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Ritonavir-Boosted Atazanavir May Show Promise for Maintenance Therapy in HIV

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July 29, 2005 (Rio de Janeiro) — Preliminary results of a study with ritonavir (Norvir)-boosted atazanavir (Reyataz) suggest that this protease inhibitor monotherapy can keep HIV RNA replication rates below clinically detectable levels in carefully selected patients for more than three years. However, concerns about virus replication rates detected in the cerebrospinal fluid and semen of some patients suggests that compartmentalization risks must be watched closely, according to findings presented here at the 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment.

"If [this study] proves correct, it will be a milestone," said Breno Riegel Santos, MD, from the Hospital Nossa Semhora da Conceicao, Porto Alegre, Brazil, who was moderator of the session.

"I was talking about this trial with my colleagues," Dr. Santos told Medscape. "In real life, nobody is confident to [use this form of monotherapy], it is still experimental. The lesson to be taken home is to wait for more data. It is not safe enough [now] to switch from a potent therapy to a single drug."

The study was presented by Pietro L. Vernazza, MD, of Cantonal Hospital, St. Gallen, Switzerland. Dr. Vernazza reported the data on the 28 patients recruited so far for this trial, which has a goal of 30 patients, after 48 weeks of follow-up. At entry, all patients had stable suppression of HIV RNA levels below 50 copies per mL, and all said they had no history of previous antiretroviral therapy failure.

Patients received ritonavir-boosted atazanavir (300/100 mg) daily and their HIV RNA values were measured every four weeks. The researchers defined treatment failure as two consecutive HIV RNA results above 400 copies per mL, or three or four consecutive measures above 200 or 100 copies per mL, respectively.

Dr. Vernazza reported that of the 28 patients (25 men) so far two have experienced treatment failure. "One patient told us he stopped treatment. His virus was of the wild type," Dr. Vernazza said. The second patient experienced treatment failure early, at week 8, even though he told researchers that he was taking his medications regularly.

"It was found out later that the patient had been treated by another physician, many years ago, he was suppressed, and it was found out that he had an antiretroviral drug failure," Dr. Vernazza told the audience. "So this patient was actually a protocol violator."

Some patients consented to spinal taps and semen sample testing. At week 24, among patients whose HIV RNA replication remained suppressed in blood tests, the researchers found that two of 50 semen samples had HIV RNA values above 100 copies per mL. Also, of the 12 patients who consented to cerebrospinal fluid testing, two showed an HIV RNA value above 100 copies per mL at week 24. "One patient had a quite high level of 1,700," Dr. Vernazza noted.

For future trials of this monotherapy, Dr. Vernazza recommended careful monitoring of compartmental HIV RNA values and obtaining a thorough medical history, to avoid including patients whose disease has previously failed to respond to this protease inhibitor.

"I think he is exploring it carefully, just as it should be," Joseph Eron, MD, of the University of North Carolina, Chapel Hill, who was in the audience, said during an interview. "I think we have enough information now that we need randomized trials. I now think it is okay to do the larger, comparative trials."

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Reviewed by Gary D. Vogin, MD
