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Selective Estrogen Receptor Modulator Lasofoxifene: Providing Menopausal Women the Opportunity to Prevent Breast Cancer and Prevent Osteoporotic Fractures

Dr. David Portman
CEO &
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– Dr. David Portman

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CEOCFO: ***Dr. Portman, what was the vision when you started Sermonix Pharmaceuticals in late 2014?***
Dr. Portman: I have been in clinical medicine, both practice and research, for the last two decades. I was involved in the lasofoxifene phase 2 and 3 development program as principal investigator and involved in study design. I always thought that it was an excellent treatment option for women in menopause, which is my research area of interest. It went through a long development program; a very robust program. It was ultimately approved in Europe in 2009, but not approved in the US. At that time Pfizer was in the midst of a 60 billion dollar Wyeth acquisition and left the asset to return to Ligand Pharmaceuticals, Inc. (LGND), who initially developed lasofoxifene. I have been involved in women's health drug development and approval process for other sponsors for many years, and felt that this was something I wanted to take on. I envisioned lasofoxifene as very effective drug that could be approved and made available to women for a number of very common conditions. Therefore, it was really having worked with the drug early on in its development, seeing it unable to get over the finish line and a desire to make the treatment made available to women that led me to found Sermonix Pharmaceuticals.

CEOCFO: ***Would you tell us about the drug?***
Dr. Portman: I have lived through several stages of menopausal care for women; both the hormone stage where estrogen-based hormones were

felt to be wonderful preventative strategies for women to treat many common symptoms and help reduce certain chronic conditions. Then in 2002, with the women's health initiative, there was a watershed moment where hormones, which do have their utility in managing women transitioning though menopause and still occupy a large market, fell significantly out of favor, with prescriptions for estrogens dropping by close to 80%. At that time there was only one alternative to estrogen for addressing osteoporosis and reduce the risk of breast cancer. That was Evista from Lilly. However, Evista did not really relieve any symptomatic conditions of menopause and only prevented vertebral, or spine fractures, not other types of osteoporotic fractures. Lasofoxifene reduces vertebral and non-vertebral fractures as well as breast cancer. Recently, a drug in the class, Osphena, was approved by the same division that will review lasofoxifene. It treats painful sex in menopause; a symptom of vulva vaginal atrophy. The data from lasofoxifene also supports VVA treatment and seems to show that it may offer additional benefits compared to these two types of drugs; namely Evista, which has benefits for the bone and breast, and Osphena, which has benefits only at the vaginal level. Therefore, it really is a unique medication that treats and addresses three very common conditions and concerns of menopausal women where there has not been one therapy that ever did that. Some doctors could stitch together, let us say, a vaginal estrogen for the sexual symptoms and then put them on a bone sparing drug such as Fosamax. However, I do think that prescribers and patients would not prefer to take two drugs when one could suffice. I really felt that there was an opportunity to get a product in the marketplace where there was this unmet need.

CEOCFO: ***There was previous work done in this area with this drug. Where were you able to jump into the process? Where was your starting point?***
Dr. Portman: The starting process, as I had mentioned, was being very familiar with the clinical development program in the Phase II to III stages. Then the asset was returned to Ligand and was picked up for a few years by a Chinese company who were not really well versed in the women's health space. Then when I realized that it was available for out-licensing from Ligand I arranged for a meeting with their scientists and the business development team to address how I felt Sermonix could get lasofoxifene over the finish line and help commercialize it.

CEOCFO: ***Where are you in the process today?***
Dr. Portman: We have engaged with the FDA. We have had meetings. We are represented in Europe by our regulatory experts helping us to navigate the path to resubmission in Europe. Therefore, we have a dual strategy of both resubmitting where the drug was previously approved and that is in the European Union, with the opportunity to get approved there and shortly after that submit to the FDA with our data, with our new drug application and address all of the concerns that led to the non-approval earlier in its development cycle. We put together a management team and a scientific advisory board who are without peer in this space. My VP of Clinical Development is James Symons, PhD, who was a global project lead for Pfizer on the drug development for lasofoxifene. Therefore, he is very familiar with the entire clinical dataset. Our VP of Business Development is Elizabeth Attias, who has been working as well in the women's health space for the last two decades. The three of us have known each other for that period of time and worked together on other projects and came to a conclusion that this

really was one of the best opportunities for a later stage asset that had a lot to offer the space and the unmet need.

CEOCFO: ***How does the drug work?***
Dr. Portman: As I mentioned, the concern about hormones in 2002 really created a need for women to look for medication that had the benefits of estrogen without the downside; the downside being an increase in breast cancer, coronary heart disease events and stroke. What we have discovered with the estrogen receptor is that it can be both activated and deactivated. A drug that is very antagonistic to the breast, such as tamoxifen, is similar in that regard to lasofoxifene; both have anti-estrogenic, protective affects on the breast. That is why they reduce the incidence of breast cancer among women. Likewise, estrogen is good for bone and activates the estrogen receptor at the bone level and that is what lasofoxifene does well or better compared to data from other Selective Estrogen Receptor Modulators (SERMsa). Like ospemifine, it also activates the receptors in the genital tissues, which are highly dependent on estrogen and a very common cause of women to seek treatments in the menopause for symptoms related to changes in the vaginal tissue, such as dryness or pain. Therefore, whether or not it activates the estrogen receptor or blocks it is really the key to how these drugs work. They activate some estrogen sensitive tissues and block others. That is really what women are looking for; the best of both worlds, to try to get some of the benefits that they thought perhaps hormone therapy offered, but then recently they have grown very skeptical about, and yet also get some of the benefits that we do know these tissues are dependent upon as women go through menopause.

CEOCFO: ***What will be your commercialization plan. How far through would you like to go?***
Dr. Portman: We are a small company, so the possibility of commercialization would likely benefit from a partnership with a larger company with a sales force and distribution that would allow us to use our clinical expertise and regulatory expertise in concert with those whose core competencies are in area we would have to develop. However, it is not beyond the realm of possibility that as a small specialty pharma company we could look to a contract sales forces as well as all the other channels of distribution in order to become fully operational and commercialize lasofoxifene at approval and launch. That would require further capital and perhaps even an IPO. Right now we are currently privately funded, but may engage in partnering arrangements sometime in the near future, as we have had very fruitful discussions with several large potential healthcare partners. Alternatively, we would proceed with a Series A in order to continue to fund the work of our clinical development program.

CEOCFO: ***I would imagine that it is an area that is easy to see the need and the potential market. What are you finding, as certain conditions fall in and out of interest in the investment community? Where is this area today?***
Dr. Portman: I think that there is great interest in the women's health therapeutic area, especially drugs that are somewhat novel in their mechanism of action and where there are benefits to both the patients, the provider and the payers. Therefore, a drug that may reduce the risk of certain chronic conditions and symptoms as well as decrease the number of medications that a woman might be on could be very attractive from a payer standpoint. Accountable care organizations and

formulary directors are looking for value and outcomes data, and that helps position us very nicely. That is because we have preventative benefits in reducing breast cancer and in reducing vertebral and non-vertebral fractures, both of which are quite morbid and costly to the healthcare system. Additionally treating a common symptom of menopause—dryness and painful sex—helps keep a patient feeling healthy and encourages compliance. Regarding breast cancer, there are certainly the immune-oncology and cancer therapeutic area that are very hot right now. Those are very high-cost drugs, but they also tend to treat patients much later in the disease process. I have been a firm believer in prevention. Unfortunately, because of the size of prevention trials and the duration, many new prevention trials are no longer really undertaken. Therefore, we were quite fortunate that the lasofoxifene program, which was a billion dollar development program under Pfizer—was a prevention programs started when they were still in vogue and we have that wealth of data to support our submission and our indications. The investment community has heard our story and the market size as well as the market opportunity and it has been very well received. I think that it is a therapeutic area that will remain of interest. Being a trained ObGyn, I never think taking care of women's health falls out of favor. I cannot see how having a medication that meets many of their health needs with a wealth of supportive data would not be attractive to the investment community and the healthcare community. Evista ultimately did over one billion dollars in peak annual sales as a drug. Therefore, we really feel that our SERM that has demonstrated an even more robust profile ultimately has blockbuster potential. Our primary qualitative and quantitative researcher of high-prescribing ObGyns and primary care doctors supports the product profile and identifies highly-motivated prescribers and patients for this type of therapy.

CEOCFO: ***Is there competition? Are you aware of newer treatments and different research that might have effect on the potential of the product?***

Dr. Portman: There is a competitive landscape that we are very much aware of and attune to. I think it also demonstrates that these therapeutic categories are of great interest to companies on the investigational side as well as partners on the commercialization side. There are several drugs in development for a more severe osteoporosis. We think that we fit in with women who are potentially in the fifty-five to seventy or seventy five year range with less severe disease and, although we have studied the drug in women up to eighty, the more potent new agents do compete for the exact same patient type. We will preserve bone and prevent fractures. Some of the newer drugs, often injectable, are looking to increase bone mass considerably and will be a helpful addition to the therapeutic armamentarium, but are likely to focus on more severe, older patients. The price point will be higher and there are fewer candidates for those drugs. Therefore, while they do compete with lasofoxifene, we feel that our patient population is somewhat unique and looking for a different set of benefits. Merck has an oral osteoporosis agent in late development we are watching with interest. There are some drugs in development for vaginal symptoms that we are keeping an eye on as well. These are all limited due to being administered vaginally. One of the market findings that we have seen and I think may gain more traction for Osphena over time is, that while women may experience symptoms in the genital area, they do not necessarily want that to be the route of administration for their medication. A vaginal inserts or creams are often found to be unacceptable to many, usually contain hormones which

women fear and are inconvenient and messy. Therefore, even though there are drugs in development for particular menopausal vaginal symptoms, we feel that we offer a unique value proposition to the patient and the clinician by being administered orally once daily. Again, a non-injectable, oral, once daily tablet is a very attractive option for patients because of its convenience of dosing and simplicity.

CEOCFO: ***What might people miss when they look at Sermonix Pharmaceuticals that they should understand about the company and about the drug?***
Dr. Portman: I think that our mission is fairly obvious. We are a group, especially our core management team, that have been involved for decades in the development, the marketing and commercialization of therapies that have had a great impact on women's health and their quality of life. While we are very committed to regulatory and commercial success, we are committed to the science and to the patient. As a clinician, someone who is a third generation physician and that has been taking care of female patients for the last two decades; this is really a contribution that I and my entire team see as being incredibly valuable to the medical community. We think it advances women's health in a significant way. We are very excited and thrilled to be a part of it!

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

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