Isotretinoin Makers Reach Agreement with Celgene on S.T.E.P.S. (R) Risk Management Patents

Covance Inc. Selected to Handle Complex Program Development

and Implementation Effort

NUTLEY, N.J., Nov. 23 /PRNewswire-FirstCall/ -- The four manufacturers of isotretinoin have reached an agreement with Celgene Corporation to license patents directed to certain pharmaceutical delivery and restrictive distribution programs, including S.T.E.P.S. (System for Thalomid Education and Prescribing Safety).

Isotretinoin is sold by Barr Pharmaceuticals (NYSE: BRL) as Claravis, Mylan/Bertek, a wholly owned subsidiary of Mylan Laboratories Inc., (NYSE: MYL) on behalf of Genpharm as Amnesteem, Ranbaxy as Sotret and Roche (OTC: RHHBY) as Accutane. The drug, which is prescribed for the treatment of severe recalcitrant nodular acne that is not responsive to other treatments, is known to cause birth defects. Isotretinoin has a highly restrictive risk management program that is now undergoing an enhancement process to minimize pregnancy exposures to isotretinoin by incorporating a patient registry, among other elements.

An isotretinoin pregnancy prevention program has been in place since 1988, and has included a prescriber registry since 2002.

The four manufacturers of isotretinoin have entered into an agreement whereby they will pay Celgene an up-front payment and continuing royalties in consideration for a license under the Celgene patents.

Most important to note, since the U.S. Food and Drug Administration (FDA) Advisory Committee meeting in February, and while the Celgene patents were being evaluated, the companies continued to move forward with planning and initial development of the new system. Covance Inc., one of the largest and most comprehensive drug development services companies in the world, was selected to design, build, implement and run the program.

The manufacturers of this drug will require adherence to the enhanced pregnancy risk management program developed after extensive discussions between the FDA and the companies pursuant to the Advisory Committee meeting.

It is being implemented as a means to further reduce the number of pregnancies in patients taking isotretinoin. Such pregnancies have continued to occur despite strong verbal and visual warnings on the packaging, in patient education materials, and in a patient agreement, and despite the requirements that female patients use two forms of birth control and undergo monthly pregnancy tests.

Currently, the isotretinoin manufacturers' programs require registration of prescribers as part of their pregnancy risk management system. The enhanced pregnancy risk management program will now include patient and pharmacy registration. In addition, instead of home or in-office pregnancy testing, the new system developed by the manufacturers will require test results from certified laboratories be recorded in the system and the prescriber and pharmacist must verify negative pregnancy results each month before writing the prescription and dispensing the drug. Finally, the enhanced system will require patients to interact with the system on a regular basis about their pregnancy prevention practices.

Isotretinoin, available in the U.S. from Roche since 1982, has been used by more than 13 million patients worldwide for the treatment of severe recalcitrant nodular acne that has not responded to other treatments. Generic formulations, approved by FDA in late 2002 and 2003, are marketed by Barr, Mylan/Bertek for Genpharm, and Ranbaxy.

SOURCE Barr Pharmaceuticals; Mylan Laboratories Inc.; Genpharm Inc.; Ranbaxy