KP-1461 Update

May 23, 2009 By Paul Dalton

The drug KP-1461 has long fascinated me (1, 2). It's novel mechanism- called Viral Decay Acceleration attempts to treat HIV infection by coaxing the virus into mutating itself to death. Years ago, I met with Koronis, the company developing the drug, as the were ramping up their development program. Fascinated by the sheer audacity of this mechanism, I have followed this drug a bit more closely than other drugs at similar stages of development.

As I wrote about in the earliest days of my blog, KP-1461 hit a major road block a while back. While still at Project Inform, I received a panicky sounding phone call from Stephen Becker- then the medical director for Koronis- and I knew something was up. Without rehashing details here, conflicting study results led to a full stop hold on development.

Last week Koronis issued a press release- copied below- claiming that their scientific advisory board had reviewed all of the clinical trials and laboratory data on KP-1461 and confirmed that it has measurable anti-viral activity and development of this compound will move forward.

As is typical, the press release is short on details. It states that 'recently completed passaging experiment' confirmed results from earlier, similar work. It was those passaging studies that were in question- the first set showed activity, a second set did not, and now apparently this third set confirms the first set of results.

I am not satisfied. I am awaiting a formal presentation of these results, with a thorough explanation of what went wrong with round 2. I have high hopes for this drug, but the discordant passaging results plus the hasty, quiet departure of Dr. Becker have cast a bit of a pall over things. I haven't lost hope in the drug, or the Koronis- but they need to do more to convince me that all is well in KP-1461 world.

Koronis Pharmaceuticals' Scientific Advisory Board Confirms KP-1461 Clinical Drug Activity, HIV Ablation

Seattle, WA (May 19, 2009) - Koronis Pharmaceuticals,

Inc., a biotechnology company focused on the development of antiviral therapeutics, today announced that its Scientific Advisory Board (SAB) completed a comprehensive review of the current in vitro and in vivo data for its lead HIV drug, KP-1461. The SAB concluded that recently completed in vitro serial passage studies corroborated the original published data, demonstrating that KP-1212, the active form of the oral prodrug KP-1461, ablated HIV in equivalent laboratory experiments. Additional studies are underway to assess ablation with greater sensitivity.

The SAB also reviewed statistical analyses of in vivo data from clinical trials of KP-1461. They concluded that KP-1461 demonstrated a statistically significant decrease in HIV RNA at the highest dose level as compared to placebo in the Phase 1b study. Decreases in HIV RNA were seen in some patients in Koronis’ Phase 2a study, though the results were not statistically significant. Each clinical study met its primary endpoint of demonstrating that KP-1461 was generally safe and

well tolerated.

“The current data confirms that the drug results in a substantial loss of HIV in tissue culture, demonstrates antiviral activity in HIV-positive patients and supports the continued development of KP-1461 and Viral Decay Acceleration?,” stated James Mullins, Ph.D., Professor of Microbiology and Medicine at University of Washington and Koronis SAB Chair.

According to Dr. Mullins, “Koronis has shown that in a repeat of previous work KP-1461 reduces HIV titer to below detectable levels without noting the drug resistance that is seen with currently approved HIV drugs. This demonstration of the VDA mechanism, if confirmed by further clinical studies, will dramatically alter the treatment paradigm for HIV patients.”

Koronis is in the process of completing formulation refinement and designing the next clinical studies of KP-1461.

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