

FOR IMMEDIATE RELEASE

CHEMGENEX RECEIVES A COMPLETE RESPONSE LETTER FROM THE FDA FOR OMAPRO[™]

MELBOURNE, Australia, and MENLO PARK, California U.S.A. (12th April 2010) – ChemGenex Pharmaceuticals announces that the U.S. Food and Drug Administration's (FDA) Office of Oncology Drug Products has issued a complete response letter regarding the new drug application (NDA) for OMAPRO[™] (omacetaxine mepesuccinate) for the treatment of adults with chronic myeloid leukemia (CML) who have failed prior therapy with imatinib and have the Bcr-Abl T315I mutation.

The complete response letter does not contain a request for a new study, nor is there a request for enrollment of additional patients into the pivotal study on OMAPRO.

Commenting on the correspondence from the FDA, Greg Collier, PhD, CEO for ChemGenex said, "The complete response letter from the FDA provides the initial guidance towards our endeavor to bring a new therapy to CML patients who harbour the T315I mutation and currently have very limited or unsatisfactory treatment options. Because the principal issues raised by the FDA were similar to those discussed during the 22 March meeting of the Oncology Drug Advisory Committee (ODAC), and based upon our interpretation of the scientific requirements underpinning the complete response letter, we are confident that we can work in a positive manner with the FDA to address the outstanding matters. We appreciate the constructive comments made by the agency in the response letter and ChemGenex will seek a meeting with the FDA to discuss and find agreeable solutions for each of the FDA's requests."

Minutes from the 22 March ODAC meeting can be accessed from the FDA's website (http://www.fda.gov/downloads/AdvisoryCommittees/Committees/MeetingMaterials/Drugs/OncologicDr ugsAdvisoryCommittee/UCM207638.pdf).

ChemGenex also met on April 9th with the US FDA's Center for Devices and Radiological Health (CDRH) to discuss a path forward for the development of a well defined diagnostic test for the T315I mutation. Both parties agreed to work together toward the validation of the T315I assay that meets the FDA's requirements.

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 has been accepted by the U.S. Food and Drug Administration and a Marketing Authorisation Application has been validated by the European Medicines Agency for CML patients who have failed imatinib therapy and have the Bcr-Abl T315I mutation. ChemGenex has established a corporate alliance with Hospira 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

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Australian Stock Exchange under the symbol "CXS" For additional information on ChemGenex Pharmaceuticals, please visit the company's website at <u>http://www.chemgenex.com</u>.

OMAPRO[™] is a trademark of ChemGenex Pharmaceuticals Limited.

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