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US nod nears for first Herceptin biosimilar as the European fight begins

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The US FDA is expected to approve the first biosimilar version of Roche's blockbuster breast cancer therapy Herceptin this week; after weathering delays on manufacturing issues, its developers Mylan and Biocon will be keen to secure this notable win.

Not that they will be able to race straight to market – analysts expect a launch sometime in the first half of 2019, but the exact timing is unclear as the terms of a settlement with Roche earlier this year were not disclosed. Biosimilar makers will be taking the fight to Roche in Europe much sooner, however, where Samsung Bioepis won a green light earlier this month and where Herceptin's patents have already expired.

Merck & Co will sell the product for Bioepis in Europe, where it has been trademarked Ontruzant. The US pharma giant has yet to reveal its launch plans, and a spokesperson would not confirm whether the biosimilar's arrival was imminent, telling *EP Vantage* only that the timing would be based on "an ongoing assessment of the business and legal landscape for the product".

Herceptin's IP in Europe expired back in July 2014, so it is not immediately clear what Merck is waiting for. Roche has said it expects several competitors to launch early next year, and analysts' forecasts point to launches for Celltrion and Amgen, as well Merck, in 2018.

Pfizer and Mylan are slightly behind, the latter again held up by Biocon's manufacturing problems. But get there they will, and by 2019 there are likely to be five biosimilars fighting to take a bite out of Herceptin in Europe. This market is shaping up to be crowded and competitive.

Breaking a blockbuster – sales forecasts for Herceptin and its main challengers								
			US sales ($m)			Europe sales ($m)		
Product	**Company**	**Status**	**2016**	**2019e**	**2022e**	**2016**	**2019e**	**2022e**
Herceptin	Roche	Marketed	2,547	2,376	1,314	2,328	1,616	1,235
PF-05280014	Pfizer	Filed US & EU - decisions 2018	-	20	134	-	12	92
Canmab	Mylan/Biocon	Filed US & EU - decisions 2017/18	-	35	127	(not available)		
Herzuma	Celltrion (WW)/Teva (US & Canada)	Filed US & EU - decisions 2018/17	-	8	50	-	55	134
ABP 980	Amgen/Allergan (royalties)	Filed US & EU - decisions 2018	-	4	41	-	19	42
Ontruzant	Merck & Co/Samsung Bioepis (royalties)	US status unclear, approved EU	-	-	-	-	17	64
Source: EvaluatePharma.								

Of course Roche has not sat back and simply watched all this unfold, and has been building its biosimilar defence for years. Perhaps the most successful strategy has been to develop a subcutaneously delivered Herceptin, which represents as much as half the market where it is available. Perjeta and Kadcyla were also both developed with Her2 franchise protection in mind, and to varying degrees have been successful.

Ronny Gal, an analyst at Bernstein, also points out that this is a market in which survival depends on the drug, and thus there is some apprehension about biosimilar use. He adds that Roche could also use bundled discounts in some areas – all of which puts the Swiss pharma giant in a strong position.

The unknown here is how fiercely the biosimilar rivals will compete on price. But should all five reach the market it is probably safe to assume that the cost of infused Herceptin will drop sharply in the coming years in Europe, with Roche retreating to its subcutaneous product.

The US market, which has been much slower to embrace biosimilars, could well be a different case. And with Herceptin's so-called Cabilly patents good until December 2018, and manufacturers litigating over several others that stretch into 2019, Roche looks safe here for a while yet.

However, by early 2019, four of the Herceptin biosimilar manufacturers should have FDA approvals in place – and possibly all five, if Samsung Bioepis confirms a US filing any time soon.

All are still fighting Roche in the patent courts, except Mylan, which settled in March in a deal that gave it licences for its trastuzumab product in various markets around the world. Nothing about the deal, in terms of how much it cost Mylan or when it might launch and where, was disclosed.

However, the US generics firm is confident of being first to launch in the US. FDA approval represents an important step towards that.

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