Product Withdrawals

Generic Name (Trade Nameâ€"Company)

January 26, 2017

Alirocumab

(Praluent—Sanofi, Regeneron)

Judge orders removal from market, but manufacturers will appeal

Uses/Notes

A District Court judge has ordered Sanofi and Regeneron Pharmaceuticals to take alirocumab (Praluent), a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor, off the U.S. market.

Amgen filed suit in October 2014 seeking a stop to Sanofi and Regeneron selling alirocumab, claiming infringement on its patent for a similar agent, evolocumab (Repatha). A jury found in favor of Amgen in March 2016. Sanofi and Regeneron then moved to have a judge overturn that ruling, but on January 5, 2017, Judge Sue L Robinson denied that motion.

Both Praluent and Repatha facilitate the removal of LDL from the blood by blocking PCSK9. Compared with placebo, Repatha reduced LDL by approximately 60%, while trial participants taking Praluent had an average reduction in LDL ranging from 36% to 59%.

Sanofi and Regeneron immediately issued a statement confirming their intention to appeal, noting that alirocumab will continue to be available in the interim.

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