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FDA approves 1st pregnancy sickness drug in 30 yrs

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Singapore: The US FDA granted approval for Duchesnay's Diclegis (doxylamine succinate 10mg, pyridoxine hydrochloride 10mg) delayed-release tablets for the treatment of nausea and vomiting of pregnancy (NVP) in women, who do not respond to conservative management.

It is the only FDA-approved treatment for NVP, more commonly known as morning sickness, in more than 30 years. Diclegis is expected to be widely available in the US by the end of May 2013.

The drug was granted Pregnancy Category A status, which means that the results of controlled studies have not shown an increased risk to an unborn baby during pregnancy. The two active ingredients in Diclegis that reduce nausea and vomiting in pregnancy, doxylamine succinate and pyridoxine hydrochloride, or vitamin B6, have been recommended as a first-line pharmacotherapy by the American Congress of Obstetricians and Gynecologists (ACOG) guidelines for the last nine years.

Dr Gilbert Godin, CEO, Duchesnay, US, said that, "The FDA approval of Diclegis provides an important new treatment to the millions of women suffering from nausea and vomiting of pregnancy, and fills a 30-year void in the treatment of NVP. Duchesnay US is honored to bring the only FDA-approved treatment to help control symptoms of morning sickness to market. Duchesnay has been dedicated to the health of pregnant women and their unborn children for years and is taking every step to make Diclegis available for women suffering from NVP."

Dr Shannon Clark, associate professor, Division of Maternal and Fetal Medicine, University of Texas Medical Branch, Galveston, said that, "Millions of pregnant women suffering every year from nausea and vomiting of pregnancy now have a safe and effective FDA-approved treatment. Until now, women have been without an FDA-approved prescription option to help treat NVP symptoms, also known as morning sickness. Diclegis provides a safe and effective option for pregnant women. Its active ingredients are the most studied for this purpose."