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AstraZeneca's oncology drugs receive regulatory boost

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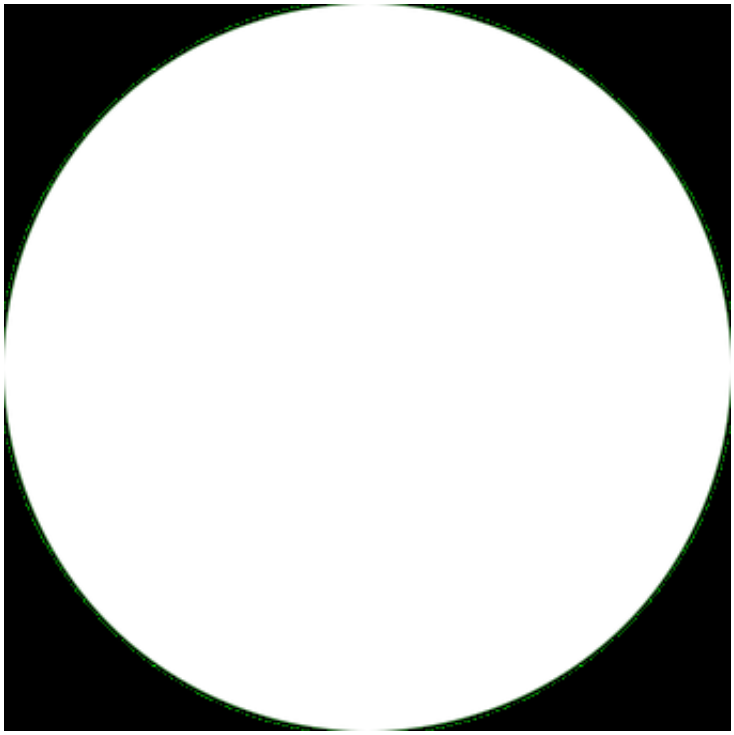
US FDA has granted priority review for its AstraZeneca's candidate that treats leukemia while EU has accepted the Marketing Authorisation Application) for Lynparza



Global pharma giant AstraZeneca’s oncology drugs received regulatory boost with bothe the US FDA and EU accepting regulatory submissions for its drug candidates for cancer.

AstraZeneca and MedImmune, its global biologics research and development arm, announced that the FDA has accepted the Biologics License Application (BLA) for moxetumomab pasudotox, an investigational anti-CD22 recombinant immunotoxin and a potential new medicine for the treatment of adult patients with hairy cell leukaemia (HCL) who have received at least two prior lines of therapy.

The FDA has granted the moxetumomab pasudotox BLA Priority Review status with a Prescription Drug User Fee Act date set for the third quarter of 2018 Priority Review is granted by the FDA to applications for medicines that, if approved, would offer a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions

Separately, AstraZeneca and Merck today announced that the European Medicines Agency has validated for review the Marketing Authorisation Application (MAA) for *Lynparza* (olaparib) for use in patients with deleterious or suspected deleterious *BRCA*-mutated, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

Once approved the drug would be the first poly ADP-ribose polymerase (PARP) inhibitor in breast cancer in Europe. Also, the identification of a patient's *BRCA* status could become a critical step in the management of their disease alongside current consideration of their hormone receptor and HER2 status.

In January 2018, *Lynparza* was approved by the US Food and Drug Administration for use in the treatment of *BRCA* -mutated HER2-negative metastatic breast cancer, becoming the first PARP inhibitor to be approved beyond ovarian cancer. *Lynparza*is available in nearly 60 countries and has been used to treat more than 20,000 patients. AstraZeneca and MSD are working together to bring *Lynparza* to more patients across multiple cancers.