Evaluate Vantage

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Upcoming events – Filgotinib's ulcerative colitis data and serlopitant takes on pruritus

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Gilead and Galapagos's filgotinib might not be a match for Rinvoq in ulcerative colitis, while Menlo needs to prove serlopitant works after previous setbacks.

Welcome to your weekly roundup of approaching clinical readouts. Gilead and Galapagos are gearing up for US regulatory action on filgotinib in rheumatoid arthritis later this year, but in the meantime a trial of the Jak 1 in ulcerative colitis will report.

The second quarter will see data from the phase IIb/III Selection1 study. This tests 100mg or 200mg of filgotinib once-daily versus placebo in 1,351 adults who have and have not been treated with biologicals. A 10-week induction phase selected those who met response or remission criteria, before a further 48-week maintenance portion.

The primary objective is proportion of participants achieving remission based on components of Mayo Clinic Score. Filgotinib's safety profile will also be scrutinised owing to thrombosis concerns with older Jaks.

The question is whether filgotinib can differentiate itself from the competition. Abbvie's Rinvoq's, another Jak 1 inhibitor, showed a statistically significant clinical remission of 14-20%, as per the adapted Mayo score, at its highest dose versus placebo. Full data, as well as the two other phase III trials that make up Rinvoq's pivotal programme in UC, are expected in 2021 and 2022.

Of the Jaks in the autoimmune space, Rinvoq, approved in RA last year, will lead the market by 2024, according to *EvaluatePharma* sellside consensus. UC is expected to make up a smaller portion of both Rinvoq's and filgotinib's sales than RA.

With Abbvie's marketing machine behind it Rinvoq is expected to take a huge lead against Gilead and Galapagos in UC, with 2024 sales of $903m versus filgotinib's $69m, according to *EvaluatePharma*'s sales by indication data.

Jak inhibitors in autoimmune diseases					
				Annual sales ($m)	
Product	**Company**	**Mechanism of Action**	**Notes**	**2020e**	**2024e**
Rinvoq	Abbvie	Jak 1 inhibitor	On the market for RA. UC trials: U-Achieve, U-Accomplish, NCT03006068.	382	2,830
Xeljanz	Pfizer	Jak 1, 2 and 3 inhibitor	Marketed for RA, UC and psoriatic arthritis.	2,530	2,769
Filgotinib	Gilead/ Galapagos	Jak 1 inhibitor	US decision on RA due H2. UC Selection1 data due Q2. UC extension study NCT02914535 to complete 2023.	26	1,281
Olumiant	Lilly	Jak 1 and 2 inhibitor	On the market for RA.	582	956
RA = rheumatoid arthritis, UC = ulcerative colitis. Source: EvaluatePharma.					

An itch worth scratching?

Meanwhile, serlopitant has been the source of much woe to Menlo since the company's $137m IPO two years ago. Menlo's shares are off 82% since the float owing to serlopitant's failure to treat pruritus associated with atopic dermatitis and its miss in a chronic cough trial. Data from a separate pruritus trial could provide a chance for the NK1 receptor antagonist to redeem itself – and are vital to Menlo for another reason.

Data from two phase III studies of serlopitant, which Menlo licensed from Merck & Co in 2012, ought to appear in March or April. The trials are assessing the product as a therapy for itching associated with prurigo nodularis, a chronic skin disorder that causes inflamed skin nodules on the arms, legs and trunk.

The two phase III studies, MTI-105 and MTI-106, are identical except for being conducted in the US and in Europe respectively. They test 5mg of serlopitant versus placebo in a total of 580 patients. The primary endpoints are the proportion of patients showing an improvement of at least four points on the worst itch numeric rating scale (WI-NRS) at week 10, and aim to show a 19% treatment effect difference versus placebo.

For now, analyst sentiment looks more positive than investors', with consensus forecasts pegged at $144m in 2024, according to *EvaluatePharma* data. HC Wainwright points to "positive" studies completed before the IPO, including a post-hoc analysis of a phase II prurigo nodularis trial that showed a 20.9% difference in the four-point WI-NRS responder rate between treatment and placebo (p=0.05).

The results of the upcoming phase III trials are key for Menlo's merger with Foamix, announced last November. Foamix and Menlo shareholders would own approximately 59% and 41% of the combined company respectively, but should one of the serlopitant trials fail on or before the end of May Foamix's shareholder ownership would increase to 75%. This rises to 82% if both studies fail.