

FDA Approves Makena[®], the First and Only Treatment to Reduce the Risk of Preterm Birth in Women With a Singleton Pregnancy Who Have a History of Singleton Spontaneous Preterm ...

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ST. LOUIS, Feb. 4, 2011 /PRNewswire/ -- K-V Pharmaceutical Company (NYSE: KVa/KVb) (the "Company"), a specialty pharmaceutical company, announced today that it has been informed by Hologic, Inc. that the U.S. Food and Drug Administration (FDA) granted approval for Makena[™] (hydroxyprogesterone caproate injection). Makena, commonly referred to as "17P," is the first and only FDA-approved treatment indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity. While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

"The communities of healthcare providers and advocacy organizations who are on the front lines of this issue now have access to the benefits of an FDA-approved product," said Greg Divis, Chief Executive Officer, K-V Pharmaceutical Company and President, Ther-Rx Corporation. "The approval of Makena is not only a milestone for the Company; more importantly, it represents a significant step forward for the thousands of women whose families have been impacted by preterm birth."

According to the March of Dimes, preterm birth, or the birth of a baby at less than 37 completed weeks of pregnancy, affects one in eight babies born in the United States. Additionally, the rate of preterm birth has increased more than 35 percent in the last 25 years, and late preterm births - babies born at 34 to 36 weeks of pregnancy - account for nearly three quarters of

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