Evaluate Vantage

June 18, 2019

Vanflyta's path to the US could be tougher than in Japan

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It is not all that common for Japan to approve a drug before it gets a US green light, and the case of Daiichi Sankyo's quizartinib looks particularly interesting. The acute myelogenous leukaemia product, now trademarked Vanflyta, got the nod in Japan having earlier suffered an advisory panel vote against its approval in the US, on the grounds that its benefit did not outweigh the risk. The US FDA is notoriously lenient towards cancer drugs, so approval is still possible by Vanflyta's August 25 PDUFA date, though this is not guaranteed. One consideration for Daiichi is commercial: as a Flt3 inhibitor Venflyta would, in the relapsed Flt3-mutated AML setting, compete against two similarly acting US-approved drugs: Novartis's Rydapt and Astellas's Xospata. Only the latter has already been approved in Japan. Separately, Roche's Rozlytrek (entrectinib), acquired through the Swiss group's purchase of Ignyta, was approved in Japan today for treating NTRK fusion-positive solid tumours, also before a US FDA verdict. In Rozlytrek's case US approval, due by August 18, is a near certainty.

Selected Flt3-targeting agents in clinical development for AML

Project	Company	US status	Japan status
Rydapt	Novartis	Approved (1st-line, Flt3+ve)	Phase III (1st-line)
Xospata	Astellas	Approved (r/r, Flt3+ve)	Approved (r/r, Flt3+ve)
Vanflyta	Daiichi Sankyo	Phase III (1st-line)	Approved (r/r, Flt3+ve)
Crenolanib	Arog (ex Pfizer)	Phase III (1st-line & r/r)	No studies found
FF-10101	Fujifilm	Phase I (r/r)	No studies found
HM43239	Hanmi	Phase I (r/r)	No studies found
SKI-G-801	Oscotec	Phase I (r/r)	No studies found
MEN1703/SEL24	Menarini/Selvita	Phase I (r/r)	No studies found
TAK-659	Takeda	Phase I (r/r)	No studies found
AGS62P1/ASP1235	Astellas	Phase I (r/r)	No studies found

Source: company filings & clinical trial registries. r/r=relapsed/refractory.