

Waiting game continues with Mircera launch



[Amy Brown](#)

For all the headlines Express Scripts generated by dropping Amgen's Epogen and Aranesp from its approved products list, in the grand scheme of things it is a storm in a teacup. Analysts estimate only 1% of Amgen's erythropoiesis stimulating agent (ESA) sales are retail, with the bulk coming from contracts with dialysis providers like DaVita Health Care Partners and Fresenius Medical Care (FMC).

What might eventually hit the \$3bn plus sales Amgen chalked up last year for the two ESA products are Roche's as yet unannounced plans for its rival Epogen product, Mircera.

Deafening silence

Roche has been able to launch Mircera in the US since July 1, but as yet there is no sign of the drug on pharmacy shelves. When contacted by *EP Vantage* about a possible launch date Roche would only say: "We are currently exploring opportunities to bring Mircera to patients in the US".

Without any experience of the US ESA market, and the recent move to bundle all dialysis services to reduce payer costs, Roche would be very brave to undertake a solo launch.

The dialysis space and the role of ESAs within it has also been further clouded by the threat of more generic epo products in 2015, when Amgen's Epogen patents expire. Which means Roche would be sensible to nail down an exclusive supply agreement with a dialysis provider ahead of more competition.

Amgen has already inked such a deal with DaVita and will supply it with Epogen until 2019, leaving FMC as the natural partner for Roche. Alongside an exclusive supply agreement, UBS analysts have speculated Roche might also consider selling FMC US rights to Mircera.

Buddying up

FMC appears to be already considering the possibility of a tie-up with Roche. In its second-quarter results last week the group said that it would be starting pilot trials of Mircera as a replacement for Epogen by the end of the year.

Mircera is not directly substitutable for Epogen, so internal trials are a sensible. But with the trials yet to begin it is unlikely FMC will start using the product on any scale before 2015, the year when Amgen's US patents end. So Roche could be working hard on getting a firm commitment on a supply deal now.

UBS estimates the benefits to Roche could be significant if it manages to sign an exclusive agreement with FMC at a 30% discount to Epogen. The bank's analysts calculate that a deal would result in a 1.6% rise in core operating profits in 2016.

Cost reduction

In turn, FMC has a strong incentive for substitution, if it can negotiate a discount on the price it pays for Epogen. Mircera's pegylated formula offers the potential for fortnightly or monthly dosing, rather than the every two to three days required with Epogen, meaning less time spent in costly clinics for patients. And with dialysis bundle prices fixed until 2019, any reductions FMC can make within the bundle should flow down to its bottom line.

At the moment forecasts for Mircera are \$345m in 2015 rising to \$552m in 2020, reflecting sales made outside the US. This compares with a 35% decline in Epogen sales during the same period to \$1.13bn, as competition from Mircera and biosimilars, like by Sandoz' Binocrit, reach the markets.

A decade in the anaemia market - 10 products seen top sellers in 2020				Annual Sales (\$m)		
Product	Generic Name	Company	Markets sold	2010	2015e	2020e
Aranesp	darbepoetin alfa	Amgen	WW ex Japan and others	2,486	1,667	1,321
Epogen	epoetin alfa	Amgen	USA (dialysis only)	2,524	1,728	1,128
Procrit	epoetin alfa	J&J	WW ex Japan, China (US ex dialysis & Dx)	1,934	1,105	637
Mircera	methoxy polyethylene glycol-epoetin beta	Roche	WW ex Japan	245	345	552
Nesp	darbepoetin alfa	Kyowa Hakko Kirin	Japan, China, and other Asia	488	521	406
NeoRecormon	epoetin beta	Roche	WW ex US & Switzerland	778	387	298
Mircera	methoxy polyethylene glycol-epoetin beta	Chugai	Japan	-	270	256
EPIAO	epoetin alfa	3SBio	China	37	84	126
Epoetin alfa BS	epoetin alfa (biosimilar)	Kissei	Japan (co-promote with JCR)	14	69	69
Retacrit	epoetin zeta (biosimilar)	Hospira	US & Canada; EU distribution rights	21	46	67
			Total market incl others*	9,172	6,385	5,003

**Sales are not available for a number of products on the market worldwide*

Source: EvaluatePharma

Analysts at UBS, however, believe Epogen sales could also be hit if Keryx's Zerenex is approved by its September 7 PDUFA date. The oral drug, an iron-based phosphate binder, has reduced ESA use by 24% in phase III.

Zerenex's approval would naturally also affect sales of Mircera, as could the advent of newer oral ESA drugs in the form of the HIF inhibitors ([Therapeutic focus - Big pharma takes high-level interest in anaemia pills, August 28, 2013](#)). So if Roche does want to capitalise on the drug for which it won US approval seven years ago, it will need to make clear its intentions and soon.

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