the clinical trials for publication in respected peer-reviewed journals confirms the quality of the data gathered during the development program.

During the period between approval and publication of pivotal data, the product monograph can be relied on for information, since it provides a summary of the findings as assessed by independent reviewers from the Health Protection Branch of Health Canada. The product monograph for donepezil, which includes a lengthy section on clinical trial data, has been made available to all physicians since the start of commercialization of this drug.

Notwithstanding the information provided here, we are sorry that the request to our company for the results of the 24-week study was not fulfilled, and we apologize for the inconvenience.

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[Dr. Serge Gauthier comments:]

There is indeed a lag time between completion of pivotal studies leading to regulatory approval and publication of results in peer-reviewed journals. In addition to reports on the main 24-week study[1] and open-label extension over 98 weeks,[2] 2 sets of guidelines for the proper use of the drug have been published.[3,4]

The cost-effectiveness of symptomatic anti-dementia drugs is a broad issue that is still under discussion. Pharmacoeconomic models have been proposed for tacrine, most recently from Sweden.[5] The main savings are expected to arise from delays in disease milestones (accompanied by the retention of high quality of life) and delays in the emergence of neuropsychiatric symptoms and subsequent admission to an institution.

Careful clinical observation of patients treated with such drugs will demonstrate improvement in cognition, activities of daily living and global functioning to a variable extent between individuals. This heterogeneity is inherent to Alzheimer's disease, and further research is needed on the clinical and biological predictors of response to treatment for patients with this condition.

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