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Boehringer Ingelheim´s Volasertib gets orphan drug designation in EU, US

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Singapore: US Food and Drug Administration (FDA) and the European Commission have granted orphan drug designation to Boehringer Ingelheim's volasertib for the treatment of patients with acute myeloid leukaemia (AML).

AML is an aggressive cancer of the bone marrow and blood. It accounts for approximately one third of all adult leukaemias in the Western world and has one of the lowest survival rates of all leukaemias. AML is primarily a disease of later adulthood; the average age of an AML patient is 65-70 years. The recommended standard of care is currently intensive chemotherapy, but many patients due to age and co-morbidities cannot tolerate this therapeutic approach. For them, options are limited and their prognosis is poor.

Professor Klaus Dugi, Chief Medical Officer at Boehringer Ingelheim commented, "We are pleased that both the FDA and European Commission have decided to grant orphan drug designation to volasertib. This coupled with the FDA Breakthrough Therapy Designation awarded to the compound last year, recognises the potential of volasertib as a possible new treatment for patients with acute myeloid leukaemia (AML). Due to the targeted way in which volasertib works, we hope it will offer a new alternative for those patients who are currently left with limited options. In parallel with the on-going Phase III trials, we will work closely with both agencies and hope patients will benefit from our medicine as soon as possible."