

Press Release

REMINYL[®] XL (galantamine hydrobromide) A NEW ONCE-DAILY FORMULATION IS NOW AVAILABLE FOR PATIENTS WITH MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE

Basingstoke, UK 10 June 2005 – Shire Pharmaceuticals Group plc (LSE: SHP, NASDAQ: SHPGY, TSX: SHQ) announces that Reminyl[®] XL (galantamine hydrobromide) prolonged release capsules are now available in the UK and Ireland. Reminyl XL is a new once-daily treatment for the symptoms of mild to moderately severe Alzheimer's disease.

In clinical trials, Reminyl XL demonstrated comparable efficacy, safety and tolerability to twice-daily Reminyl tablets with the added convenience of once-daily dosing. In particular, a clinical study of 965 patients showed there was no significant difference in cognitive benefits between patients treated with Reminyl XL and Reminyl according to the Alzheimer's Disease Assessment Scale (ADAS-cog/11).¹ This study also showed that the ADAS-cog/11 scores of patients taking Reminyl XL were significantly better than those taking placebo at six months ($p < 0.001$).¹

There is also evidence that the prolonged release mechanism of Reminyl XL 24 mg o.d. is tolerated as well as Reminyl 12 mg b.d. in healthy subjects² and that the side effect profile may be improved.^{3,4}

"I've found that patients on Reminyl XL are less likely to suffer gastrointestinal problems and that it is easier to increase the dose of Reminyl in the once-daily formulation, Reminyl XL," said Dr Gillian McLean, Consultant Old Age Psychiatrist at Falkirk and District Royal Infirmary and Chair of the Scottish Division of Old Age Psychiatrists. "This increase in tolerability and the fact that it only needs to be taken once a day has definitely improved compliance."

There is evidence to suggest that Reminyl may slow the decline in cognitive function for up to four years and that patients maintained on Reminyl generally have a similar ADAS-cog rating at four years as the estimated rating for untreated patients at two years.⁵

In the only long-term randomised head-to-head study of Aricept[®] and Reminyl, 70% more Reminyl patients achieved the same or improved Mini Mental State Examination (MMSE) scores against baseline than patients taking Aricept.⁶ In this study of 182 patients, 67% of caregivers of Reminyl[®] treated patients reported maintenance or improvement in objective caregiver burden at 13 weeks; significantly more than the 52% of caregivers of Aricept treated patients ($p < 0.05$).⁶ However, the two drugs exhibited similar efficacy and safety on other parameters.

In another study, caregivers of patients taking Reminyl reported that they provided about an hour less a day helping patients with everyday tasks compared to caregivers of patients on placebo after six months.⁷ Patients who had been receiving Reminyl for three or more years spent a median of more than five years living in their own homes.⁸ Analyses suggest that long-term use of Reminyl is associated with a reduced relative risk of institutionalisation, equivalent to 27% for each year of treatment.⁸

People with Alzheimer's disease are often admitted to a residential or nursing home when they have become totally reliant on a caregiver, often a family member, for day-to-day care. At this stage, the burden of care is so extensive that caregivers can no longer cope with the commitment required for such an emotionally and physically demanding job.

"Postponing admission to a residential or nursing home for as long as possible is very important," explains Dr Peter Passmore, Consultant Physician in Elderly Care, Belfast City Hospital. "The caregivers of the patients on the new Reminyl XL obviously like the convenience of a once-daily dose as well. Many have seen a considerable improvement in the ability of patients to think things through and look after themselves, reducing the burden of care."

Dementia is a progressive brain dysfunction that leads to a gradual loss of a patient's ability to carry out daily activities. The most common and well-known type of dementia is Alzheimer's disease, which affects cognitive function (ability to think, reason and learn), personality and behaviour. Alzheimer's disease is the fourth-leading cause of death in Western countries, preceded only by myocardial infarction, cancer and stroke.⁹

Reminyl XL offers the benefits of galantamine in a once-daily prolonged release capsule. Reminyl XL capsules contain pellets that allow the immediate-release galantamine to be made readily available from the surface of the pellet and the prolonged-release galantamine to be released gradually through the micropores of the membrane as it dissolves.

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References

1. Data on file. GAL-INT-10. Shire Pharmaceuticals Ltd, 2005.
2. Data on file. GAL-NED-8. Shire Pharmaceuticals Ltd, 2005.
3. Brodaty H et al. Poster presented at the 8th European Federation of Neurological Societies, Paris, France, 2004.
4. Florence AT et al. *Drug Safety* 1994;10(3):233-266.
5. Truyen L et al. Poster presented at the 18th Alzheimer's Disease International Annual Conference, Barcelona, Spain, 2002.
6. Wilcock G et al. *Drugs Ageing* 2003; 20: 777-789.
7. Lilienfeld S et al. Poster presented at the 5th Congress of European Federation of Neurological Societies, Copenhagen, Denmark, 2000.
8. Feldman H et al. Poster presented at the 8th European Federation of Neurological Societies, Paris, France, 2004.
9. Nilsson AK *et al.* C3 and factor B deficient mice as a tool to study the role of the complement system in the pathogenesis of AD; Presented at Neuroscience Day, Lund.
<http://www.formonline.se/nd2000/abstracts/abstr39.html>

Reminyl[®] XL (galantamine hydrobromide) is a registered trademark of Shire Pharmaceuticals Development Limited in the UK and Ireland.

Shire Pharmaceuticals Group plc

Shire Pharmaceuticals Group plc (Shire) is a global specialty pharmaceutical company with a strategic focus on meeting the needs of the specialist physician and currently focuses on developing projects

and marketing products in the areas of central nervous system (CNS), gastrointestinal (GI), and renal diseases. Shire has operations in the world's key pharmaceutical markets (US, Canada, UK, France, Italy, Spain and Germany) as well as a specialist drug delivery unit in the US.

For further information on Shire, please visit the Company's website: www.shire.com

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