FDA approves biosimilar ogivri for breast, stomach cancers

December 4 2017

(HealthDay)—Ogivri (trastuzumab-dkst) has been approved by the U.S.

Food and Drug Administration as the nation's first biosimilar drug to treat certain breast and stomach cancers, the agency said Friday in a news release.

The maker of a biosimilar must demonstrate that the new product is highly similar to an already approved medication, and that it has no clinically significant difference in terms of its potency, safety, and purity, the FDA said.

Ogivri is approved to treat breast and gastric or gastroesophageal junction adenocarcinoma cancers attributed to human epidermal growth factor receptor 2. The FDA said its maker, Mylan, provided sufficient evidence that the drug is biosimilar to the Genentech drug Herceptin, which was approved by the agency in 1998.

Expected side effects for Ogivri include headache, diarrhea, nausea, chills, fever, infection, congestive heart failure, insomnia, cough, and rash, the FDA said. Like Herceptin, Ogivri's label will include a boxed warning about an increased risk of heart disease, serious allergic-like reactions, lung damage, and harm to a developing fetus, the agency said.

Mylan is based in Canonsburg, Penn.

More information: More Information