Trial 100 Global Commercial Strategy Summary

July 2003

Promotional Strategy

- When necessary, we will use combined Trial 99 and 100 pooled date to attain certain efficacy claims when Trial 99 data alone won't allow achievement. Most notable is the Day 7 onset claim in adjunct. Without the pooled data, we'd be left with Trial 99's Day 21 onset, which isn't competitive.
- Where Trial 99 data can stand on its own to make a competitive claim, we use it without Trial 100 augmentation – we do not add in Trial 100 data.
- We do not use Trial 100 efficacy data in isolation at any time.
- We use Trial 100 data in all safety claims as per the regulatory submission strategy.

Publications Strategy

- We will not publish Trial 100 by itself nor show any abstracts/posters.
- We must however publish Trial 99 and Trial 100 pooled data so that MCs can use efficacy claims arising from pooled data (e.g. Day 7).
- We also have prepared and presented Trial 99/100 pooled data in abstract/poster form, most recently at ICBD in Pittsburgh.

PR Strategy

- Jim Minnick has prepared and distributed a Q/A document approved by GPT that specifically states the Company line on why Trial 100 failed. This was most recently updated and distributed to all team members (including marketing companies) prior to APA.
- The key messages from this document about Trial 100's outcome have been disseminated in discussions with international KOLs at advisory boards and conference calls.
- Jim has also prepared and distributed a reserve press statement regarding Trial 100.

Caveat

The only exception to the above thus far comes from the UK. They cannot use Trial 99 data in visual promotional materials on its own unless they boldly state that we had another trial

that failed (Trial 100). As this would, be unacceptable, ALL adjunct claims in the UK are based on Trial 99/100 pooled data. With the adjunct data used in this fashion, the regulatory promotional requirement for full Trial 100 disclosure disappears.