

## STUDY FINDS SEROQUEL EFFECTIVE AND WELL TOLERATED

AstraZeneca today announced results from a study involving elderly patients with Alzheimer's disease (AD) treated with the atypical antipsychotic SEROQUEL (quetiapine) at the annual meeting of the American Association of Geriatric Psychiatry in San Diego, USA. The study found that SEROQUEL at 200 mg/day was effective in reducing agitation in elderly patients with AD without leading to a decline in cognitive function. SEROQUEL was also generally well tolerated with no incidence of cerebrovascular adverse events during treatment, which have been associated with the use of other atypical antipsychotics in this patient population. In the 30-day follow up, one cerebrovascular event was reported in the 100mg/day group.

The trial studied a sub-group of Alzheimer's disease patients from the STAR study. The primary goal of the STAR clinical trial was to examine elderly patients with dementia, including Alzheimer's disease and vascular dementia.

Dementia is a term for various progressive brain disorders, the most common being Alzheimer's disease, vascular dementia and dementia with Lewy bodies, that result in a loss of brain function. Symptoms of dementia include memory loss, problems with reasoning, judgement and speech, and the inability to perform everyday tasks. Behavioural disturbances, including agitation, have been reported in up to 90 percent of patients with dementia, which can result in patients becoming distressed and aggressive, putting an immense strain on caregivers and affecting their ability to care for the individuals.

"Agitation is a significant issue for both patients and their carers, as it is both difficult to manage and can be emotionally troubling," said Pierre Tariot, M.D., Professor of Psychiatry, Medicine and Neurology at the University of Rochester. "This new sub-group analysis in Alzheimer's patients adds further weight to the results from the STAR study released last year and justifies the continued investigation of SEROQUEL for agitation in this patient population."

The Alzheimer's analysis was from a 10-week, double-blind, placebo-controlled trial and included 260 patients with AD who were randomised to receive SEROQUEL 200mg/day, SEROQUEL 100mg/day or placebo. The key efficacy measures were improvements in the Positive and Negative Syndrome Scale-Excitement Component (PANSS-EC) scale, designed to measure symptoms such as hostility, tension and excitement; and the Clinicians' Global Impression of Change (CGI-C) scale, designed to enable clinicians to rate the level of improvement in symptoms. Cognitive decline was assessed using the Mini Mental State Examination (MMSE). The trial results showed:

- AD patients receiving SEROQUEL 200mg/day experienced significantly reduced symptoms of agitation compared to placebo as measured by PANSS-EC scores ( $p < 0.05$ ) and CGI-C scores ( $p < 0.05$ )
- A significantly greater percentage of AD patients receiving SEROQUEL (200mg/day) were rated "much improved" or "very much improved" in CGI-C scores (54 percent) compared with those in the placebo group (26 percent) ( $p < 0.01$ )
- Significantly more AD patients receiving SEROQUEL 200mg/day exhibited a less than or equal to 40 percent reduction in PANSS-EC scores compared to placebo ( $p < 0.05$ )
- Completion rates among AD patients was similar across the three groups: 67 percent, 66 percent and 63 percent for SEROQUEL 200mg/day, 100mg/day and placebo, respectively

· The mean ( $\pm$  Standard Deviation) changes from baseline in MMSE for SEROQUEL 200 mg/d, 100 mg/d and placebo were 0.2 ( $\pm$  2.6), -0.2 ( $\pm$  2.8), and -0.1 ( $\pm$  2.0), respectively, indicating no worsening of cognitive function in this patient population

"Due to the progressive nature of Alzheimer's disease, the ability to manage agitation without causing a decline in cognitive function is of notable clinical importance," added Professor Tariot.

SEROQUEL has been licensed for the treatment of schizophrenia since 1997 and is available in 82 countries for the treatment of this condition. SEROQUEL is also licensed in 63 countries for the treatment of mania associated with bipolar disorder, including the US, Canada and several European countries. SEROQUEL has not been approved for the treatment of agitation in Alzheimer's disease patients. To date, over 8 million people have been treated with SEROQUEL worldwide. SEROQUEL sales reached a new milestone in 2004, exceeding \$2 billion in annual sales for the first time.

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#### **Notes to Editors:**

· In Neuroscience, AstraZeneca is dedicated to providing medicines that have the potential to change patients' lives. The company already markets several products including SEROQUEL, one of the fastest growing global antipsychotics with proven efficacy and a very favourable side effect profile; and ZOMIG, a reliable migraine therapy and a leader within the triptan market. The Neuroscience pipeline includes leading approaches for the treatment of depression and anxiety, overactive bladder, dementia, stroke, pain control and anaesthesia.

SEROQUEL is a trademark of the AstraZeneca group of companies