

## Neuren to get early results from Glypromate® Phase 3 trial

- Phase 3 trial will end early based on interim review showing significantly better data quality than originally anticipated
- Same ability to determine efficacy can be achieved with 320 completed patients
- Recruitment in Phase 3 trial is now in excess of 300 patients and will be completed by the end of July
- Top level trial results will be released in late 2008, 6 months ahead of schedule

<u>SYDNEY Australia 30 June 2008</u>: Neuren Pharmaceuticals (ASX: NEU) today announced that an independent review of clinical data from the first 99 completed patients in the Phase 3 trial of its lead compound, Glypromate<sup>®</sup>, indicates that the trial will be able to achieve its goal of definitively assessing the efficacy of the drug with complete data from 320 patients rather than the 606 originally targeted.

The original sample size of the study was based on statistics from previous studies conducted in the field. A routine review of data quality and completeness conducted by the study statistician as part of the recently completed positive safety review indicated significantly better data quality as well as fewer missing observations than anticipated.

As a result, a decision was made to conduct an independent, blinded review of the statistical assumptions underlying the trial. This review indicated that Neuren will be able to complete the study with the same power and precision with only 320 completed patients, with top level efficacy and safety results released by the end of 2008, 6 months ahead of schedule. This change in the protocol has been submitted to the FDA as an amendment to the IND.

Commenting on this finding, Dr. Parmjot Bains, Neuren's co-Chief Executive Officer, said: "We are focused on doing all we can to reduce the time and cost of getting our promising drug compounds for central nervous system disorders and brain injury closer to registration. The revised patient numbers will allow us to announce the safety and efficacy results for Glypromate<sup>®</sup> later this year ahead of our published milestone of 2Q 2009 and at a lower cost than originally forecast."

Dr. Robin Congreve, Neuren's Chairman, said: "It's a credit to the professionalism and enthusiasm of the Neuren staff, and the Glypromate<sup>®</sup> global team and the sites conducting the trial that the quality of the data is better than in comparable studies in this patient population. For shareholders and patients, these results mean that we will be able to determine the effect of Glypromate<sup>®</sup> in cardiac surgery patients sooner than we had planned. This will permit us to speed the development of Glypromate<sup>®</sup> and assemble the resource base necessary to advance our other clinical programs for Motiva<sup>®</sup> and NNZ-2566 which we believe offer the potential to significantly enhance shareholder value."

## Explanation of the data

The recent analysis conducted reveals that actual variance in the data is lower and that fewer patients have been lost to follow-up than originally estimated when calculating sample size. Variance is a measure of the average distance between a set of data points and their mean value. This measure dictates the sensitivity of the comparison of efficacy results between patients receiving the drug and those receiving the placebo. The smaller the variance, the more sensitive is the comparison between active and placebo patients and the fewer patients that are required to achieve the trial end points. The initial sample size was based on a variance of 4.87 in the endpoint assessing change in cognitive function. The actual variance in the first 99 patients analysed is approximately half this, at 2.75. In addition, the initial projections on loss to follow up were based on losing 10% of patients, whereas, actual loss to follow up is also less at 7% of patients. As a result of this improvement in data quality and variance, the sample size requirement based on the same power and precision has been recalculated at 320 completed patients.

## About Neuren

Neuren Pharmaceuticals is a biopharmaceutical company developing novel therapeutics in the fields of brain injury and diseases and metabolic disorders. The Neuren portfolio comprises eight product families targeting markets with large unmet needs and limited competition. Neuren has three clinical-stage molecules — Glypromate<sup>®</sup>, Motiva<sup>™</sup> and NNZ-2566 — focused on a range of acute and chronic neurological conditions. For more information visit *www.neurenpharma.com* 

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