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Hygeia Therapeutics Announces Successful Completion of Preclinical Studies for Lead Product HYG-102

HOLDEN, Mass.--Hygeia Therapeutics, Inc. announced today the successful completion of a series of preclinical studies for HYG-102, their lead product for the treatment of vulvar and vaginal atrophy (VVA) and age-related skin fragility. HYG-102 is the lead biodegradable estrogenic candidate in a portfolio of 23 similar compounds licensed from the laboratory of Dr. Richard Hochberg of Yale University. "These compounds were designed to be degraded rapidly by enzymes at or near the site of application after the therapeutic effect is achieved so that there are no systemic effects on other organs and that's exactly what they do in our new studies," stated Dr. Yael Schwartz, CEO. Currently marketed FDA-approved treatments for VVA carry strong Black Box warnings of increased risk of breast and endometrial cancers as well as stroke. Because of the risk profile for currently marketed topical estrogens, the FDA mandates that estrogens be used for the shortest time possible and at the lowest effective dose.

The safety and efficacy of HYG-102 in a rat model of menopause showed significant proliferation of vaginal wall epithelium with intravaginal doses as low as 0.3 µg/kg with no untoward effects on the uterus, the most estrogen sensitive target organ, at doses as high as 100 µg/kg, resulting in a therapeutic index of greater than 300. In human hepatocytes, HYG-102 quickly formed (7-minute half-life) the inactive metabolite as expected and no other metabolites. "This is in stark contrast to the many estradiol metabolites that are active or can be re-converted to estradiol in the body and which can lead to prolonged unwanted systemic effects," stated Dr. Craig Abolin, CSO.

"The rapid breakdown of HYG-102 is a classic one-two punch," Dr. Schwartz emphasized. "The first punch is delivered by esterases near the site of application and the KO punch is delivered by liver esterases if any HYG-102 gets into the bloodstream."

In preclinical studies to date, HYG-102, has demonstrated a significantly higher safety potential relative to currently marketed estrogens. Dr. Craig Abolin, CSO, stated, "The wide safety margin indicates that the dosing of HYG-102 could be pushed for maximal efficacy without compromising safety."

HYG-102 also demonstrated significant proliferation of human keratinocytes, cells that comprise 90% of skin.

"We are very excited by these data, which demonstrate significant local proliferation of skin epithelium and vaginal mucosa. Coupled with a very wide margin of safety this bodes well for clinical success in the treatment of VVA and entry into the skin market." said Dr. Schwartz.

Dr. Schwartz presented these data at the 2010 Healthcare and Venture Summit in NYC where she won *Best Presenter* and *Top Innovator*.

About HYG-102

HYG-102, the lead estrogenic candidate, is under development for the topical treatment of vulvar and vaginal atrophy (VVA) and age-related skin fragility. HYG-102 is the first estrogenic drug candidate engineered to be rapidly deactivated to a non-estrogenic metabolite by hydrolytic esterase enzymes and represents a new generation of topically effective estrogens with minimal systemic liability. HYG-102 is expected to enter clinical trials in 18 to 24 months.

About Hygeia Therapeutics, Inc.

Hygeia Therapeutics, Inc. is a privately held Delaware C-corporation incorporated in 2007 and located in Central Massachusetts. Hygeia's pipeline of estrogen and anti-androgen drug products were designed to exert their effects locally but deactivate quickly to minimize unwanted systemic and environmental effects. Hygeia's robust drug pipeline of 23 estrogenic compounds and 4 classes of anti-androgenic compounds was obtained through an exclusive license with Yale University. The company is managed by highly experienced veterans of the pharmaceutical industry guided by a world-class advisory board of key opinion leaders in women's health and dermatology.

Forward-Looking Statements

This release contains forward-looking statements that involve risks and uncertainties. Hygeia cautions readers that any forward-looking information is not a guarantee of future performance and actual results could differ materially from those contained in the forward-looking information. Words such as "expect," "estimate," "project," "potential," and similar expressions are intended to identify such forward-looking statements. Such forward looking statements include, but are not limited to, statements about Hygeia and its plans, objectives, expectations and intentions and other statements that are not historical facts. Hygeia product candidates may have unexpected adverse side effects or inadequate therapeutic efficacy; and positive results in clinical trials may not be sufficient to obtain FDA approval. There can be no assurance that any product in the company's product pipeline will be successfully developed or manufactured, that final results of clinical studies will be supportive of regulatory approvals required to market licensed products, or that any of the forward-looking information provided herein will be proven accurate.

Hygeia disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.