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Levact(R) (bendamustine) Recommended for Approval in Europe for Treating Blood Cancers

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Cambridge, England, March 19, 2010 (ots/PRNewswire) - Mundipharma announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending that marketing authorisations can be granted in Germany and the following Member States of the EU: Austria, Belgium, Denmark, Finland, France, Ireland, Italy, Luxembourg, Norway, Poland, Spain and the United Kingdom (UK) for the use of bendamustine in the treatment of patients with indolent non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL) and multiple myeloma (MM).[1] If adopted by EU authorities, bendamustine will be another vital treatment in the fight against blood cancers.

Dr Thomas Mehrling from Mundipharma commented, "We are delighted with this decision and believe it represents a dramatic step towards improved treatment for patients with haematological malignancies."

Following a European Commission decision on this positive opinion and the granting of national licences, the first launches of bendamustine in the European Union are anticipated in mid-2010 in Austria, Denmark, Finland and the UK.

Bendamustine is a highly effective chemotherapy agent which differs from those that are already available due to its unique chemical structure and activity.[2] The announcement is particularly important for those patients with common white blood cell malignancies, notably indolent NHL, CLL and MM, including those patients with indolent NHL that have not responded to other therapies, or those patients where their cancer has returned after a period of absence.

Bendamustine is currently licensed in Germany (under the brand name Ribomustin(R)) for CLL, first-line therapy of advanced indolent NHL in a combination protocol, and in combination with prednisone for advanced MM stage II with progress or stage III.[3] Between 2008 and 2009, bendamustine was used to treat 13,357 patients in Germany.[4] In the United States, bendamustine is indicated for the treatment of indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen and also for the treatment of patients with CLL.[5] Since its launch, 14,000 patients have been treated in the United States.[6]

"New treatments capable of inducing further remission without excessive toxicity are urgently needed. Many of the patients who may benefit from bendamustine currently have no or few treatment options available. This product provides these patients with renewed hope" commented Professor Marco Montillo, Department of Haematology, Niguarda Ca'Granda Hospital, Milan, Italy.

References

[1] European Medicines Agency website: Accessed March 2010: <http://www.ema.europa.eu/>

[2] Leoni LM et al, Bendamustine (Treanda) Displays a Distinct Pattern of Cytotoxicity and Unique Mechanistic Features Compared with Other Alkylating Agents. Clin Cancer Res 2008; 14(1):309-317

[3] Ribomustin SPC

[4] IMS Oncology Analyzer- data on file

[5] Treanda website: Accessed March 2010: <http://www.treanda.com/>

[6] Tandem Audit 2010-data on file

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