European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 February 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
CONBRIZA

International Nonproprietary Name (INN): ***bazedoxifene***

On 19 February 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Conbriza, 20mg, film-coated tablets, intended for treatment of postmenopausal osteoporosis in women at increased risk of fracture. The applicant for this medicinal product is Wyeth Europa Limited.

The active substance of Conbrizais bazedoxifene, a Selective Oestrogen Receptor Modulator (ATC code G03XC02), whose biological actions are largely mediated through binding to oestrogen receptors. It has oestrogen-like agonistic effects on some tissues such as bone, whereas it has oestrogen-antagonistic or neutral effects on some other tissues, such as the breast.

The benefits with Conbrizaare its reduction in the incidence of new vertebral fractures compared to placebo in postmenopausal women. The rate of new vertebral fractures in women treated with bazedoxifene 20mg per day over 3 years was reduced by 42%. Bazedoxifene also increased the bone mineral density at the lumbar spine and other sites. The most common side effects are hot flushes and muscle spasms (including leg cramps). The most serious adverse reactions related to CONBRIZA were venous thromboembolic events, which were 1.9-fold more common than with placebo with treatment over 3 years.

A pharmacovigilance plan for Conbriza, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Conbrizais indicated for the treatment of postmenopausal osteoporosis in women at increased risk of fracture. A significant reduction in the incidence of vertebral fractures has been demonstrated; efficacy on hip fractures has not been established.
When determining the choice of Conbrizaor other therapies, including oestrogens, for an individual postmenopausal woman, consideration should be given to menopausal symptoms, effects on uterine and breast tissues, and cardiovascular risks and benefits (see section 5.1).”

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit to risk balance for Conbrizaand therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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