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Author: Cytokine PharmaSciences Completes Phase II Study of Controlled Release Misoprostol Vaginal Insert (MVI)

Company:

KING OF PRUSSIA, Pa., June 15 /PRNewswire/ -- Cytokine PharmaSciences, Inc. today announced the completion of a Phase II study of the misoprostol vaginal insert (MVI), a proprietary, controlled-release and retrievable polymer chip containing prostaglandin E(1) (PGE1). Results of the dose-finding study in pregnant women at term gestation confirm the efficacy and safety of this investigational product and suggest that the MVI may reduce time to delivery after induction, support more natural labor, and reduce the rate of cesarean delivery.

The randomized, double-blind, multi-center study tested three doses of the MVI in 374 women undergoing cervical ripening and induction of labor at 11 sites across the U.S. The MVI 200 reduced time to vaginal delivery by more than 9 hours ($p < 0.018$) compared to the lowest dose reservoir, MVI 100 (100 mcg reservoir). Oxytocin use was required in less than half the women tested with the MVI 200, and women exposed to this dose also spent an average of 8 hours less in the labor and delivery suite (both $p < 0.001$ compared to the MVI 100). Safety was primarily assessed by frequency of cesarean section. The rate of cesarean deliveries was 22.9% for the MVI 200 compared to 31.4% for the MVI 100 ($p = 0.153$). The MVI was well-tolerated at all doses with mostly mild and moderate adverse events. The most common adverse event was non-reassuring fetal heart rate; the frequency of this event was similar among the groups. Immediate neonatal outcomes were also similar across the three dose reservoirs tested and showed no safety signals of concern (median Apgar score of 9 at 5 minutes).

"We have now demonstrated that the MVI 200 led to a notable reduction in the rate of cesarean section in this population of induced women," said Barbara Powers, M.S.N., Ph.D., Vice President of Clinical Development at Cytokine PharmaSciences. "This may be the first time that a labor induction product has been shown not only to reduce time to delivery, but may also reverse the recent, disturbing trend of the rising rate of cesarean deliveries. In addition, avoiding oxytocin in more than 50% of induced women allowed the MVI 200 to mimic the spontaneous labor process and more naturally lead into labor by gradually inducing contractions."

A Phase III study in patients requiring cervical ripening and induction of labor is planned for 2H 2010.

About the Misoprostol Vaginal Insert

Text: The misoprostol vaginal insert (MVI) delivers PGE(1) via a unique, patent-protected delivery system. The delivery system, currently employed in a successfully marketed cervical ripening product approved in more than 30 countries (the Cervidil(R)/ Propess(R) vaginal insert), controls the gradual release of misoprostol, a potent cervical ripening and labor induction agent. The retrieval system enhances safety by facilitating rapid and complete removal in the event of onset of labor or adverse reaction. Each woman receives her own unique dose ("self-titrating") and the product can be quickly removed once this dose has been delivered.

About Induction of Labor

Labor induction is required in approximately 23% of the more than 4 million annual births in the United States; this rate has doubled since the 1990s and is continuing to rise. Assisted cervical ripening (the softening, effacement and dilation of the cervix necessary before active labor) is required in about half of these inductions. The obstetrics field was revolutionized by the introduction of prostaglandins, which made it possible to ripen the cervix before beginning induction of labor.

About Cesarean Sections

The rate of cesarean section continues to rise and now represents almost one-third of deliveries in the U.S. Cesarean delivery doubles the cost of childbirth and in some studies has been associated with a higher incidence of adverse outcomes in newborns as well as in subsequent pregnancies. Recovery from this surgery also negatively affects the ability of the mother to care for her newborn.

About Cytokine PharmaSciences

Cytokine PharmaSciences, Inc. is a specialty pharmaceutical company engaged in developing anti-inflammatory and autoimmune therapeutics. The Company is headquartered in King of Prussia (near Philadelphia), Pennsylvania. A wholly owned subsidiary, Controlled Therapeutics (Scotland) Limited (CT), is located in East Kilbride (near Glasgow). CT develops and manufactures controlled-release drug delivery products and has a strong focus in the area of women's health, including manufacturing the successful cervical ripening product, the Cervidil(R) vaginal insert (Propess(R) in Europe and elsewhere). Cytokine PharmaSciences has three products in clinical development and employs 78 people at its locations in the U.S. and Scotland. For more information, please visit the company's websites at and .

SOURCE Cytokine PharmaSciences, Inc.

CONTACT: Dennis F. Willson, President and CEO of Cytokine PharmaSciences, Inc., +1-610-687-1776 ext. 211

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