Evaluate Vantage

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Axsome soars on non-pivotal data

Elizabeth Cairns

When Axsome decided to stop the Accord study of AXS-05 in Alzheimer's disease agitation early, hopes for that trial took a nosedive. So it was clearly a pleasant surprise today when the company announced that the study had hit. Axsome's stock opened up 33%, and some investors might be hoping for an earlier-than-expected filing, despite the fact that results from the pivotal Advance-2 study are not due until 2025. Accord had initially been intended as a second pivotal, alongside the previously completed Advance-1, but when the number of agitation events turned out lower than expected, management decided to switch focus to Advance-2. Despite this, Accord met its primary endpoint, time to relapse of agitation, and a key secondary, relapse prevention. One potential fly in the ointment could be Accord's randomised withdrawal design; it comprised an open-label lead-in phase in which all 178 patients were given AXS-05, and those that had a sustained clinical response to the agent were randomised to either continue treatment or switch to placebo. AXS-05, a combination of dextromethorphan and bupropion, is approved in depression as Auvelity and moving into Alzheimer's agitation would be an important expansion.

Accord data (from double-blind period)		
	AXS-05	**Placebo**
N	53	55
Time to relapse	Stat sig vs pbo	-
Hazard ratio	0.275	-
P value	0.014	-
Risk of relapse	3.6-fold lower vs pbo	-
Proportion of pts relapsing (%)	7.5	25.9
P value	0.018	-
Rate of adverse events (%)	28.3	22.2
Discontinuations due to AEs (%)	0	1.9
Source: company release.		

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Evaluate HQ
44-(0)20-7377-0800

Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754

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