New NNRTI Called RDEA806 Shows Promise

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Once-daily RDEA806, an experimental non-nucleoside reverse transcriptase inhibitor (NNRTI) being developed by Ardea Biosciences, appears highly active against HIV, is unlikely to have significant interactions with other meds and may have a useful side effect—reducing uric acid levels. These were the findings of a Phase IIa study reported at the 2008 joint meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Disease Society of America (IDSA) in Washington, DC.

RDEA806, at least in test tube studies, is active against HIV strains resistant to the NNRTI Sustiva (efavirenz), according to Graeme Moyle, MD, who presented the new data at ICAAC/IDSA. The drug also has a very limited effect on CYP450, the enzyme system responsible for breaking down many of the commonly used antiretrovirals (ARVs), meaning that RDEA806 can likely be used with other HIV meds without concerns of drug-drug interactions.

Ardea Study 201 enrolled 48 treatment-naïve patients to test two RDEA806 formulations: a capsule (dosed 400 mg twice daily or 600 mg once daily, both on an empty stomach) and an enteric-coated (EC) tablet (800 mg once daily, with food, and 1,000 mg once daily, on an empty stomach). One quarter of the study volunteers received a matching placebo.

All patients were men between ages 18 and 65 and were treated for 10 days. CD4 counts, upon entering the study, averaged 325 cells and viral loads averaged 39,000 copies.

Ten days of treatment with the three highest doses resulted in viral load reductions of about 1.7 log, Dr. Moyle reported. These results, along with reported pharmacokinetic data—reflecting the study of RDEA806 levels in the blood—suggest that the 800 mg capsule dose, along with the two tablet doses, be taken with food and be evaluated more fully in larger studies.

An apparent side effect of RDEA806 noted in the study may, in fact, prove beneficial—dramatic reductions in uric acid levels in all four dosing groups tested. Uric acid is produced from the natural breakdown of the body's cells. Higher-than-normal levels, while not necessarily associated with illness, can lead to problems such as kidney stones and the joint disease gout and ankylosing spondylitis.

For HIV-positive people with high uric acid levels, not only does RDEA806 have potential anti-HIV

benefits, but it may also help protect against diseases associated with high uric acid levels.

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http://beta.docker.poz.com/article/hiv-rdea806-experimental-15524-5449