Pharmasset Pulls Drug From Study on Account of Toxicity Concern

December 22, 2011

Pharmasset has announced plans to amend one of its Phase II clinical trials in the wake of liver toxicity concerns among some study volunteers receiving the company's experimental nucleotide analogue PSI-938. The clinical trial, dubbed the QUANTUM study, will continue with its evaluation of PSI-7977, another nucleotide analogue being developed by the company that continues to show promise and hasn't raised safety concerns.

PSI-928 will be discontinued by all 235 individuals currently receiving the agent in the QUANTUM study, according to a December 16 Pharmasset announcement. "During routine safety monitoring," Pharmasset reports, "the company detected laboratory abnormalities associated with liver function in subjects receiving PSI-938 300 [milligram] once daily."

The QUANTUM study amendment stemming from the liver toxicity concerns surrounding PSI-938 sent shockwaves through the financial community, in light of pharmaceuticals giant Gilead Sciences November 21 announcement that it plans to acquire the smaller Princeton-based Pharmasset for $11 billion.

While an 'escape clause' in the penned purchase agreement allows Gilead to cancel the deal if serious safety issues arise with a key Pharmasset drug, a Gilead spokesperson told The Wall Street Journal that is not planning to invoke the clause based on the PSI-938 findings because the company is primarily interested is PSI-7999, The Journal report notes. "Since the announcement from Pharmasset regarding PSI-938 does not impact the development of PSI-7977, we do not believe the fundamental value of the deal has been impacted," Gilead's Amy Flood told the Journal.

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