

## Aslan fails to roar with atopic dermatitis data



[Lisa Urquhart](#)

Dupixent has set such a high bar in atopic dermatitis anyone coming for its crown had better come prepared. This could be why questions around Aslan Pharmaceuticals' trial design and results contributed to a 31% fall in the group's share price. In the phase 1 trial a 600mg dose of ASLAN004 showed [a statistically significant 65% change in skin clearance](#) from baseline at week 8. However, there were concerns about the removal of nine patients from the original intent-to-treat population and the study using a one-sided p value. Perhaps more worrying was that the number of patients achieving a IGA score of 0/1, ie clear or almost clear skin, was not significant at 48.3% versus 15.4% for placebo (p=0.107); this is important as the IGA 0/1 score is used for US approval. Arguably the sample size of 29 – reduced from 38 – was not powered to show a definitive result, but the result also appeared to show reduced efficacy; [in March 22% of patients achieved IGA or 0/1, compared with 0% on placebo](#). Aslan is looking to begin a phase 2 trial before the end of the year and one concern is that [what looks like waning efficacy](#) could be exacerbated with larger numbers.

ASLAN004 phase 1 trial						
Endpoint (8 weeks)	RITT (n=29)			ITT (n=38)		
	600mg	Placebo	p-value <sup>1</sup>	600mg	Placebo	p-value <sup>1</sup>
	(n=16)	(n=13)		(n=22)	(n=16)	
Mean % change from baseline in EASI	-64.9	-27.2	0.021	-61.3	-31.9	0.023
EASI-50 (%)	81.3	30.8	0.008	77.3	37.5	0.016
EASI-75 (%)	68.8	15.4	0.005	50	12.5	0.018
EASI-90 (%)	37.5	15.4	0.183	27.3	12.5	0.245
IGA 0/1 (%)	43.8	15.4	0.107	31.8	18.8	0.301
Mean % change from baseline in peak pruritus	-38.6	-15.3	0.051	-37.1	-15.7	0.032

*RITT = revised intent to treat; p-value<sup>1</sup> (one-sided p-value). Source: Company announcement.*

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