

## Abbvie exit forces Ablynx into plan B



[Madeleine Armstrong](#)

Phase IIb data with Ablynx's vobarilizumab in rheumatoid arthritis could at best have been described as mixed, and today its partner Abbvie confirmed the worst by walking away from the project. The Belgian company now has to push on alone while simultaneously looking for a new deal.

With phase III RA programmes elsewhere enrolling thousands of patients, Ablynx will need more than the €289m (\$317m) it had in the bank at the end of June to get very far; unless it can find a new partner quickly it will need to raise extra cash. The crowded IL-6 space and competitive RA field generally means there are not many big players that might be looking for this kind of asset (see tables below).

Jefferies analysts suggested Pfizer, Amgen, Gilead, Novartis and Johnson & Johnson as potential collaborators. All have a presence in RA with other mechanisms of action so could perhaps consider buying in a new approach – although it is hard to see J&J being tempted when it has its own anti-IL-6 antibody, sirukumab, already filed.

A crowded IL-6 space					
			Global sales (\$m)		
	Product	Company	2016	2019	2022
Marketed	Actemra	Roche/Chugai	1,688	1,918	1,637
Filed	Sarilumab	Sanofi/Regeneron	14	430	837
	Sirukumab	Johnson & Johnson/GSK	-	379	1,134
Phase III	Olokizumab	R-Pharm/UCB	-	-	-
Phase II	ALX-0061 (vobarilizumab)	Ablynx	-	23	116
	Clazakizumab	Vitaeris/Alder	-	-	-
	Gerilimzumab	Bird Rock Bio/Argenx	-	-	-
		<b>Total IL-6 sales</b>	<b>1,702</b>	<b>2,776</b>	<b>3,818</b>

Still, the late-stage IL-6-targeting pipeline already looks busy with sarilumab due to hear on FDA approval by the end of the month, and sirukumab recently filed with regulators. The other contenders probably cannot be considered real competition unless much larger partners emerge. For example clazakizumab's development has stalled since Bristol-Myers Squibb returned rights in 2014; it was picked up by Vitaeris in May.

This highlights the risk that Ablynx now faces. It could take 12-18 months to find a new collaborator, Bryan Garnier analysts estimate, particularly if any interested parties wait for phase II data in lupus, due in 2018. Abbvie has separate opt-in rights in this indication.

Abbvie's continuing involvement in lupus further complicates the picture, with Ablynx's chief executive, Edwin Moses, admitting on a conference call that he is unsure whether the group can regain full rights in RA independently of lupus. He added that this would be discussed with Abbvie, and said he was sure this would not get in the way of potential partnering negotiations.

On top of the crowded IL-6 space a partner must also consider the burden of running a competitive phase III programme for vobarilizumab. This could involve around 5,000 patients if the development of other late-stage RA assets is anything to go by.

The weight of a phase III RA programme				
Product	Pharmacology class	Company	# of phase III trials initiated	# of patients sought for pivotal programme
Baricitinib	JAK-1/2 inhibitor	Lilly	6	6,458
Sarilumab	Anti-IL-6R MAb	Sanofi	9	4,224
Filgotinib	JAK-1 inhibitor	Gilead Sciences	3	3,273
Sirukumab	Anti-IL-6 MAb	Johnson & Johnson	5	5,048

Ablynx shares were down as much as 19% today on the news, even as it tried to reassure investors with a [presentation](#) of its phase IIb data, which it described as excellent.

The company highlighted secondary measures such as DAS28CRP, where it said vobarilizumab monotherapy had outperformed Actemra head to head, as well as bettering both Actemra and Humira's stats, when combined with methotrexate, from separate studies - although in the latter the usual caveats about across-trial comparisons apply.

However, it cannot escape the fact that the trial missed its primary endpoint of ACR20 score, which Ablynx blamed on a high placebo response ([Why Abbvie might think twice before exercising Ablynx option, August 10, 2016](#)).

### Taking heart?

Maybe Ablynx will be hoping that investors take heart from the case of Galapagos, which saw Abbvie turn down its RA candidate filgotinib only for Gilead to come in with a better deal just three months later ([Galapagos turns the tables on AbbVie, courtesy of Gilead, December 17, 2015](#)).

But there are differences: filgotinib had unequivocally positive data. Of course vobarilizumab does not have unequivocally negative data, and the IL-6 inhibitors are projected to be one of the fastest-growing RA classes.

While finding a new partner is not an impossibility, there are also reasons why many will think twice.

The dominant RA classes			
	Global sales (\$bn)		
	2015	2022	CAGR
TNFA inhibitors	16.1	14.1	-2%
Anti-IL-6 MAbs	1.5	3.7	14%
JAK inhibitors	0.5	3.2	30%
T-cell costimulation blocker	2.0	2.3	2%
Other	1.7	1.9	2%
<b>Total</b>	<b>21.8</b>	<b>25.2</b>	<b>2%</b>

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[+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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