Evaluate Vantage

October 03, 2019

Durect’s Posimir Persistence earns it a reprieve

Madeleine Armstrong

It is not often that news of an FDA advisory committee meeting sends a company’s share price up. But the 7% rise in Durect’s stock yesterday, after the agency scheduled an adcom on January 16 to discuss the group’s painkiller Posimir, reflected the fact that it could have been worse. After all, the FDA rejected Posimir in 2014, and the subsequent Persist trial, designed to address the agency’s concerns, failed in 2017. Despite losing Novartis as a partner Durect pressed on, saying in February that it planned to reply to the FDA’s original complete response letter. Posimir had previously been set for an FDA approval decision by December 27; as a long-acting formulation of bupivacaine the project could benefit from not being an opioid. Stifel analysts give it a 30% chance of success, noting that the company has overhauled its previously confusing filing package to focus on six trials: two of these, in hernia and shoulder pain, were at least partially positive, while the other four trended in the right direction. This might not be enough for the FDA but there is now at least a chance, however slim, for Posimir.

"Positive" trials of Posimir				
			Co-primary endpoints	
Trial description	**ID**	**Dosing**	**Mean pain intensity 1-72h post-surgery**	**% pts using opioids**
Phase II in hernia repair	NCT00974350	Posimir 2.5ml or 5ml vs control	31% less pain with 5ml vs placebo; p=0.0031	53% with 5ml vs 72% with placebo 0-15 days post-surgery; p=0.09
Phase II in shoulder surgery	NCT00993798	Posimir 5ml vs placebo vs bupivacaine	20% less pain with 5ml vs placebo; p=0.012	67% reduction vs placebo 0-72h post-surgery; p=0.013
Source: Stifel note Oct 2, 2019; company releases.				