Avexa Closes Phase III Trial of HIV Drug Apricitabine

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Avexa announced that it is closing a planned 48-week Phase III study of its antiretroviral drug apricitabine (ATC) early in order to analyze the data and make decisions about the drug's fate, according to a press release the company issued October 2.

Apricitabine is a second-generation nucleoside reverse transcriptase inhibitor (NRTI) in the same family as Epivir (lamivudine) and Emtriva (emtricitabine) and was designed to work against HIV resistant to those two drugs. A Phase IIb study indicated that ATC does, in fact, work against Epivir- and Emtriva-resistant virus.

The more recent Phase III study, which was expected to run through 2011, further explored ATC's long-term safety and effectiveness for treatment-experienced patients. The exact reason for the study's closure, with only 24 weeks of follow-up data available, is not clearly spelled out in Avexa's press release.

"The rationale for closing the trial…was based on two key factors. First, the results may offer key insight into ATC's role in the overall HIV treatment landscape, and discussions with regulatory authorities may clarify the ATC approval path. Secondly, this will allow for a mature enough data point to enable potential partners the ability to make a definitive decision on licensing of ATC," stated Julian Chick, PhD, Avexa's chief executive officer.

Avexa's press statement comes on the heels of an announcement in June 2009 that a safety monitoring board had terminated a study arm using a higher dose of apricitabine. The 24-week data from the study, potentially with details regarding the termination of the high-dose arm and the early closure of the Phase III study, are due in early 2010.

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