Gilead Reports Success With Quad Pill and Boosting Drug

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Gilead Sciences is reporting early signs of success in two Phase II studies involving its experimental drug GS 9350, which boosts the blood levels of other drugs, according to a press release issued today by the company. The first study compared Atripla (efavirenz, tenofovir and emtricitabine) with Gilead's "Quad" pill containing GS 9350 plus three other drugs. The second study compared GS 9350 with Norvir (ritonavir) as a booster for the protease inhibitor Reyataz (atazanavir).

GS 9350 generated excitement when it was debuted at a conference in early 2009. At that time, Gilead announced it would be combining GS 9350 into a single once-daily pill with its experimental integrase inhibitor, elvitegravir, and Truvada (tenofovir plus emtricitabine). The company also reported it would develop GS 9350 as a stand-alone agent for use with non-Gilead antiretrovirals (ARVs) requiring boosting.

The Phase II study of the Quad pill covered in today's press announcement—the actual results of which have not been reported publicly—randomized 71 people who'd never taken ARV therapy before to take the Quad pill or Atripla. The goal was to achieve and sustain a viral load of less than 50 copies after 24 weeks of therapy.

Gilead reported the Quad pill was roughly similar to Atripla in terms of efficacy. The company did not include the specific numbers in its release, though it stated a similar number of people in both arms discontinued the drug. It is expected that data from the study will be reported at a future conference, possibly the 17th Conference on Retroviruses and Opportunistic Infections next month in San Francisco.

The second study compared Reyataz and Truvada combined with either GS 9350 or low-dose Norvir in treatment first-timers. Fifty people received the combination with GS 9350, and 29 received the combination with Norvir. Similar to the previous study, treatment success was defined as achieving and sustaining a viral load of less than 50 copies at 24 weeks. Though Gilead did not report the details, it did state the two arms had similar rates of effectiveness.

Phase III studies of both the Quad pill and GS 9350 as a booster for other drugs are planned.

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