



FOR IMMEDIATE RELEASE

FDA Grants Orphan Drug Designation to ChemGenex's Omacetaxine for the Treatment of Myelodysplastic Syndromes

MELBOURNE, Australia, and MENLO PARK, California U.S.A. (January 20, 2009). ChemGenex Pharmaceuticals Limited (ASX:CXS and NASDAQ:CXSP) announced today that the United States Food and Drug Administration (FDA) has granted Orphan Drug designation to omacetaxine for the treatment of Myelodysplastic Syndromes (MDS).

Orphan drug designation is intended to support the clinical development of new drugs in diseases affecting less than 200,000 people in the United States. The FDA often provides technical and financial assistance to expedite and optimize drug development and on approval, grants a seven year period of market exclusivity.

MDS describes a group of bone marrow disorders that are characterized by a defect in stem cells. MDS is most common in elderly patients as they are more prone to bone marrow damage but it can occur in any age group. Approximately 15,000 people per year in the USA are diagnosed with MDS (overall incidence is approximately 5 cases per hundred thousand people per year).

Hagop Kantarjian M.D., Professor of Medicine and Chairman of the Department of Leukemia at MD Anderson Cancer Center in Houston, Texas, said: "MDS is a very important blood disorder with significant unmet clinical needs in patients who fail approved therapies. Published data has demonstrated the clinical activity of omacetaxine in this patient population and we look forward to future possible clinical trials to consolidate our understanding of this product in the treatment of MDS".

Dr. Greg Collier, ChemGenex's Managing Director and Chief Executive Officer added: "Orphan designation for omacetaxine reflects our corporate strategy of expanding the use of the drug to other hematological conditions where new treatment options are needed to improve patient outcomes."

"Whilst expansion into MDS is integral to realizing the full commercial potential of omacetaxine, we remain focused on our primary objective of seeking regulatory approval for the drug in CML patients with the T315I mutation. The enrollment target for our registration-directed clinical trial for omacetaxine was achieved on schedule in December, and we remain on track to complete the rolling NDA submission to the FDA in mid 2009."

About Omacetaxine

Omacetaxine mepesuccinate is a first-in-class cetaxine with established clinical activity as a single agent in a range of hematological malignancies. Omacetaxine has a novel mechanism of action, and

induces apoptosis by inhibition of protein synthesis, particularly Mcl-1. As omacetaxine acts independently of tyrosine kinase inhibitors, it has therapeutic advantages for patients who have developed resistance to tyrosine kinase inhibitor therapy. Omacetaxine is administered subcutaneously.

The most recent clinical data from the pivotal study in CML patients who harbor the T315I mutation were presented at ASH in December 2008. The highlights were;

- Complete hematologic responses (CHR) in 80% of chronic phase patients, median response duration 11.5+ months (range 3.5-25.4+ months)
- Major cytogenetic responses (MCyR) in 20% of chronic phase patients, median response duration 4.8+ months (range 0.3-9.7+ months)
- Progression Free Survival (PFS) rates for chronic phase patients of 80% at 1 year and 70% at 2 years
- Hematologic responses in 45% of accelerated phase patients (median duration 9.6+ months) and 13% of blast phase patients
- In 64% of patients, the T315I clone is reduced to below the limits of detection

Investigators reported that omacetaxine is generally well tolerated, and that the most common side effect, reversible and transient myelosuppression, rarely results in serious clinical complications

Data were presented from 44 patients: 25 in chronic phase, 11 in accelerated phase and 8 in blast phase

About MDS

Myelodysplastic syndromes (MDS) encompass a broad range of hematologic malignancies that are characterized by ineffective blood cell production. MDS can arise *de novo* or secondarily, as a result of contact with harmful chemical agents or exposure to intensive cancer-related therapy. Due to the insufficient production of red, white, or platelet blood cells, MDS patients are more susceptible to chronic anemia, infections, and bleeding. The failure of the bone marrow (BM) causes death from hemorrhage and/or infection in the majority of patients, while a transformation to acute myeloid leukemia (AML) occurs in up to 30% of patients.

Despite the growing number of treatment options for patients with MDS, current therapies still exhibit certain limitations. Although allogeneic bone marrow transplantation offers curative hope, it is available to a very small segment of those with MDS due to factors such as age and challenges in finding matched donors.

Novel therapeutics such as imatinib and lenolidamide are limited by their regulatory approval in a small subset of MDS patients. The recently described survival benefit for azacitidine treatment (two year survival rate of 51%) is an improvement, although the need for patients to make frequent hospital visits while receiving therapy is considered burdensome. A significant majority of MDS patients relapse after treatment with the available approved therapies, as none of these therapies cure the condition.

About ChemGenex Pharmaceuticals Limited (<http://www.chemgenex.com>)

ChemGenex Pharmaceuticals is a pharmaceutical development company dedicated to improving the lives of patients by developing personalized oncology medicines. ChemGenex harnesses the power of genomics both to discover novel targets and drug compounds, and in clinical trials to develop more individualized treatment outcomes. ChemGenex's lead compound, omacetaxine mepesuccinate, is currently in phase 2/3 clinical trials for chronic myeloid leukemia (CML). ChemGenex has a second anticancer compound, amonafide dihydrochloride (Quinamed[®]) which is in phase 2 clinical development for various solid cancers, and a portfolio of assets in pre-clinical development. ChemGenex currently trades on the Australian Stock Exchange under the symbol "CXS" and on NASDAQ under the symbol "CXSP".

Details on the clinical trials can be accessed from the following websites;

<http://clinicaltrials.gov/ct2/show/NCT00375219?term=homoharringtonine&rank=9> and

<http://www.tkiresistantcmltrials.com>

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Certain statements made herein (including for this purpose sites to which a hyperlink has been provided) that use the words "estimate", "project", "intend", "expect", "believe" and similar expressions are intended to identify forward-looking statements within the meaning of the US Private Securities Litigation Reform Act of 1995. These forward-looking statements involve known and unknown risks and uncertainties which could cause the actual results, performance or achievements of the company to be materially different from those which may be expressed or implied by such statements, including, among others, risks or uncertainties associated with the development of the company's technology, the ability to successfully market products in the clinical pipeline, the ability to advance promising therapeutics through clinical trials, the ability to establish our fully integrated technologies, the ability to enter into additional collaborations and strategic alliances and expand current collaborations and

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obtain milestone payments, the suitability of internally discovered genes for drug development, the ability of the company to meet its financial requirements, the ability of the company to protect its proprietary technology, potential limitations on the company's technology, the market for the company's products, government regulation in Australia and the United States, changes in tax and other laws, changes in competition and the loss of key personnel. These statements are based on our management's current expectations and are subject to a number of uncertainties that could change the results described in the forward-looking statements. Investors should be aware that there are no assurances that results will not differ from those projected.

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