EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2010
EMA/CHMP/397789/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Sycrest

asenapine

On 24 June 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sycrest, 5 mg, 10 mg, sublingual tablet intended for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults. The applicant for this medicinal product is N.V. Organon.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Sycrest is asenapine (as maleate), a psycholeptic, antipsychotic (N05AH05). Based on its receptor pharmacology, the efficacy of asenapine is mediated through a combination of antagonist activity at D2 and 5-HT2A receptors. Actions at other receptors e.g., 5-HT1A, 5-HT1B, 5-HT2C, 5-HT6, 5-HT7, D3, and α2-adrenergic receptors, may also contribute to the clinical effects of asenapine.

The benefits with Sycrest are its ability to reduce manic symptoms in bipolar I disorder (moderate to severe manic episodes) and to maintain its effect during the episode for up to 12 weeks. The addition of Sycrest as adjunctive therapy has also shown superior efficacy over lithium or valproate monotherapy in reducing manic symptoms in bipolar I disorder and this effect was maintained for up to 12 weeks.

The most common side effects (seen in more than 1 patient in 10) are anxiety and somnolence. Other common side effects (seen in between 1 and 10 patients in 100) are weight gain, increased appetite, dystonia (slow or sustained muscle contractions), akathisia (restlessness), dyskinesia (involuntary muscle contractions), parkinsonism (slow movements, tremor), sedation, dizziness, dysgeusia (change in taste), hypoaesthesia oral (numb feeling of the tongue or in the mouth), alanine aminotransferase increased (increase in the level of liver proteins), muscle rigidity (muscle tightness) and fatigue.

A pharmacovigilance plan for Sycrest will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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The approved indication is: treatment of moderate to severe manic episodes associated with bipolar I disorder in adults.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Sycrest and therefore recommends the granting of the marketing authorisation.