to explain without getting into too many details, but as an example, if you can think of when you drink something that is too cold -- sometimes my kids call it a brain freeze -- and you get that pain in the base of your brain. That is a form of cold allodynia, and that is perhaps the best way to give you an example of an acute form of neurotoxicity that would be engendered by oxaliplatin, which is the most recent platinum chemotherapy. We did a lot of work at the Brain Science Institute at Johns Hopkins to prove with *in vivo* animal studies that we do not engender this form of acute neurotoxicity that is basically a real dose-limiting characteristic of oxaliplatin. The results were quite compelling. Our chemistry advantage seems to prevent these symptoms from readily forming. The same goes for the different form of chronic neurotoxicity seen often in oxaliplatin patients. Our electrochemistry substantially reduces the conditions that lead to this problem.

CEOCFO: ***How is your drug different from others?***
Mr. Fallon: It has to do with the integrity of the drug when it is in the body and in plasma. The earlier generations tend to basically de-ligate or break down very easily. They are compounds and molecules that will break down in plasma and in many cases bind rapidly with blood proteins. They can lose their efficacy and cause toxicities as our consequence. Ours,

because it has a very different electrochemistry, is much more stable, much less prone to de-ligate. It also does not have the same degree of importation into the nerve cells as the other generations – this makes it safer. There are also some fascinating new findings on the mechanism of action that make it quite different from its peers. We believe these novel advantages will translate into a better therapeutic index. Therapeutic index really means a graph of two axes, with efficacy on the X axis and safety on the Y axis. Where you want to be is in the quadrant that has high safety and high efficacy. If you can dose more of a drug, such as ours, that is working more efficiently on several different cancer signaling pathways, you have a better chance of efficacious results.

CEOCFO: ***You have announced that your first patients have been successfully dosed. Where are you today in your phase one trial?***
Mr. Fallon: We are early in our phase one trials. We are in the dose escalation period, which means we are administering doses that we think are safe and tolerable, but we will escalate the dose only slowly over time as we observe the reaction of patients being treated. That does not mean the patients who receive the earlier lower doses are eliminated from the trial, they may continue on and they will be able to increase the dosage as well. This is measured very carefully under the protocols set forth by the FDA. Once we complete the initial dose escalation portion of our phase one, we will have what would be determined as a therapeutic dose. We will then confirm that dose regimen in the second portion of our phase one, the expansion cohorts, where we will be able to give patients a therapeutic dose from the beginning.

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CEOCFO: ***Are there particular types of cancer patients or cancers you are aiming at?***
Mr. Fallon: The dose escalation portion of the phase one is open to all solid tumor patients who qualify, so it is up to the principal investigators at the cancer centers to determine which patients are invited in to the trials. Basically, they are likely to be candidates who may respond to chemotherapy, but who have not had success with prior regimens with solid tissue tumors. So you are talking about lung cancer, pancreatic cancer, colorectal cancer, ovarian cancer, or even prostate cancers. These are all cancers that respond to the platinum chemotherapies and may respond to our compound.

CEOCFO: ***Is the medical community aware of Phosplatin?***
Mr. Fallon: For the broadly defined medical community I would say no because we are a private company and have just put out our press release about beginning our clinical trials. However, within the circle of conversations that we have had with key opinion leaders at the major centers like MD Anderson in Houston and NYU Langone in New York, as well as other sites where we are doing our clinical trials, we have had considerable discussions. Our Scientific Advisory Board with several well-known oncologists have greatly added to that dialogue. Within a fraternity of extremely well-informed oncologists, we are on their radar screen, and they are quite interested because they know this class of drugs very well and they are quite excited that there may be a newer, novel platinum chemotherapy coming down the pike.

CEOCFO: ***What are the next steps for you?***
Mr. Fallon: We are in our phase one now. We will complete the first part of that in late spring, and then we will move into our expansion phase, which is larger. That will likely continue for another year, and by the end of that we will have some pretty good data as to where we stand in terms of specific cancer types. The step after that is to then go to the FDA and say we want to do a phase two pivotal trial; a proof of concept trial where we definitively establish our advantage both in terms of therapeutic index of safety and efficacy. We could be there basically from where we are here 18 months to 24 months from now. We could go down the road and try to muscle our way through phase three clinical trials on our own, or we could partner with a large pharma company who would be quite willing to adopt you into their stable of compounds. Partnering with a large pharma company would bring regulatory and marketing muscle that would really benefit us in terms of deploying the drug ultimately into a broader population of cancer therapy.

CEOCFO: ***Put it together for our readers. Why Phosplatin?***
Mr. Fallon: We believe our drug is the best-in-class molecule in what remains the largest class of cancer drugs, and that it can be used in a wide range of settings where patient need still exists, and done so in combination with a wide variety of other drugs because of its tolerability. This speaks to a significant medical and commercial opportunity. We have been

fortunate to survive thus far entirely on private capital, even though we were encouraged over the last year to consider going public by two investment banks. We decided not to because of the simple reason that we do not have any revenue yet, and the longer we can basically develop our proof of concept, the better opportunity we do have, if we do go public, to realize a more attractive evaluation. That still means we have to raise money, and the money we have raised so far has largely come from high net worth investors and family offices. We have been particularly encouraged by the family offices, which seem to be for us quite interesting and very supportive investors. They also tend to lead to other like-minded family offices. It is kind of a universe that does not get a lot of exposure and coverage, but it does exist. What we've found is for those family offices that are investing in life sciences, a novel compound that is a chemotherapy is something that they can understand. They can get their hands around it, they know what chemotherapy is, they know what cancer is, and when we begin to explain the novelty of our compound, it resonates.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

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Phosplatin Therapeutics LLC

For more information visit:
www.phosplatin.com

Contact:
Naveen Bazaj
646-380-2441
nbazaj@phosplatin.com