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Kura Oncology & Kyowa Kirin ink billion dollar deal to develop and commercialise Ziftomenib for acute leukemia treatment

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Companies to jointly pursue broad development programme targeting acute leukemias, including frontline indications, combinations with targeted therapies and post-transplant maintenance setting

US-based Kura Oncology, Inc. and Japanese pharmaceutical firm Kyowa Kirin have entered into a global strategic collaboration to develop and commercialise ziftomenib, Kura's selective oral menin inhibitor, being investigated for the treatment of patients with acute myeloid leukemia (AML) and other hematologic malignancies.

Under the terms of the agreement, Kura will receive an upfront payment of $330 million and expects to receive up to $420 million in near-term milestone payments, including a payment upon the launch of ziftomenib in the monotherapy relapsed/refractory (R/R) setting.

In addition, Kura is eligible to receive additional development, regulatory and commercial milestone payments of $741 million, totaling up to $1.161 billion in payments for milestones and the opt-in for solid tumor indications.

In the US, Kura will lead development, regulatory and commercial strategy and be responsible for manufacturing ziftomenib. The companies will jointly perform commercialisation activities in accordance with a co-created US territory commercialisation plan and will share equally in any potential profits and losses.

Outside the US, Kyowa Kirin will lead development, regulatory and commercial strategy and is responsible for commercialising ziftomenib. Kura will be eligible to receive tiered double-digit royalties on net product sales.

Ziftomenib is the first and only investigational therapy to receive breakthrough designation from the US Food and Drug Administration (FDA) for the treatment of R/R NPM1-mutant AML, a mutation that is associated with poor outcomes