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US FDA approves drug for chronic leukemia

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Singapore: The US Food and Drug Administration has approved Bosulif (bosutinib), marketed by Pfizer, to treat chronic myelogenous leukemia (CML), a blood and bone marrow disease that usually affects older adults.

Most people with CML have a genetic mutation called the Philadelphia chromosome, which causes the bone marrow to make an enzyme called tyrosine kinase. This enzyme triggers the development of too many abnormal and unhealthy white blood cells called granulocytes. Granulocytes fight infection.

Bosulif is intended for patients with chronic, accelerated or blast phase Philadelphia chromosome positive CML who are resistant to or who cannot tolerate other therapies, including imatinib. Bosulif works by blocking the signal of the tyrosine kinase that promotes the development of abnormal and unhealthy granulocytes.

"With the approval of tyrosine kinase inhibitors, we are seeing improvements in the treatment of CML based on a better understanding of the molecular basis of the disease," said Dr Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "These improvements have been observed in chronic and accelerated phases of CML."

Other drugs recently approved by the FDA to treat various forms of CML include imatinib (2001), dasatinib (2006) and nilotinib (2007).

The safety and effectiveness of Bosulif was evaluated in a single clinical trial that enrolled 546 adult patients who had chronic, accelerated or blast phase CML. All patients had disease that progressed after treatment with imatinib or imatinib followed by dasatinib and/or nilotinib, or who could not tolerate the side effects of prior therapy. All patients in the trial were treated with Bosulif.

"BOSULIF is the third new medicine from Pfizer Oncology's pipeline to be approved by the FDA in 13 months," said Mr Garry Nicholson, president and general manager, Pfizer Oncology Business Unit. "By focusing our pipeline on those compounds best positioned for advancement, we have been able to bring yet another important therapy to patients who urgently need it."