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Regeneron, Sanofi brain drug has side effects: US FDA

11 March 2014 | News | By BioSpectrum Bureau

Singapore: Regeneron Pharmaceuticals and Sanofi have been asked by the US FDA to assess potential neurocognitive side effects of their experimental cholesterol drug. Amgen also highlighted that it has also been communicating with the US FDA with respect to a similar drug that they are developing.

Although the FDA said that it could not discuss specific development programs, it revealed that it is "aware of concerns raised with neurocognitive adverse events and other lipid-lowering therapies, including statins, and as part of our oversight of new drug development, we are carefully monitoring these events."

The new drugs are part of an experimental class known as PCSK9 inhibitors, which are designed to block a protein that maintains LDL cholesterol in the bloodstream. Rare side effects such as memory loss, impaired concentration, and paranoia have been associated with the use of statins for lowering LDL cholesterol, and their labels include warnings about cognitive impairment.

Sanofi and Regeneron said they did not know how the FDA learned of the potential side effects, and they were not aware of any such side effects with alirocumab. In their filings, Sanofi and Regeneron said that if studies detect neurocognitive or other adverse side effects, development of alirocumab could fail or be delayed.

Amgen, which has said it could file for regulatory approval of PCSK9 drug evolocumab this year, said it has been proactively monitoring for cognitive impairment in its trials.