

Event - Novo's longer-acting FVIII heads towards crowded market



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Phase III results from Novo's long-acting haemophilia A candidate N8-GP are expected in the first half of the year. The product will be the third long-acting factor VIII to report pivotal results, as several companies look set to compete for market share in this space.

Biogen's Eloctate looks like it could be the first to launch, but candidates from Bayer and Baxter are not far behind. With fierce competition Novo ideally needs N8-GP to hit the once-a-week dosing benchmark with a robust safety profile if it intends to carve out its share of the market.

Novo Nordisk: N8-GP

The phase III programme in haemophilia A includes an open label, two-arm trial testing on-demand treatment and prophylaxis. The trial, Pathfinder 2, recruited 132 male patients; another open label, one-arm surgery trial, Pathfinder 3, has 18 male patients. The patients in both trials were aged 12 years and over. Last year the company started a paediatric trial in male patients aged up to 11 called Pathfinder 5.

In its phase I trial in 27 male patients aged between 18 and 65, the mean terminal half-life of N8-GP was 18.4 hours, which the company noted was 1.6 times longer than the half-lives of previous FVIII products. No patients developed inhibitors or binding antibodies.

Novo received approval for its short-acting version, Novoeight, last October, but it is awaiting the expiration of an unspecified third-party patent before releasing it onto the market, meaning its launch in the US will not come until 2015. Novoeight was launched in Europe in January.

Market share

The current standard of care for haemophilia A is Baxter's Advate, also a factor VIII. It is indicated for use in patients aged 0-16 years old. The half-life in adolescents aged 12 to 16 years old is 11.7 hours. The recommended dosing of Advate for prophylactic use is once every other day but dosing every third day is permitted to keep blood levels at least 1% of normal.

With the need for central IV lines for repeat infusions in many cases, any agent that permits reduced dosing frequency would be welcomed by both physicians and patients. Therefore the race for a longer-acting alternative is highly competitive.

Biogen's Eloctate could be the first longer-acting FVIII to market; it has a PDUFA date next month. The coagulant, previously known as rFVIII-Fc, showed a median dosing interval of 3.5 days. However, only 30% of patients achieved mean dosing of five days, which disappointed investors when the results were announced ([Biogen's blood data prove a little anaemic for some investors](#), November 1, 2012). Despite this Eloctate has not displayed any safety issues or inhibitors.

First mover advantage is reflected in Eloctate's sales forecasts, with total worldwide sales alongside partner Swedish Orphan Biovitrum forecast at \$694m according to *EvaluatePharma*.

Competition

Although a year behind Eloctate Bayer has also reported pivotal data on its FVIII, BAY 94-9027, that could see it be dosed as infrequently as once a week. Few details were given on its safety profile, but the company did state that two cases of hypersensitivity were reported ([Bayer closes the gap on Biogen's haemophilia candidate](#), February 18, 2014).

Hot on Bayer's heels is Baxter's BAX-855, which is based on Advate. Data are expected from the phase III program in September, according to JP Morgan analysts. In phase I the half life was 1.5 fold higher than Advate and no inhibitors occurred.

Forecasts for Novo's N8-GP are unimpressive at \$62m in 2018 according to *EvaluatePharma*, while sales for its

shorter acting form Novoeight are set at \$261m in the same year. Bayer's BAY 94-9027 seems to be the product to beat in terms of efficacy, while Biogen Idec has a big head start. Novo has a fight on its hands to win a position in this space.

Selected FVIII pipeline					
Market status	Product	Short or Long acting?	Company	Annual 2018 WW sales (\$m)	Trial ID
Approved	NovoEight	Short	Novo Nordisk	261	-
Filed	Eloctate	Long	Biogen Idec/Swedish Orphan Biovitrum	694	-
	Human-cl rhFVIII	Short	Octapharma	-	-
Phase III	BAY 94-9027	Long	Bayer	261	NCT01580293 Protect-VIII
	BAX-855	Long	Baxter International	232	NCT01736475 Prolong-Ate
	N8-GP	Long	Novo Nordisk	62	NCT01480180 Pathfinder 2 NCT01489111 Pathfinder 3 NCT01731600 Pathfinder 5
	BAY 81-8973	Short	Bayer	-	NCT01311648
	CSL627/Recombinant Factor VIII	Long	CSL	-	NCT01486927

All information is sourced to analyst notes and the *EvaluatePharma Calendar of Events* tool.

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