

Upcoming events - Obseva's first fibroid foray and Newron's test in Retts



[Joanne Fagg](#)



Obseva awaits data that could make linzagolix third to market, while Newron looks for a starring role in Retts.

Welcome to your weekly roundup of approaching clinical readouts. In the fourth quarter Obseva will see data from the first of two phase III trials of its gonadotropin-releasing hormone (GnRH) antagonist linzagolix in uterine fibroids.

[Primrose 2](#) evaluates whether linzagolix reduces heavy menstrual bleeding associated with fibroids. A second phase III trial, [Primrose 1](#), is due to report early next year, and Obseva will file an NDA by the end of 2020.

Both placebo-controlled studies have a primary endpoint of the percentage of responders, based on a reduction in menstrual blood volume, at week 24; they test linzagolix with and without hormonal add-back therapy (ABT), which is often needed to counteract the menopause-like symptoms that result from full oestrogen suppression with GnRH inhibition.

Because ABT has side effects of its own, and certain patients are particularly ill suited to it, monotherapy could represent a major advance. Obseva hopes that linzagolix 100mg will be suitable for monotherapy, and that 200mg plus ABT will be used in patients who are not properly controlled on the lower dose.

It has set a target of a 40-50% response rate for the monotherapy dose, rising to around 70% with 200mg plus ABT. Looking across trials this would put linzagolix on par with competitors on a non-placebo adjusted basis, but a fairer comparison would be placebo-adjusted results, something to look out for when the linzagolix data are released.

Cross-trial comparison of GnRH inhibitors in uterine fibroids - response rates

	Orilissa (Abbvie)		Relugolix (Myovant)	
	Elaris UF-1	Elaris US-2	Liberty 1	Liberty 2
	300mg bid	300mg bid	40mg daily	40mg daily
Active arm	69%	76%	73%	71%
Placebo	9%	10%	19%	15%
Placebo adjusted	60%	66%	55%	57%

Note: both drugs were given with ABT; bid=twice daily. Source: company presentations.

In terms of competitors Abbvie's Orilissa has first-mover advantage, having been filed in uterine fibroids last month. Myovant, [soon to become 46%-owned by Sumitomo Dainippon Pharma](#), is looking to file the more conveniently dosed relugolix in the fourth quarter.

If linzagolix comes third to market Obseva will need something special to compete.

GnRH antagonists in uterine fibroids

Product	Company	Indication status	2024e fibroid sales (\$m)
Orilissa (elagolix)	Abbvie	Filed	769
Relumina (relugolix)	Myovant/Takeda/Aska Pharmaceutical	Phase III (marketed in Japan)	599
Linzagolix	Obseva	Phase III	253

Source: EvaluatePharma.

Rett readout

Getting to market in a rare disease with no approved products is the dream of many biotechs, and Newron could take a step closer to this if it scores a win in the [pivotal Stars trial](#) of its lead project, sarizotan, in apnoea in Rett syndrome; topline data are due in the fourth quarter.

Rett syndrome is [a rare neurological disorder](#) that almost exclusively affects girls. Newron says 70-90% of Rett sufferers experience respiratory abnormalities, and is trying to treat breathing dysfunction rather than the disorder's underlying cause.

Stars enrolled 129 with severe apnoea at baseline, and will evaluate the number of apnoea episodes during waking hours over 24 weeks' sarizotan treatment versus placebo.

Newron's lack of any human Rett data going into the pivotal study is a major concern. Another is slow recruitment: Newron had originally expected data at the end of last year and a 2019 filing, but now hopes to file in 2020 and to market sarizotan itself. Consensus compiled by *EvaluatePharma* puts 2024 sales at \$182m.

Newron had licensed the asset from Merck KGaA, which had been developing it in Parkinson's disease. The company is also not alone in going after the Rett market, but none of its competitors looks likely to get a product to market before late 2021.

Rett syndrome market

Product	Company	Phase	Sales (\$m)	
			2022e	2024e
Sarizotan	Newron Pharmaceuticals	Phase III	89	182
Trofinetide oral	Acadia Pharmaceuticals	Phase II	8	57
Epidiolex	GW Pharmaceuticals	Phase III	17	37
ANAVEX 2-73	Anavex Life Sciences	Phase II	11	36
BHV-5000	Biohaven Pharmaceutical	Phase I	-	27
AVXS-201	Novartis	Phase I	-	20
GWP42006	GW Pharmaceuticals	Phase II	4	18
Total			128	377

Source: EvaluatePharma.

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Evaluate HQ
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas
[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

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