

Event - US approval could put Glaxo's dolutegravir at the top of the class



[Elizabeth Cairns](#)

With priority review status, solid clinical data, and having been hailed by some analysts as the best drug in its class, expectations for GlaxoSmithKline's dolutegravir are blockbuster high. The FDA's decision on whether to approve it, expected mid-month, means that Glaxo is poised to leap up the rankings in HIV, knocking lumps out of Merck & Co and perhaps Gilead Sciences on the way.

As ever, much depends on the label. Bernstein analysts have been concerned that dolutegravir, also called GSK1349572, may be directed for use in patients who have already failed on other HIV integrase inhibitors, namely Merck's Isentress. But antivirals are not like antibiotics, and with HIV still one of the most alarming diagnoses a patient can receive, the agency will be under pressure to allow doctors to use their most powerful weapons first.

Company	GlaxoSmithKline	Shionogi
Product	Dolutegravir	
Market cap	\$128bn	\$7.4bn
Product NPV	\$2.4bn	\$801m
% of market cap	2%	11%
Event type	PDUFA	
Date	August 16, 2013	

Half the market

Dolutegravir's showing in the clinic has been impressive, proving itself a better virus suppressor than Isentress in patients who had not been treated with an integrase inhibitor ([Dolutegravir sailing toward key regulatory dates](#), March 7, 2013).

This led analysts from Bernstein to state that they believed it to be the best-in-class integrase inhibitor, though they pointed out that despite its success in integrase inhibitor-naïve patients it might come to be used primarily in Isentress failures.

Analysts from Leerink Swann predict rapid declines in Isentress's market share after launch of dolutegravir - unsurprising given that Isentress is the only integrase inhibitor on the US market at the moment, commanding therefore a share of 100%.

EvaluatePharma's consensus data suggests that US approval of dolutegravir, and to a lesser extent Gilead's elvitegravir, will cut Isentress's share to just 34% in the next five years, though as the market overall will grow 19%, Isentress sales will remain healthy (see table). Dolutegravir itself is predicted to scoop just over half the integrase inhibitor market, with sales increasing by a CAGR of 87% between 2013 and 2018.

Dolutegravir is not solely a Glaxo project. Developed under the auspices of Viiv, Glaxo's HIV-focused joint-venture with Pfizer and Shionogi, the latter company - dolutegravir's originator - will get royalties in the high teens on sales of the drug.

Dolutegravir's reach could be extended further after its approval: Viiv is already trialling it along with its fixed-dose combination of abacavir and lamivudine, branded Epzicom in the US. The combination of all three drugs is currently referred to as 572-Trii or dolutegravir-Trii. Results from the dolutegravir/Epzicom trial are expected this year.

In short, with a safety record as good as or better than Isentress and apparently better efficacy, US approval of

dolutegravir looks more or less assured. Approval in Europe is also expected in short order too, and will help propel the drug to blockbuster status.

HIV integrase inhibitors annual US sales (\$m)										
Product	Generic Name	Company	Current phase	2011	2012	2013	2014	2015	2016	2017
Dolutegravir	dolutegravir	GlaxoSmithKline	Filed	-	-	55	211	432	737	980
Isentress	raltegravir potassium	Merck & Co	Marketed	681	822	855	848	836	815	800
Elvitegravir	elvitegravir	Gilead Sciences	Filed	-	-	24	68	122	171	220
Total				681	822	935	1,126	1,390	1,723	2,000

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