Evaluate Vantage

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Esmo 2021 – Beyondspring experiences winter of discontent

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Beyondspring's pledge to file plinabulin with the FDA next year has failed to reassure investors. The group's shares sank 33% yesterday, after full results from the Dublin-3 trial were presented at Esmo – a stark contrast to the 176% surge Beyondspring enjoyed after toplining the data in August. Even then there were questions around the results' relevance given that fewer than a quarter of the Dublin-3 patients had failed on a PD-(L)1 regimen, which is standard of care in first-line use; the trial largely recruited in China. A new subset in PD-(L)1 treated patients was unveiled, showing a 32% reduction in death, albeit with no significant median survival difference between the two arms. Esmo discussant Dr Maurice Pérol of the Léon Bérard Cancer Centre in France did not sound wholly convinced, pointing out that plinabulin achieved similar efficacy to Cyramza, the Lilly drug that is already approved third line, but with different safety profile. "It is difficult to know in which subset of patients [plinabulin] might be of interest... maybe frail patients where the haematological toxicities of [Cyramza] are a concern," he told the cancer conference. With so few options for these late-stage patients plinabulin might yet convince regulators, but it seems that not everyone is on side.

Dublin-3 trial					
Intent-to-treat population			**Subset PD-(L)1 analysis n=129**		
	Plinabulin + docetaxel	**Docetaxel**		**Plinabulin + docetaxel**	**Docetaxel**
Primary endpoint			**Primary endpoint**		
Mean OS	15.1 mths	12.8 mths	Mean OS	18.3 mths	14 mths
Median OS	10.5 mths	9.4 mths	Median OS	12.3 mths	12.1 mths
Log rank p value	0.039		***Log rank p value***	N/A*	
Hazard ratio	0.82		***Hazard ratio***	0.68	
**Sample size too small. Source: company presentation.*					