

Clavis Pharma receives US Orphan Drug Designation for CP-4126 to treat pancreatic cancer

Oslo, Norway, 7 January 2010

Clavis Pharma (OSE: CLAVIS); the Norwegian cancer drug development company, announced today that the US Food & Drug Administration (FDA) has granted orphan drug designation to CP-4126 for the treatment of pancreatic cancer. The designation follows the equivalent designation given by the European Commission in October last year.

“There is an urgent need for new drugs to treat pancreatic cancer, which currently has very limited treatment options and high mortality. The incentives provided by orphan drug designation in US may accelerate the clinical development of Intravenous CP-4126,” said Geir Christian Melen, CEO of Clavis Pharma. “We are therefore pleased to receive this orphan drug designation for CP-4126, in addition to the European Commission designation received last year.”

The US Orphan Drug Act provides incentives to encourage the development of drugs for rare disease conditions affecting fewer than 200,000 persons in the United States of America (USA). The designation allows for amongst others a possible exemption from the FDA-user fee and assistance in clinical trial protocol design. If CP-4126 receives marketing approval for pancreatic cancer in the USA, the designation will entitle the marketing authorisation holder to exclusive marketing rights for pancreatic cancer for seven years following the approval.

It should be noted that orphan drug designation does not limit a drug to less common diseases. The drug may, in parallel or afterwards, be developed for more common diseases.

Clavis Pharma entered a partnership agreement with Clovis Oncology Inc., in November last year for the further development and commercialisation of the Clavis Pharma drug candidate, CP-4126, currently in Phase II development in pancreatic cancer. CP-4126 is a novel, patented, lipid-conjugated form of the anti-cancer drug gemcitabine that has the potential to improve treatment outcomes in a large subset of patients with pancreatic cancer and certain other solid tumours.

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About Intravenous CP-4126

Intravenous CP-4126 is based on Clavis Pharma's proprietary Lipid Vector Technology (LVT) and aimed at improving the therapeutic profile of the current standard treatment for advanced pancreatic cancer, gemcitabine (Gemzar®). Currently it is estimated that pancreatic tumours in up to two-thirds of patients have a deficient cellular uptake of gemcitabine due to deficient expression of a necessary transport protein, hENT1 (human equilibrative nucleoside transporter 1) on the tumour cell membrane. This is known to limit the efficacy of gemcitabine treatment in these patients. In contrast, cellular uptake of Intravenous CP-4126 is independent of hENT1, which offers a potential clinical advantage for the product in the treatment of pancreatic cancer. Clavis Pharma is developing Intravenous CP-4126 in collaboration with Clovis Oncology.

Clovis Oncology is focused on acquiring, developing and commercializing innovative anti-cancer agents in the US, Europe and additional international markets. The company was founded in 2009 by former executives of Pharmion Corporation, a leading global oncology company, which was acquired by Celgene Corporation in 2008 for \$2.9 billion.

Clovis Oncology secured \$146 million in start-up financing from leading international healthcare-focused investors, including Domain Associates, New Enterprise Associates (NEA), Versant Ventures, Aberdare Ventures, Abingworth, Frazier Healthcare Ventures, ProQuest Investments and the Company's management team in 2009. The Company is headquartered in Boulder, Colorado, and has additional offices in San Francisco, CA and London, UK.

About Pancreatic cancer

Pancreatic cancer is a very serious disease and an indication with a high unmet medical need. Approximately 37,000 new cases of pancreatic cancer were recorded in the USA in 2007. The 1-year and 5-year overall survival rates are estimated at 23% and 4%, respectively. The majority of these patients has unresectable disease or will recur after surgery. Median overall survival in these patients is approximately 8-12 months. The standard first-line therapy for patients with unresectable disease is gemcitabine monotherapy. Unfortunately, many of these patients fail to benefit from treatment.

About Clavis Pharma

Clavis Pharma ASA is a clinical stage oncology drug development company based in Oslo, Norway with a portfolio of novel anti-cancer drugs in development. These patented New Chemical Entities (NCEs) are novel, improved versions of commercially successful drugs, made using Clavis Pharma's Lipid Vector Technology (LVT) chemistry. Data generated suggests these potential breakthrough products may offer improved efficacy and reduced side effects through enhanced pharmacokinetic properties, greater tissue penetration, altered metabolism and, in certain cases, additional modes of action.

Clavis Pharma's has several drug candidates in formal development studies:

- Elacytarabine, an improved form of Ara-C, a leukaemia drug – about to commence a Phase III randomized, controlled registration study in late-stage acute myeloid leukaemia;
- Intravenous CP-4126, an improved version of gemcitabine – currently in a Phase II comparative study with gemcitabine for the treatment of pancreatic cancer;
- Oral CP-4126 – currently being evaluated in an escalating dose Phase I study in solid tumours; and
- CP-4200, an azacitidine derivative – in preclinical development for myelodysplastic syndrome (MDS), often a precursor to myeloma or leukaemia.

Clavis Pharma intends to commercialise its products through strategic alliances and partnerships with experienced oncology businesses and, where and when commercially

appropriate, by establishing its own sales and marketing capabilities. CP-4126 is licensed to Clovis Oncology in the Americas and Europe. Clavis Pharma has retained rights in other territories and an option to co-promote CP-4126 in Europe.

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

Disclaimer

This news release contains forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on results of operations and the financial condition of Clavis Pharma. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements. These factors include, among other things, risks associated with technological development, the risk that research & development will not yield new products that achieve commercial success, the impact of competition, the ability to close viable and profitable business deals, the risk of non-approval of patents not yet granted and difficulties of obtaining relevant governmental approvals for new products.

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