FDA Puts a Hold on Development of ViiV HIV Drug

February 10, 2011

ViiV Healthcare announced that the U.S. Food and Drug Administration (FDA) has placed a hold on the development of a non-nucleoside reverse transcriptase inhibitor (NNRTI) that it was studying, a drug it had licensed from Idenix Pharmaceuticals in 2009.

The reason for the FDA development hold on GSK-2248761 (GSK-761; formerly known as IDX899) involved four reports of seizures as part of a clinical trial involving treatment-experienced patients. “As a result,” the company told HIV treatment activists on February 11, “the responsible course of action is to put the [GSK-761] studies on hold while we gather more information. The clinical team is now in the process of gathering further information on the cases in order to provide further guidance on next steps with [the drug].”

GSK-761 has been previously studied in several small Phase I and Phase IIa trials, and it was currently in two Phase IIb studies, including the one in which the seizures were reported. In earlier trials, the drug had shown effectiveness at low once-daily doses, and it was active against strains of HIV that are resistant to other NNRTIs.

“Two letters have been sent to the study investigators informing them of the serious adverse events,” explained the company officials. “These letters provide a summary of the adverse events, and guidance that investigators are to contact their patients, inform them of the risk of seizures and bring them in as soon as possible to change their medication from [GSK-761] to a suitable alternative and arrange for follow up care.

“This does not mean that the overall development program of [GSK-761] has been halted,” the company added.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.poz.com/article/hiv-gsk761-idenix-19885-4233