PL-6983 for Female Sexual Dysfunction

PALATIN
TECHNOLOGIES, INC.

INTRODUCING PL-6983

PL-6983 is the lead compound in a new series of melanocortin receptor-specific peptides developed by Palatin Technologies. PL-6983 has demonstrated efficacy in inducing erections in animal models and in inducing sexual behavior in an animal model of female sexual dysfunction (FSD).

Palatin Technologies is developing PL-6983 primarily for FSD, a major unmet medical need. Depending on results of clinical trials, Palatin Technologies may also seek to develop PL-6983 for erectile dysfunction (ED).

WHY PL-6983?

Palatin Technologies discontinued development of bremelanotide for sexual dysfunction following concerns raised by the U.S. Food and Drug Administration (FDA) about the acceptable benefit/risk ratio as a first-line therapy for erectile dysfunction related primarily to increases in blood pressure observed in some patients. Palatin Technologies applied its expertise in the melanocortin field to develop a new series of novel and proprietary peptides specifically designed to treat sexual dysfunction but with limited effects on systemic blood pressure.

Palatin Technologies has filed patent applications on its new series of peptides. Based on priority dates for the patent applications, patents granted on these applications will have a patent term through 2029, and may be eligible for patent term extensions. Palatin Technologies intends to seek patent protection both in the United States and internationally.

PRECLINICAL DEVELOPMENT

Palatin Technologies has developed a novel screening platform that examined the effectiveness of peptides both in animal models of sexual response and sexual dysfunction and the cardiovascular effects of the peptides, primarily looking at changes in blood pressure. Based on these studies, Palatin Technologies selected PL-6983 for further development. While PL-6983 has some effect on blood pressure in animal models, the minimum effective dose required to induce an erection in male animals is approximately one-tenth the minimum effective dose required to increase blood pressure. In the same models, bremelanotide induced blood pressure increases at a lower dose than that required to induce erections.

Palatin Technologies is planning preclinical toxicology and other studies required by the FDA prior to initiating human clinical trials.

CLINICAL TRIALS

Initial human clinical trials will be designed to measure safety parameters, including changes in blood pressure following administration. It is anticipated that these initial studies will be conducted in men, but assuming favorable efficacy results without significant increases in blood pressure, future studies will be conducted in women with FSD.

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MARKET POTENTIAL

Female sexual dysfunction is a multifactorial condition that has anatomical, physiological, medical, psychological and social components. There are no FDA approved pharmaceutical products for FSD. Studies estimate FSD is prevalent in approximately 50% of women over the age of 30, and that more than 35 million women in the United States may be afflicted with some form of FSD. FSD includes disorders associated with desire, arousal, orgasm and pain.

More About FSD

Female sexual disorder is defined by the American Foundation for Urologic Disease as: "The persistent or recurrent inability to attain or maintain sufficient sexual excitement, causing personal distress. It may be expressed as a lack of subjective excitement or a lack of genital or other somatic responses." FSD consists of four components, hypoactive sexual desire disorder, female sexual arousal disorder (FSAD), dyspareunia or painful intercourse and anorgasmia. To establish a diagnosis of FSD, these components must be associated with personal distress, as determined by the affected woman.

Erectile dysfunction is defined as the consistent inability of a male to attain and maintain an erection sufficient for sexual intercourse. The condition is correlated with increasing age, cardiovascular disease, hypertension, diabetes, hyperlipidemia, and smoking. In addition, certain prescription drugs and psychogenic issues may contribute to ED. It is estimated that some degree of ED affects 50% of all men over the age of 40 and that 150 million men worldwide suffer from ED.

OPPORTUNITIES AND COMPETITION

There is tremendous competition and incentive to develop, market and sell drugs for the treatment of FSD. A number of hormonal therapies, including progestin, androgen and localized estrogen therapies, have been commercialized; however, these are effective in a comparatively small percentage of cases, and have not gained widespread market acceptance. Despite the fact that a number of drugs are in various stages of research or development for FSD, none utilize melanocortin pathways as their mechanism of action. Clinical trials using bremelanotide conducted by Palatin Technologies validates the potential utility of MC4-R agonists for treatment of FSD.

Although the current ED market is primarily served by PDE-5 inhibitors which target the vascular system, such as Viagra® (sildenafil), Levitra® (vardenafil) and Cialis® (tadalafil), there is a substantial unmet medical need for alternative sexual dysfunction therapies. Many patients are contraindicated for, or non-responsive to, PDE-5 inhibitors. In addition, current literature indicates that about one half of all patients who receive an initial prescription for a PDE-5 inhibitor do not renew the prescription due chiefly to adverse side effects, drug interaction issues, and/or the lack of an acceptable level of responsiveness.

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