PRESS RELEASE

TOSEDOSTAT OPAL STUDY IN ACUTE MYELOID LEUKAEMIA PUBLISHED IN LANCET ONCOLOGY

Oxford, 4 March 2013 ñ Chroma Therapeutics Limited announced today that The Lancet Oncology has published the results of the OPAL Study, a Phase 2 study of two dosing regimens of tosedostat in elderly patients with relapsed or refractory acute myeloid leukaemia (AML). Tosedostat is a novel, oral aminopeptidase inhibitor which deprives tumour cells of the amino acid building blocks they need to make proteins necessary for tumour cell survival. The lead investigator for the study was Dr. Jorge Cortes, Professor of Medicine and Internist, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center in Houston, Texas.

The study addressed the unmet medical need in older patients who have failed to adequately respond to conventional first line treatment and in whom further treatment options are limited by toxicity concerns. Twenty-two percent of patients had responses to tosedostat of partial remission or better and a further 29% had stable disease. The most marked effects appeared to occur in patients who had previously suffered with myelodysplastic syndrome (MDS) or those that had received previous treatment for AML with hypomethylating agents (HMA). Adverse events were generally mild, predictable and manageable.

About the OPAL Study
This Phase 2 multicenter, randomised study evaluated the safety and efficacy of two dose regimens of tosedostat to determine an appropriate regimen for future clinical studies. The study treated 73 patients randomised between two treatment arms: tosedostat 120 mg once daily for six months or 240 mg once daily for two months followed by 120 mg once daily for four months. The median age of the patients was 72 years old. Prior primary induction for AML had been Ara-C plus anthracycline or other Ara-C regimens for 58% of patients, HMAs for 36% and other regimens for 7%. Fifty-two percent of patients had not obtained a complete remission from primary induction. As previously presented at the 53rd American Society of Hematology Annual Meeting, other results included:

- 10% (7/73) achieving a complete remission (CR) or CRp and a further 12% (9/73) achieving a partial remission or morphological leukaemia free state.
- High response rates were observed in patients who previously received HMAs or initially were diagnosed with MDS, with 38% (10/26) and 37% (7/19), respectively, achieving partial remission (PR) or better.
- Median overall survival (OS) for patients achieving <5% blasts (CR, CRp, MLFS) was 322 days; PR 195 days; and SD 162 days.
- Adverse events were similar between dosing groups. Tosedostat was generally well-tolerated, with the majority of adverse events of grade 1 and 2. The most common serious adverse event was febrile neutropenia reported in 29% of patients.
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There are limited therapeutic options available for elderly patients who, after failing hypomethylating agents, experience AML progression from MDS," said Dr. Cortes. "The novel mechanism of action and observed response rate in this completed Phase 2 study suggests that tosedostat could address this unmet medical need. We are currently conducting a Phase 2 study investigating the combination of tosedostat with azacytidine or low-dose cytarabine - a standard leukemia therapy in patients with relapsed or refractory AML and MDS - to determine if tosedostat would be safe and more effective when used in combination with these agents."

Dr Martin Toal, Chief Medical Officer at Chroma, commented: "The results of OPAL maintain the promise seen in earlier studies with tosedostat. Along with the data from ongoing combination studies, this study provides an excellent basis for designing a Phase 3 programme for a new therapeutic approach for older patients who require a tolerable but effective treatment option."

The publication by Dr. Cortes, et al. titled "Results of a Phase 2 study of two dosing regimens in elderly patients with relapsed or refractory acute myeloid leukemia - The OPAL Study," is available at http://www.thelancet.com/journals/lanonc/issue/current.

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About Chroma Therapeutics

Chroma Therapeutics, based in Oxford (UK), is a drug development company focused in the fields of oncology and inflammatory disorders. Chroma is building a broad pipeline of first- or best-in-class treatments utilising its expertise in chromatin biology and its novel intracellular accumulation technologies, which include the ability to selectively target drugs to macrophages. Chroma is backed by a number of leading specialist investors, including Abingworth, Essex Woodlands, Gilde, Phase4 and The Wellcome Trust. More information about Chroma can be found at www.chromatherapeutics.com.
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About Tosedostat
Tosedostat is an orally dosed aminopeptidase inhibitor which deprives sensitive tumour cells of amino acids by blocking protein recycling, resulting in tumour cell death. Tosedostat has been studied in Phase 1 and Phase 2 clinical trials both as a single agent and in combination with other chemotherapeutic agents. Such studies have demonstrated significant anti-tumour response without the typical side effects of conventional, non-targeted cytotoxic therapies. Tosedostat is licensed by Chroma from Vernalis plc and is sub-licensed to Cell Therapeutics, Inc. in the Americas.