

## FOR IMMEDIATE RELEASE

# ChemGenex to Align European and US Regulatory Strategies for Omacetaxine

- Existing Marketing Authorization Application (MAA) for omacetaxine in T315I positive CML patients to be withdrawn
- ChemGenex to submit a new MAA for omacetaxine in larger population of CML patients who have failed two or more tyrosine kinase inhibitors

### MELBOURNE, Australia, and MENLO PARK, California U.S.A. (5 January 2011)

ChemGenex Pharmaceuticals Limited (ASX:CXS) announced today that following discussions with its commercial partner in Europe, Hospira, a decision has been made to align the European regulatory strategy for omacetaxine with the approach being pursued in the USA. As such, ChemGenex has informed the European Medicines Agency (EMA) that it wishes to withdraw its current Marketing Authorization Application (MAA) for CML patients who have failed imatinib therapy and who have the T315I mutation. In parallel ChemGenex has informed the EMA that it intends to submit a new MAA for CML patients who have failed therapy with two or more tyrosine kinase inhibitors (TKIs). This submission is planned for H2 2011.

The new MAA will use combined data from ChemGenex's two pivotal studies, CGX-CML-202 and CGX-CML-203 which were designed to evaluate the safety and efficacy of subcutaneously administered omacetaxine in patients who; (a) had failed imatinib and had the T315I mutation, or (b) were intolerant to two or more TKIs. ChemGenex will submit this combined data in its New Drug Application (NDA) which is scheduled for submission to the U.S. Food and Drug Administration (FDA) in H2 2011. Data on the therapeutic profile of omacetaxine in this patient population were presented at the 52nd Annual American Society of Hematology (ASH) Meeting in Orlando, Florida on 5 December 2010.

"Harmonization of the regulatory strategies in the USA and Europe offers significant operational and potential commercial benefits," said Greg Collier, Ph.D., Managing Director and Chief Executive Officer of ChemGenex. "With this approach we will maximize the efficiency of our clinical and regulatory teams, focusing on data analysis and preparation rather than preparing responses to questions arising from the current MAA filing. We are confident that these questions can be addressed but believe that the most appropriate option at this stage is to file a new MAA for the expanded indication. The population of patients who fail to respond adequately to two or more TKIs is

also significantly larger than the sub-set of patients with the T315I mutation, which is commercially attractive."

#### About OMAPRO<sup>™</sup> (omacetaxine mepesuccinate)

Omacetaxine mepesuccinate is administered subcutaneously and acts differently from TKIs. It may have a therapeutic advantage for patients who have failed currently approved TKIs. Omacetaxine is currently completing global phase 2/3 clinical trials for CML and has been granted Orphan Drug designations by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

Omacetaxine is a first-in-class cetaxine with demonstrated clinical activity as a single agent in a range of hematological malignancies. Omacetaxine has a novel mechanism of action, specifically binding to the ribosomal A-site cleft and inhibiting protein translation of short-lived oncoproteins that are up-regulated in leukemic cells (particularly Cyclin-D1, Mcl-1 and c-Myc). In addition, pre-clinical research presented at the 14th Congress of the European Hematology Association (EHA) in Berlin, Germany in 2009, demonstrated that omacetaxine kills human CML stem cells that are known to be insensitive to TKIs.

Omacetaxine mepesuccinate is an investigational drug and not approved for market in any jurisdiction.

#### About Chronic Myeloid Leukemia (CML) and TKI Failure

Chronic myeloid leukemia (CML) is a cancer of the bone marrow with a worldwide prevalence of approximately 200,000 patients. The bone marrow is responsible for the production of specialized cells that constitute blood; these cells include red blood cells (to carry oxygen around the body), thrombocytes (to help stop bleeding) and certain white cells (part of the body's defense system against infection). In patients with CML the cell production system is diseased and defective. Cells multiply uncontrollably and do not fully develop (differentiate) into functional blood cells.

The majority of CML patients initially respond well to treatments with drugs called tyrosine kinase inhibitors (TKIs). However, significant proportions of patients fail or become intolerant to, one or more TKIs and this has created a significant unmet medical need in the management of CML.

#### About ChemGenex Pharmaceuticals Limited

ChemGenex is an oncology focused biopharmaceutical company developing small molecules with new mechanisms of action to treat malignancies with significant unmet medical needs. A New Drug Application is in preparation for submission to the U.S. Food and Drug Administration in H2 2011 for omacetaxine in CML patients who have failed two or more currently approved tyrosine kinase inhibitors. A parallel Marketing Authorisation Application is in preparation for submission to the European Medicines Agency in H2 2011. ChemGenex has established a corporate alliance with Hospira Inc. to develop and commercialize omacetaxine in Europe, the Middle East and parts of Africa, and is seeking to establish commercial partnerships in the rest of the world. ChemGenex plans to commercialize omacetaxine itself in North America. ChemGenex trades on the Australian Securities Exchange under the symbol "CXS". For additional information on ChemGenex Pharmaceuticals, please visit the Company's website at http://www.chemgenex.com.

OMAPRO<sup>™</sup> is a trademark of ChemGenex Pharmaceuticals Limited.

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the ability to enter into additional collaborations and strategic alliances and expand current collaborations and 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.