

US trial setbacks for Takeda cholesterol drug

By [Jobs4dd.com](#)

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Development of Takeda Pharmaceutical's cholesterol-lowering agent, TAK-475 (lapaquistat), will be held back following a request from the US Food and Drug Administration for additional clinical data. Takeda has indicated that this will delay lapaquistat's US registration filing beyond the company's original target date of April to June 2008.

The FDA has also recommended suspension of clinical trials involving higher doses of TAK-475 because of concerns over elevated levels of the enzyme transaminase - an indicator of possible liver damage. An increased frequency of elevated transaminase - including some severe cases - was observed compared with that in control groups in a pooled analysis of Phase II and III US and European study data. This pattern has not been seen to date with lower doses of TAK-475, however, where frequencies are comparable with those in control groups.

TAK-475 is a squalene synthase inhibitor currently in Phase II trials in Japan and Phase III trials in the US, Europe and Latin America, either alone or in combination with a statin, for the treatment of hypercholesterolaemia.

Takeda said it would "immediately study the future plans for TAK-475 in the US, Europe and Japan, and such plans will be announced once fixed through discussion with the relevant regulatory authorities".
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