

Sage gets a postpartum reprieve



[Madeleine Armstrong](#)

Sage Therapeutics has finally had some good news: its Gaba-A modulator zuranolone produced a convincing win in Skylark, its pivotal postpartum depression study. The question is how much this will impress investors, who have their eye on the bigger use of major depressive disorder – and here there are [still doubts about zuranolone's approvability and commercial prospects](#). Sage and its partner Biogen have started a rolling submission in MDD, and plan a separate PPD filing early next year. One question is cost: Stifel analysts have speculated that Sage will price the drug for the larger MDD indication, although the company is staying tight-lipped for now. Sage estimates that around 500,000 women in the US have PPD, but only 28% of these are currently diagnosed; it hopes that an oral therapy will drive up this number. Sage already has a PPD drug in Zulresso, but that is given via a 60-hour infusion. The main downside in Skylark was a higher incidence of side effects like somnolence versus the lower-dose Robin trial, for arguably no additional clinical benefit. Sage reckons 50mg will be the go-to dose, with the option to reduce if required. The company's stock climbed 4% this morning.

Flying high or wings clipped? Zuranolone's post-partum depression data

HAMD-17 score change at...	Skylark (NCT04442503), 50mg		Robin (NCT02978326), 30mg	
	Placebo-adjusted difference	p value	Placebo-adjusted difference	p value
- day 3	-3.4	0.0008	-2.7	0.0255
- day 15*	-4.0	0.0007	-4.2	0.0029
- day 28	-2.9	0.0203	Not given	Not given
- day 45	-3.5	0.0067	-4.1	0.0027
Somnolence	26.5%	N/A	12.8%	N/A

*Primary endpoint. Source: company releases & clinicaltrials.gov.

[More from Evaluate Vantage](#)

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)

© Copyright 2022 Evaluate Ltd.