Clavis Pharma Announces Positive Elacytarabine Phase II Results

Independent data monitoring committee confirms initial results

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Clavis Pharma ASA (OSE: CLAVIS) announces positive results from a second interim analysis of the elacytarabine (CP-4055) Phase II study in patients with late stage acute myeloid leukaemia (AML). An interim analysis of data from 40 patients has been assessed by an independent data monitoring committee. The review confirms the positive results from the first 20 patients presented earlier.

Late stage AML patients represent a difficult-to-treat patient group that have failed two previous therapeutic regimens. As part of the Phase II study, these patients received their third line treatment, also called second salvage therapy. The treatment of this patient group constitutes a significant unmet medical need, as there is currently no standard therapy available and expected survival is very short. The interim data from the Phase II study shows that six out of 40 patients attained complete response, which is higher than comparable published data for this patient group. Elacytarabine was well tolerated, also by elderly patients. The study is still ongoing.

"We are very pleased with these encouraging results from the first forty patients in a very difficult-to-treat population" says CEO Geir Christian Melen in Clavis Pharma. "The results represent a proof of concept for our first drug candidate elacytarabine as a novel treatment for AML and make our drug much more attractive amongst potential partners", he says.

Frank Giles, professor and chief of haematology and medical oncology at The University of Texas Health Science Center and co-ordinating Principal Investigator comments "Elacytarabine is an exciting agent with a strong design rationale and positive initial results in patients with resistant AML. This is a very challenging disease in which current therapies are acknowledged to be inadequate for the great majority of patients. This is particularly true for patients whose disease has failed initial therapy - the population on whom we intend to focus with future elacytarabine studies".

Preliminary interim data from the Phase II study were previously announced at the American Society of Hematology Annual Meeting in December 2008. Elacytarabine is currently in development in AML both as monotherapy for late stage patients and in combination with idarubicin for patients who have failed early therapy (1st course failures). Elacytarabine has a favourable safety profile and clinical responses have been reported throughout the Phase I and II parts of the program. A Phase I study in combination with idarubicin is completed, and a Phase II combination study in patients who have failed early therapy is under planning. The current elacytarabine AML program involves 15 major cancer centres in the USA and Europe.

Elacytarabine has previously been granted orphan drug designation by both the FDA and the European Commission for the treatment of AML. Elacytarabine is proposed by the World Health Organization as the international non-proprietary name (pINN) for CP-4055. The proposal is supported by the United States Adopted Name Council.

Contact:
Geir Christian Melen
Chief Executive Officer
Office : +47 24 11 09 50
Mobile : +47 91 30 29 65
E-mail : geir.christian.melen@clavispharma.com

Gunnar Manum
Chief Financial Officer
Office : +47 24 11 09 71
Mobile : +47 95 17 91 90
E-mail : gunnar.manum@clavispharma.com

Clavis Pharma ASA

Head Office:
Parkveien 53 B
NO-0256 Oslo
Norway
Tel: +47 24 11 09 50
Fax: +47 24 11 09 51

Porsgrunn Office:
Arthur Berbys vei 6
NO-3908 Porsgrunn
Norway
Tel: +47 35 56 69 33/35
Fax:+47 35 92 22 89

www.clavispharma.com
mail@clavispharma.com

NO 983 733 506 MVA

About Leukaemia
Approximately 300,000 new cases of leukaemia are diagnosed globally each year, resulting in around 220,000 deaths. Leukaemia represents a market with high unmet medical needs, which may open for accelerated approval processes to expedite market access for new drugs. It is a segmented market covering a broad variety of disorders. A major clinical concern is the high rate of disease recurrence. The five-year survival for the most common acute leukaemia type, acute myeloid leukaemia (AML), is in the range of 5-10% for treated elderly patients, and approximately 30% for treated younger adults.

About Clavis Pharma
Clavis Pharma ASA is an oncology focused pharmaceutical company using its proprietary Lipid Vector Technology (LVT) platform to create New Chemical Entities (NCEs), by significantly improving already established drugs. The improvements are achieved by chemically binding specific unsaturated lipids to existing, and well understood, approved pharmaceuticals. Data generated suggests the resulting patentable NCEs offer improved efficacy and reduced side effects through enhanced pharmacokinetic properties, greater tissue penetration and, in many cases, additional modes of action.

Clavis Pharma's objective is to develop its drug candidates until significant value has been created and proof of principle in man has been shown. For further clinical development and commercialisation of the products, Clavis Pharma will enter into strategic partnerships with established pharmaceutical or biotech companies. The company's product portfolio includes four new cancer drugs: Elacytarabine is in Clinical Phase II, Intravenous CP-4126 is in Clinical Phase I, Oral CP-4126 in Phase I, and CP-4200 is in early preclinical development. Results indicate that these products have promising potential for several cancer indications within solid tumours and leukaemia.

The shares of Clavis Pharma ASA are listed on the Oslo Stock Exchange (ticker: CLAVIS).

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