

National AIDS Treatment Advocacy Project

NELFINAVIR PEDIATRICS STUDY 9/14/96

Agouron is initiating a pediatric (including adolescents) study of nelfinavir, a protease inhibitor, with a powder formulation. The powder comes in fruit flavors and can be added to milk. It is an important study because pediatric research for antiretroviral therapy moves much more slowly than drug development for adults. There aren't as many treatment options for children as there are for adults. It is particularly noteworthy that this trial is studying nelfinavir in newborns.

While adults have three protease inhibitors approved for use, there are none approved for pediatrics, and there are complications for pediatric use of the three approved protease inhibitors. Ritonavir's pediatric liquid formulation is distasteful. Although indinavir is in pediatric clinical study now and it is expected to prove efficacious and safe for most children, it is yet uncertain whether newborns may be able to take indinavir because of a bilirubin-related concern. The currently approved adult formulation of saquinavir has a low bioavailability.

A total of about 30 children will be enrolled in 4 age group cohorts in this ACTG study:

1. below 3 months (newborns)
2. 3 months to 2 years
3. 2 to 7 years
4. 7 to 18 years

This is a dose ranging study; children will be assigned different doses of monotherapy of nelfinavir for 6 weeks; then, the best dose will be selected and offered to study participants on an open-label basis, whereupon study subjects can take additional approved antivirals in a continuation of the trial.

It is hoped that the results from this study will be presented at the FDA Advisory Committee hearing which will consider accelerated approval for nelfinavir. The hearing is expected to occur in 1st quarter '97, and if positive data from this study is available, Agouron may seek a pediatric as well as the expected adult approval.

If you would like more information, the 4 study sites are listed with the names and telephone numbers for the site investigator:

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