



Meda in-licenses exclusive rights to Ceplene

Meda has in-licensed exclusive rights to Ceplene (*histamine dihydrochloride*) from EpiCept Corporation, a US-based biopharmaceutical company. Meda's rights cover Europe and several key markets in Asia including Japan, China and Australia. Ceplene is indicated for remission maintenance therapy and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML). More than 16,000 new cases of AML are diagnosed in the EU every year. Most patients will suffer a relapse within one year.

Ceplene is an important advance in treating AML reoccurrence due to the lack of alternative treatments. In a multicenter study, Ceplene met its primary endpoint of prolonging leukemia-free survival for AML patients in remission. The difference between the treated and control group was highly statistically significant ($p < 0.008$).

Ceplene is approved by the European Commission as an orphan drug¹. In the EU, orphan drugs receive 10 years of market exclusivity. Similar protection is likely to be granted in other markets.

"Ceplene is a unique drug and we hope that Ceplene will be able to help patients that today have few alternatives. There is also a good fit with our pain product Onsolis, indicated for breakthrough pain in cancer patients", says Anders Lonner CEO Meda.

Ceplene is also under investigation for additional indications such as Myelodysplastic Syndrome (MDS) and Chronic Myelogenous Leukemia (CML).

¹ Orphan drugs are defined as drugs that treat rare and life-threatening conditions

In consideration of being granted the exclusive rights to Ceplene, Meda will pay EpiCept 3 MUSD upfront and an additional 2 MUSD upon launch. EpiCept is also eligible to receive 5 MUSD as a regulatory milestone. Sales based milestones will be due once Ceplene reaches annual sales of 50 MUSD and 100 MUSD. The milestone payments for those sales levels are 10 MUSD and 20 MUSD respectively. EpiCept will receive a double digit royalty on net sales.

If questions, please contact:

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