

Table 14-6.06
Shifts of Hy's Law Values During Treatment

| | Shift [1] | Placebo (N=86) | | Xan. Low (N=84) | | Xan. High (N=84) | | p- value [2] |
|--|--------------|-----------------------|---------------------|-----------------------|---------------------|-----------------------|---------------------|--------------------|
| | | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | |
| Transaminase 1.5 x ULN | n | 82 | 2 | 80 | 2 | 80 | 0 | 0.392 |
| | Normal | 79 (96%) | 0 | 79 (99%) | 1 (50%) | 77 (96%) | 0 | |
| | High | 3 (4%) | 2 (100%) | 1 (1%) | 1 (50%) | 3 (4%) | 0 | |
| Total Bili 1.5 x ULN and Transaminase 1.5 x ULN | n | 84 | 0 | 82 | 0 | 80 | 0 | 0.381 |
| | Normal | 83 (99%) | 0 | 82 (100%) | 0 | 80 (100%) | 0 | |
| | High | 1 (1%) | 0 | 0 | 0 | 0 | 0 | |

NOTES: Only subjects with baseline results are included in the summary.

The single subject with elevated transaminase and elevated bilirubin also had elevated alk phos (>3xULN).

[1] A subject is counted only once for each analyte. A change will be considered shifting from normal at baseline to abnormal or from abnormal at baseline to normal at any visit during the treatment. The treatment period is defined as any planned visit after Week 0 (Visit 3), up to and including Week 24 (Visit 12).

[2] CMH test for general association, controlling for status at baseline.

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_hyslaw.sas

21:03 Monday, June 26, 2006