Fig. 14: Comparative data of clinical remission rates across the trials

	infliximab	adalimumab	golimumab	vedolizumab	vedo sc	tofacitinib	ustekinumab	ABX464	Filgo 200 mg
week 6 or 8	38.8%	16.5%	18.7%	16.9%	18.5%	15.6%	30.0%		26,1 %
week 52 or 54	20.5%	17.3%	28.6%	44.8%	46.2%	40.6%	43.8%	63.2%	37,2 %
diff. vs pbo	*23.9%*	*7.2%*	*12.4%*	*11.5%*		*10.3%*	*10.3%*	*19.0%*	10,8 %
diff. vs pbo	*13.9%*	*8.8%*	*13.2%*	*28.9%*	*31.9%*	*29.5%*	*19.8%*		26,0 %

Source: Pr Sandborn, companies, PI documents, Bryan Garnier & Co

Once we acknowledge that the numbers are hardly comparable among each other, we can make a few comments however.

ABX464 is effective quickly and durably ...

Firstly, few drugs already have clinically meaningful efficacy after the induction phase, with the exception of infliximab, which seems to have a good onset of action. Nevertheless, we also notice that anti-TNFs in general tend to lose some efficacy or fail to improve it to a significant level over time. From this perspective, the most recent drugs seem to offer greater efficacy in the long run.

... irrespectively of a potential previous treatment

That said, and even though it is extracted from a relatively small phase II study and cohort (7 patients only were previously treated with biologics), ABX464 is doing much better and we see no real difference between naïve patients and patients refractory to anti-TNFs or vedolizumab.

Moving to safety now, there is no need to mention again here the limitations to the use in the long term of corticosteroids and immunosuppressants. Natalizumab and vedolizumab both carry a black box warning relating to the risk of PML, which refers to the mechanism of action but is now pretty well managed with the first thanks to a JC virus test while the second has had no case so far and simply has the mention in the label in reference to Tysabri. There is however a specific risk of liver injury reported. The other drug with significant black box safety warnings is the only one to have the advantage of an oral route i.e. tofacitinib, which has reported serious infections leading to hospitalizations or death, malignancies and thrombosis.

Many approved drugs carry warnings while ABX464 looks safe

So far, and including out of a large safety database coming from the studies in HIV together with the growing patient-exposure in inflammatory diseases, ABX464 can be considered as clean from this perspective. No deaths, no malignancies, no severe infections have ever been reported. Most adverse events were of mild to moderate intensity and short duration and most of them were headaches and pain. Out of the phase II trial, one patient withdrew for a transaminase elevation (but with no change to LFTs) during the induction phase and one in the maintenance phase at month 4 for a grade 2 headache. To note is that based on the guidance from the DSMB, the patient in the maintenance phase was kept on ABX464 and this episode subsided within about 10 days, indicating that ABX464 did not cause the adverse event.