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US give nod to Biocon-Mylan's biosimilar of cancer drug Herceptin

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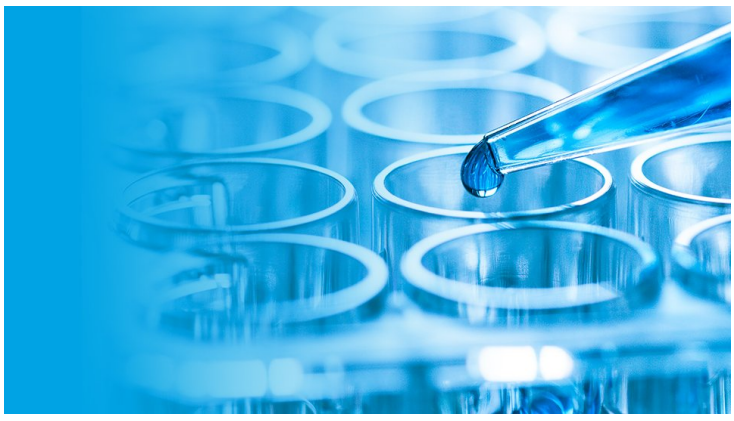
Mylan and Bioconâ??s Ogivri is the first biosimilar of Herceptin to win US approval, for certain breast cancer and metastatic stomach cancers.



The FDA said Mylan's drug Ogivri, which was co-developed with Biocon, was the first biosimilar approved in the United States to treat breast or stomach cancer.

Herceptin and other complex medicines called biologics are made from living cells, making them difficult to copy with precision. Their similar versions are called biosimilars, instead of generics.

Ogivri's permission is based on a review of evidence that included extensive structural and functional characterisation, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data and other clinical safety and effectiveness data that demonstrates its biosimilarity to Herceptin (trastuzumab).

Like Herceptin, the labeling for Ogivri (trastuzumab-dkst) contains a Boxed Warning to alert healthcare professionals and patients on increased risks of heart disease, infusions reactions, lung damage and harm to a developing fetus.

"The approval of Ogivri represents a monumental achievement for Mylan to increase patient access to biosimilars and deliver significant savings to the US healthcare system," said Mylan's chief executive Heather Bresch.

"It will allow us to bring this important biosimilar – the first of its kind to market in the US, expanding cancer-patient access to more affordable treatment."

Mylan and Biocon had reached a settlement and licensing agreement with Roche in March to launch the biosimilar in major markets.

The terms of the deal and launch dates for the biosimilar in different markets were not disclosed, Mylan said.

Barclay's analyst Douglas Tsao said "although the drug is not expected to be launched until 2019, the approval adds credibility to Mylan's biosimilar efforts".

Mylan and Biocon are also developing a biosimilar to Amgen's drug Neulasta, which got a complete response letter (CRL) from the FDA in October, asking for more data related to their manufacturing facilities.

Mylan and Biocon's biosimilar for Herceptin also is under review by regulatory authorities in Australia, Canada, Europe and several additional markets.

It is already approved in 19 countries around the world, including India,thus providing increased access to this more affordable biologic for cancer patients.