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AML [2017]: Bulletin #1

https://marketpublishers.com/r/A2F546CAD84EN.html
Date: May 2017
Pages: 0
Price: US$ 1,045.00 (Single User License)
ID: A2F546CAD84EN

Abstracts

This update bulletin presents key opinion leader (KOL) views on recent developments in the acute myeloid leukaemia (AML) market. Topics covered include: Novartis receiving US FDA approval for Rydapt (midostaurin) in newly diagnosed FLT3-mutated AML; the US FDA placing a clinical hold on several early stage studies of Seattle Genetics' novel anti-CD33 antibody drug conjugate vadastuximab talirine (SGN-CD33A) in patients with AML; and Agios Pharmaceuticals and Celgene announcing that the US FDA has accepted their New Drug Application (NDA) for enasidenib (AG-221) for the treatment of patients with relapsed/refractory AML with an isocitrate dehydrogenase 2 (IDH2) mutation.

Business Questions

How do KOLs view the FDA approval of the first FLT3 inhibitor Novartis' Rydapt in AML?

Could Rydapt capture market share in a wider population of patients; e.g. those without FLT3-mutated AML?

Do KOLs expect Rydapt to be utilised in the maintenance setting?

How do KOLs view the trade-off between efficacy and the risk of hepatotoxicity and death with Seattle Genetics' vadastuximab, and should development of the drug continue?

How does vadastuximab compare to its discontinued predecessor Mylotarg?

How will combination trials inform the best positioning for vadastuximab and its developmental pathway?

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What are the KOLs' opinions on Agios/Celgene's IDH2 inhibitor enasidenib in AML, and how likely is it that it will be approved this year by the US FDA?

If approved, do KOLs expect niche or widespread use of enasidenib in AML?

Will delays and logistical issues with companion diagnostic testing for targeted therapies be a barrier to use in the first-line setting of AML?

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