

Ambit Biosciences (AMBI) - Early Approval of Quizartinib in RR-AML = A Risk Worth Taking

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Abstracts

Regaining WW rights to Quizartinib (PhII/III, a selective oral potent FLT3, FMS like tyrosine kinase-3 inhibitor for acute myeloid leukemia, AML) from Astellas in 2013 armed AMBI to tap the unmet need in refractory/ relapsed AML (RR AML) and related hematological disorders. In the PhIIb study pts, FLT3 positive AML patients relapsed/refractory to one or more prior therapies treated with quizartinib achieved CRc rates of 46% vs.3-4% seen with other tyrosine kinase inhibitors. FDA is reviewing the data, new endpoints and is likely to announce its decision by Nov 2013. The drug has a fast track in orphan status and the company is on track to start the PhIII trial in 2014 in rrAML irrespective of the FDA's decision. Even if the drug does not get approved in ... For more detail please read our report on Ambit released on 30th August 2013, titled, "Early Approval of Quizartinib in RR-AML = A Risk Worth Taking".

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