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"Pausitive" Therapy for Hot Flashes and other Menopausal Symptoms

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"We like to say that we are working to provide 'pausitive' therapy for the tens of millions of women afflicted with severe hot flashes who are concerned about the health risks associated with hormone therapy and do not like the idea of taking anti-depressants or pain medications." - Debra M. Duke

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CEOCFO: ***Ms. Duke, what is MenoGeniX Inc?***
Ms. Duke: MenoGeniX is a clinical-stage biotech company developing MNGX-100, a version of a naturally occurring human blood protein, as a novel alternative to hormones and anti-depressants to treat hot flashes and related vasomotor symptoms of menopause. We like to say that we are working to provide "pausitive" therapy for the tens of millions of women afflicted with severe hot flashes who are concerned about the health risks associated with hormone therapy and do not like the idea of taking anti-depressants or pain medications.

CEOCFO: ***How does it work?***
Ms. Duke: MNGX-100 contains a naturally occurring human protein called G-CSF, also known as granulocyte colony-stimulating factor. G-CSF is produced at low levels to maintain normal levels of neutrophils, a subset of white blood cells. Higher levels of G-CSF are produced in response to infections to increase the number of bacteria-fighting neutrophils. However, G-CSF has many other activities in the body and has been shown to act as a neuroprotective and anti-inflammatory agent. We believe that G-CSF is acting on the hypothalamus, the body's thermostat, to counteract the effect of pro-inflammatory cytokines that are often elevated in individuals experiencing menopausal symptoms. MenoGeniX's clinical trial results show that MNGX-100 is well tolerated and can lead to a durable reduction in hot flash frequency and severity in women with natural and surgical menopause.

CEOCFO: ***When someone takes the drug, what would they experience?***
Ms. Duke: Funny you should ask this question. The genesis of discovering the effects of this drug on hot flashes was completely accidental. I actually made the discovery after being given the drug for the original purpose, which is neutropenia, and realizing that the frequency and severity of my hot flashes had dissipated. After making the observation, filing the patent, starting the company and raising the financing for a clinical trial, the goal was to see if this drug would have the same effect on reducing the frequency and severity of hot flashes in other women undergoing menopause. G-CSF is also currently being tested to treat other diseases that are unrelated to neutropenia including, stroke, dementia, and miscarriage.

CEOCFO: ***How did you proceed once you realized what was happening in your own body?***
Ms. Duke: I did what most people in my situation would have done. I commented to my husband Richard Duke, PhD, that my hot flashes had gone away and I think it may have something to do with the medication I had just been given. Unlike most husbands though, mine happens to be an Immunologist, drug developer and serial biotech entrepreneur and I happen to have a business background with a strong focus on fundraising with a lot of contacts in the medical and finance industries. So in this case, we were able to design a business and clinical development pathway to confirm and expand this observation and hopefully commercialize the drug to make it available as a therapy to treat hot flashes and other vasomotor symptoms. The really great thing about MNGX-100 is that its only competition is from two drugs that have "boxed-warnings" and which are contraindicated for women who've had cancer. G-CSF doesn't have "boxed-warnings" and can be used by cancer survivors. To more directly answer your question, I turned a personal medical observation into a business venture. The first contact was with Gladys Monroy, a Partner at Morrison Foerster, considered one of the top life science patent attorneys in the industry. We filed the patent, incorporated the company, wrote a business plan, raised equity financing and executed the confirmatory clinical trial.

CEOCFO: ***Are there any potential side effects that were a consideration for you; the known side effects from the drug as you were using it?***
Ms. Duke: Other versions of G-CSF including Neupogen®, Neulasta®, Granix®, Neutroval®, and Zarzio®, have been safely used since 1991 in more than 9 million patients to treat chemotherapy-induced and chronic neutropenia (low white blood cell counts). Our goal is to use MNGX-100 to treat hot flashes and other symptoms of menopause. Potential patients include the 70 million women in the seven major markets whose hot flashes are so severe that they seek therapy (~50% of all women >50 years of age) in addition to surgically induced menopausal women who cannot take hormone therapy. In the setting of neutropenia, the most widely reported side effects of G-CSF are mild bone pain and headaches, both of which are transient. More severe side effects have been reported infrequently in individuals that are taking high doses of G-CSF daily for several months to years. We believe that MNGX-100 will not be used more frequently than once a month, let's say, and our clinical advisors, including William "Bill" Robinson, M.D., the oncologist that co-discovered G-CSF, feel the risk of the rare side effects that occur when the drug is used daily are unlikely to occur. Ultimately, the side-

effects or the “safety-profile” of MNGX-100 in the setting of menopause will be established in clinical trials and post-marketing studies. In contrast, the existing approved drugs, hormone therapies containing estrogen and the anti-depressants have severe "boxed warnings" regarding potentially life threatening side effects. For women that reject hormone therapy, physicians have had no choice but to prescribe anti-depressants and pain medications to women. If MNGX-100 is approved, it should represent an attractive alternative for these women.

CEOCFO: ***Where are you now in the development process?***
Ms. Duke: With the equity financing raised in 2012, we’ve maintained and expanded our patent portfolio and have carried out a confirmatory Phase 1b clinical trial which was completed in early 2014. The trial was conducted under strict standards and was multi-site, randomized, placebo controlled, double-blinded and stratified for surgically induced and naturally occurring menopausal women. We obtained positive results and our next step is to design and carry out a Phase 2/3 clinical trial which we’re currently working to partner and/or finance on our own.

CEOCFO: ***Different drugs and different conditions seem to go in and out of favor with the investment community. What is the overall interest in hot flashes in menopausal women?***
Ms. Duke: Large markets are always of interest and don’t go out of favor. There are 70 million women who have symptoms so severe that they seek therapy. The only two approved therapies to treat hot flashes are hormone therapy and anti-depressants and they both have “boxed-warnings”. Prior to the Women’s Health Initiative in 2002 which reported the side effects of hormone therapy, it was the most prescribed drug ever. To this day it is still a multi-billion dollar product. Women who don’t want to take hormone therapy are being prescribed anti-depressants. This is a market that is desperately looking for an alternative to the status quo. Interest is strong because of the market size, the need and although menopause is not a disease, it is clearly a quality-of-life issue which affects many people. Some women can have more than 50 hot flashes per day and surgically induced menopausal women can have more.

CEOCFO: ***Are they skeptical that there really can be something that works, given that so many things have been tried and are only minimally effective if at all?***
Ms. Duke: When you’re trying to cure a medical problem, focusing on skeptics is not a healthy thing to do, so if there are any out there, I don’t pay too much attention to them. Our timing seems to be good, as for the most part people are pretty excited about the prospect of MNGX-100. It’s hard not to be optimistic given the dismal options available of approved drugs on the market. For instance, Nanette Santoro, MD, Head of the Department of OBGYN at the University of Colorado Anchutz Medical Campus and Head of the MenoGeniX Scientific Advisory Board thinks that MNGX-100 could be the most promising therapy in the pipeline.

CEOCFO: ***Are you ready now for the next clinical trial?***
Ms. Duke: Yes, we are quite ready to do the next clinical trial. Since the completion of the Phase 1b clinical trial in 2014, the process of designing and funding the next trial has been initiated. The goal is to get started in 2015.

CEOCFO: ***Would you prefer investment money? Would you prefer a partnership? Does it make a difference for you how you go about the next steps?***
Ms. Duke: The goal is to get MNGX-100 approved and available to the 70 million women who suffer from symptoms so severe they seek therapy. There are many options for funding available such as the ones you've mentioned as well government grants. MenoGeniX is pursuing all of them and speaking to contacts in the U.S., China, Japan, and Europe. We expect to have clarification in 2015 regarding a partnering or financing deal.

CEOCFO: ***Certainly, a lot of women want and need something!***
Ms. Duke: In addition to the 70 million women, who have symptoms so severe they seek therapy, there are many women who cannot take the approved therapies, which are hormone therapy and anti-depressants, for these women there is nothing approved. In addition there are 600,000 hysterectomies in the U.S. annually and hormone therapy is contraindicated for many of these women. Yes, there are a lot of women who need and are looking for something to relieve their symptoms.

CEOCFO: ***Why is MenoGeniX Inc a company to notice?***
Ms. Duke: In less than three years MenoGeniX has accomplished a lot. Patents have been filed and issued. A clinical trial was designed and completed yielding positive results. Now with minimal financial investment and clinical development, the drug approval pathway is shortened because MNGX-100 is based on an approved drug with a well-known safety record having been on the market for over 20 years and being used in more than 9 million patients. Cutting down the time and expense makes this a very unique and attractive opportunity for investors or partners. MNGX-100 is poised to serve a huge unmet medical condition. MNGX-100 represents an alternate choice for women who do not want to or cannot take hormone therapy or anti-depressants. As stated earlier, MenoGeniX is working to provide a "pausitve" therapy for women with hot flashes.

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

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BIO:
Debra Duke is the President and CEO of MenoGeniX which she co-founded in 2010. She has 30 years of business experience in the biotechnology and energy industries. She has been involved in all aspects of the organization starting with filing the worldwide patents, raising equity financing to fund the clinical trial, staffing and contracting the clinical trial and extensive business development activities. Prior to MenoGeniX, she was President of Duke Medical Research Group LLC, a large consulting firm she established to provide third-party independent research to the financial investment industry with clients primarily focused on healthcare. Prior to that, she had a long career in human resources as well managing a commercial REIT. In addition, she has served in several leadership, fundraising and marketing roles of various professional, civil and charitable organizations. She earned her Bachelor's degree in Labour and Industrial Relations from McGill University, Montreal, Quebec.