Clavis Pharma and Clovis Oncology Sign $380 Million Partnership for the Development and Commercialisation of Anti-Cancer Agent CP-4126

- **CP-4126 is a novel, lipid-conjugated form of gemcitabine designed by Clavis Pharma to improve treatment outcomes in patients with pancreatic and other solid tumours**
- **Clavis Pharma to receive up to $380 million in staged payments, including a $15 million signing fee, and tiered double-digit royalties on sales**
- **Clovis Oncology fully responsible for the clinical development of CP-4126**
- **Clovis Oncology to commercialise CP-4126 in the United States, Europe, Canada, Central and South America**
- **Clavis Pharma retains an option to co-promote and share profits in Europe**
- **Companies to collaborate on development of a companion diagnostic test to identify patients likely to benefit most from CP-4126 treatment**

Oslo, Norway, and Boulder, CO, USA. November 24, 2009

Clavis Pharma ASA (OSE: CLAVIS), the clinical stage oncology focused pharmaceutical company, and Clovis Oncology, Inc., the newly formed oncology company led by former Pharmion Corporation executives, announced today an agreement 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.

Under the terms of the agreement, Clovis Oncology will take over responsibility for product development and manufacturing of CP-4126, and for filing of marketing approvals in the United States, Europe, Canada, Central and South America and will be responsible for commercialisation in those territories. Clavis Pharma retains the option to co-develop and co-promote CP-4126 in Europe.

Clavis Pharma will receive an upfront cash payment of $15 million from Clovis Oncology and will be eligible to receive further payments totalling up to $365 million on Clovis Oncology's successful attainment of development, regulatory and sales milestones. Clavis Pharma will receive tiered double-digit royalties on all product sales in the licensed territories.

Under the terms of the agreement, the Companies are amending the design of the ongoing Phase II study in pancreatic cancer to enroll approximately 250 patients in an international, randomised, comparative trial of CP-4126 versus gemcitabine with overall survival as a primary endpoint.

In addition to evaluating survival in all patients, study results will be analysed based on patient classification in relation to their levels of expression of the hENT1 pancreatic tumour protein. The hENT1 (human equilibrative nucleoside transporter 1) cell membrane transporter is believed to be critical for gemcitabine entry into tumor cells, whereas CP-4126 enters and kills tumour cells in a hENT1-independent manner. Patients will be classified as being hENT1-high or hENT1-low and particular emphasis will be given to comparative overall survival in the hENT1-low population. Data from this trial are expected in the first half of 2012.

Commenting on the deal, Geir Christian Melen, CEO of Clavis Pharma, said:

"We are delighted to be working closely with the team at Clovis Oncology, who will now be responsible for bringing our new and improved anti-cancer product to market in the Americas and Europe. They have substantial experience of successful cancer drug development and marketing and will bring significant resources, expertise and commitment to the conduct of the CP-4126 clinical programme and achieving regulatory approvals in these major markets.

"We view this agreement as an important validation of Clavis Pharma's potential to generate multiple novel cancer drugs with enhanced performance over existing therapeutics. This strategic partnership for CP-4126, our second product under development, will enable us to focus resources on developing our portfolio further and provides great momentum towards our building a successful oncology business."

Patrick Mahaffy, President and CEO of Clovis Oncology added:

"We are very enthusiastic about the potential for CP-4126. Gemcitabine is the standard of care in pancreatic cancer, but accumulating data suggest that a significant percentage of patients may derive little benefit from its use because of low expression of the hENT1 transporter that allows gemcitabine to enter tumour cells. In vitro data demonstrate that CP-4126 overcomes this resistance mechanism. We now have the opportunity to show that a cytotoxic, which remains the backbone of cancer therapy, can become an effective, targeted therapy in this large subset of patients. Our development philosophy is to focus on providing meaningful benefit to subset patient populations with unmet medical need and we believe CP-4126 will do exactly that."

Confirmation of the hENT1 hypothesis offers a promising and novel enhancement to current treatments for patients with pancreatic cancer," said Daniel D. Von Hoff, M.D., Physician in Chief, Translational Genomics Research Institute and Clinical Professor of Medicine at the University of Arizona. *"This is an exciting new concept that may enable both superior targeting of an established drug, gemcitabine, as well as providing a new, rational treatment option, CP-4126, to hENT1-low patients."*

About CP-4126

CP-4126 is a new, patented, cytotoxic drug, consisting of an anti-cancer nucleoside analogue coupled to a lipid chain. It was generated using Clavis Pharma's proprietary Lipid Vector Technology and has been designed to improve the therapeutic profile of gemcitabine (Gemzar®) so that it can enter cancer cells without requiring uptake by a specific transporter molecule. Gemcitabine is the current standard treatment for advanced pancreatic cancer and intravenous CP-4126 is currently being evaluated in a Phase II clinical trial in this indication. Other potential indications for CP-4126 are those currently treated with gemcitabine, including lung, breast, ovarian and bladder cancer. An oral formulation of CP-4126 is currently in a Phase I clinical trial in pancreatic cancer.

It is estimated that pancreatic tumours in up to two-thirds of patients have limited cellular uptake of gemcitabine, due to deficient expression of the transport protein, hENT1 on the tumour cell surface. In a number of independent studies of patients with pancreatic cancer, a low level of hENT1 has been correlated with poor outcomes after gemcitabine therapy. Published research has also suggested that hENT1 levels predict outcome in lung cancer patients treated with gemcitabine-containing chemotherapy. Due to its different molecular design, CP-4126 is absorbed by cancer cells independent of hENT1 levels, raising the prospect of a major improvement in drug efficacy in the significant and potentially poorly-served group of hENT1-low patients.

CP-4126 is currently being compared to gemcitabine in an international, randomised, controlled Phase II trial in patients newly diagnosed with advanced pancreatic cancer. Originally designed by Clavis Pharma as a 120 patient study, Clovis Oncology is altering the study design to increase enrolment to approximately 250 patients, randomising between gemcitabine and CP-4126, and will use overall survival as its primary endpoint. Expression of hENT1 in tumour tissue will be measured during the trial and patients categorised into hENT1-high or hENT1-low groups prior to final analysis, with primary emphasis on comparative overall survival in the hENT1-low population.

This study is a well-powered, prospective test of two hypotheses: (1) that low pancreatic tumour hENT1 expression is associated with poor outcome after gemcitabine therapy, and (2) that CP-4126 will have superior efficacy in hENT1-low patients compared with gemcitabine. Data from this trial are expected in the first half of 2012. As a key element of the clinical programme, a validated companion molecular diagnostic test to reliably determine pancreatic tumour hENT1 expression and enable patient stratification will be developed by the two companies.

CP-4126 has been granted orphan drug status for the treatment of pancreatic cancer in the European Union and is currently being considered for a similar designation by the FDA in the US.

About Pancreatic Cancer

Pancreatic cancer presents a major unmet medical need due to the poor survival outcomes and limited number of therapeutic options available to patients. Approximately 37,000 new cases of pancreatic cancer were recorded in the US in 2007. The 1-year and 5-year overall survival rates are estimated at 23% and 4%, respectively. The majority of pancreatic cancer patients are diagnosed with locally advanced (unresectable) or metastatic disease. Median overall survival in these advanced patients is 4-10 months.

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Investor Meeting and Conference Call

A meeting for investors, analysts and press will take place in Oslo at 10.00 CET today, 24 November 2009 at Hotel Continental, Stortingsgaten 24, Oslo, Norway.

An international conference call will take place at 12:00 CET – details are given below.

Access the audio for the meeting by dialling the following and quoting confirmation code 4956336:

+47 2415 9758 (from Norway)
+44 (0)20 7806 1966 (International)

For visuals click on the direct access link:

http://www.livemeeting.com/cc/premconfeurope/join?id=4956336&role=attend&pw=pw6623

Participating in the Meeting and Conference Call will be:

Geir Christian Melen, CEO, Clavis Pharma ASA
Keith McCullagh, Chairman, Clavis Pharma ASA
Patrick Mahaffy. President & CEO, Clovis Oncology Inc.

The presentation will be made available on www.clavispharma.com in the Investors section from 09:00 CET. A webcast of the conference call will be available from Clavis Pharma's website, www.clavispharma.com for a period of 60 days.

About 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.

Earlier this year 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.

While at Pharmion, the Clovis Oncology management team increased revenues from zero to approximately $300 million, gained regulatory approval for and launched the world's first epigenetic cancer drug, Vidaza® (azacitidine), a DNA demethylating agent for the treatment of Myelodysplastic Syndromes in the US and Europe, and gained regulatory approval for Thalidomide for the treatment of multiple myeloma in Europe and other international markets. Pharmion also had a number of other oncology compounds under development, including amrubicin for lung cancer.

The Company is headquartered in Boulder, Colorado, and has additional offices in San Francisco, CA and London, UK.

About Clavis Pharma

Clavis Pharma ASA is a clinical stage oncology focused pharmaceutical company based in Oslo, Norway with a portfolio of novel anti-cancer drugs in development. These potential breakthough products are New Chemical Entities (NCEs) made using Clavis Pharma's Lipid Vector Technology (LVT) chemistry to introduce new properties to already established, commercially successful drugs. Data generated suggests the resulting patentable NCEs 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.

The shares of Clavis Pharma ASA are listed on the Oslo Stock Exchange (ticker: CLAVIS). The largest shareholders of Clavis Pharma include Neomed, Medical Venture Management and Braganza.