New Methods for the Treatment and Prevention of Preterm Labor

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Technology description

PRODUCT/SERVICE 'SOLUTION' DESCRIPTION

Pre-term birth (delivery before 37 weeks of gestation) is a serious health problem in the US. and the world, representing a leading cause of infant death and long-term illnesses. Pre-term birth accounts for nearly 11% of all births and 17% of all infant deaths in the U.S., costing >$25 billion annually. Studies have estimated that up to 30−40% of pr-eterm births are caused by maternal inflammation. To prevent pre-term birth triggered by maternal inflammation, Wayne State investigators are developing the product, a protein called PIBF1 using recombinant DNA technology.

PIBF1 suppresses pre-term birth and the associate mortality. It can be administered intravenously or intramuscularly as a preventative agent for women who may suffer from pre-term labor or potentially as a therapeutic agent for pregnant women who are undergoing pre-term labor.

MARKET POTENTIAL AND COMPETITION

4% of the 160 million women in the US are pregnant at any given time. This means that there are about 6.4 million pregnant women in the US at any given time. Among them, 704,000 women will suffer from pre-term birth, and approximately 210,000 to 280,000 pre-term births will be caused by maternal inflammation. Therefore, PIBF1 adminstration can benefit 210,000 to 280,000 pregnant women at any given time, and save the country $7.5−10 billion every year. Of note, pre-term birth is on an alarming rise due to factors such as induced fertility, twin or multiple gestations, poor prenatal care, non-optimal maternal age, obesity and smoking. Therefore, the market potential is expected to increase as time goes on.

Currently, the FDA approved therapy for pre-term birth prevention is intramuscular 17 alpha-hydroxyprogesterone caproate (17OHPC), for pregnant women with a prior history of preterm birth. However, 17-OHPC appears to be ineffective in preventing pre-term birth in multiple gestations. The FDA expressed concern in 2006 about second trimester miscarriage and stillbirth following 17OHPC use and concluded that more studies are needed to evaluate the risk of 17OHPC use. 17OHPC is currently an FDA category D progestin (ie with evidence of fetal harm). In addition, intravaginal progesterone is in trials for pregnant women with a short cervix (<25mm) detected by ultra-sound during second trimester. However, women with a short cervix only account for about 2-3% of all pregnant women, and intravaginal progesterone showed no benefit in several trials in this pregnant

population. Among the trials that found a benefit, the reduction of pre-term labor rate was less than 50%.
WSU research showed that PIBF1 administration reduced inflammation-triggered pre-term birth and neonatal death by 65-70% with no adverse effect on birth weight. The superior efficacy and the different pregnant populations of this product show that there is little market competition.

Institution

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