FDA approves Roche skin cancer drug Erivedge

30 January 2012

(AP) -- Federal regulators on Monday approved a pill that treats the most common type of skin cancer, basal cell carcinoma.

The pill is called Erivedge and is made by Genentech, a unit of Swiss drugmaker Roche. Erivedge is intended to treat locally advanced cancer for patients who are not candidates for surgery or radiation, and for patients whose cancer has spread to other parts of the body. The capsule is taken once per day.

Genentech said Erivedge is the first drug approved to treat advanced basal cell carcinoma. It said the drug will be available within one to two weeks.

The drug's label will warn that it is linked to fetal death and severe birth defects when it is used by pregnant women. The most common side effects of Erivedge include muscle spasms, hair loss, weight loss, diarrhea, fatigue, changes or loss in sense of taste, decreased appetite, constipation, and vomiting.

Curis Inc. of Lexington, Mass., which collaborated with Genentech on the drug, is getting a $10 million payment from Genentech now that the drug has been approved.

The approval comes ahead of schedule, as the Food and Drug Administration previously said it would make a decision on Erivedge by March 8. The drug was given a fast six-month review because there are no approved treatments for basal cell carcinoma.