

## **Lorus Therapeutics Announces Positive Result in its Phase II Clinical Study of LOR-2040 in Acute Myeloid Leukemia (AML)**

**- Efficacy and safety data supports advancement to a comparative trial as a strategy to support registration -**

**TORONTO, CANADA** – November 30, 2009 – Lorus Therapeutics Inc. (TSX: LOR) (“Lorus” or the “Corporation”), a biopharmaceutical company specializing in the research and development of pharmaceutical products and technologies for the management of cancer, today announced that its Phase II clinical trial in refractory and relapsed AML with LOR-2040 in combination with cytarabine has been successfully completed to the end-of-stage assessment time point, with favorable results.

The Steering Committee review required at this stage determined that the Phase II efficacy and safety results fulfilled the protocol criteria for continued patient enrolment and are consistent with the promising Phase Ib clinical findings, previously reported by Lorus. It was further agreed that based on the strength of the Phase Ib and II clinical data in a total of 48 patients treated in this indication, expansion to a definitive comparative trial is the most appropriate next step to support registration. On this basis Lorus is proceeding with protocol development for the expanded development program.

The clinical study was conducted at 6 major US centres under the overall direction of Dr. Rebecca Klisovic (Principal Investigator) and Dr. Guido Marcucci at Ohio State University as the protocol co-chairs in collaboration with Lorus. Prominent external reviewers were Dr. Elihu Estey, a leading authority on AML, and Dr. Don Berry, a leader in adaptive statistical trial design.

Twenty-five patients have been treated in the Phase II clinical trial and evaluated alone and together with the results from the prior Phase Ib trial to assess the most appropriate development path for LOR-2040 in this AML population. The Phase II results will be further analyzed for full peer review presentation and publication, and will be disclosed in more detail at that time.

It is notable that the current preliminary evaluation found the response rate to be twice that expected from a risk-matched historical control, and that this is consistent with a further similar analysis of the findings from the prior Phase Ib clinical study. Such risk-based analyses are important to predict the effect in the typically more varied refractory and relapsed AML population expected in a larger comparative trial.

“This is an important milestone for Lorus since it provides an early opportunity to accelerate the clinical development of LOR-2040 in this hard to treat refractory and relapsed AML population”, commented Dr. Aiping Young, Lorus’ President & CEO. “The comparative clinical trial plan is consistent with the requirements for market registration and with our fastest to approval development strategy.”

AML patients who fail or rapidly relapse following initial induction therapy represent a difficult treatment challenge with no currently approved treatment for most patients. The treatment approach to tolerably combine with high dose cytarabine represents a strategy to intensify treatment and benefit without having to combine 3 or 4 drugs, as in other recent treatment approaches, which can be dose limiting for each combination agent.

## **About LOR-2040**

LOR-2040 (formerly GTI-2040) is an antisense drug that specifically targets the R2 component of ribonucleotide reductase, which is required for DNA synthesis and cell proliferation. Through downregulation of R2, LOR-2040 has demonstrated strong antitumor and antimetastatic activity in a variety of tumor types in both *in vivo* and *in vitro* models and has been studied in multiple Phase I/II clinical trials. R2 has been described as a malignant determinant that is elevated in a wide range of tumors, which can cooperate with a variety of cellular cancer causing genes known as oncogenes to enhance tumor growth and metastatic potential.

## **About Lorus**

Lorus is a biopharmaceutical company focused on the research and development of novel therapeutics in cancer. Lorus' goal is to capitalize on its research, preclinical, clinical and regulatory expertise by developing new drug candidates that can be used, either alone, or in combination with other drugs, to successfully manage cancer. Through its own discovery efforts and an acquisition and in-licensing program, Lorus is building a portfolio of promising anticancer drugs. Lorus Therapeutics Inc. is listed on the Toronto Stock Exchange under the symbol LOR.

## **Forward Looking Statements**

This press release may contain forward-looking statements within the meaning of Canadian and U.S. securities laws. Such statements include, but are not limited to, statements relating to: our research program plans, our plans to conduct clinical trials, the successful and timely completion of clinical studies and the regulatory approval process, our ability to fund future research, our plans to obtain partners to assist in the further development of our product candidates, the establishment of corporate alliances, the Company's plans, objectives, expectations and intentions and other statements including words such as "continue", "believe", "plan", "expect", "intend", "will", "should", "may", and other similar expressions. Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements, including, among others: our ability to obtain the capital required for research and operations, the inherent risks in early stage drug development including demonstrating efficacy, development time/cost and the regulatory approval process; the progress of our clinical trials; our ability to find and enter into agreements with potential partners; our ability to attract and retain key personnel; changing market conditions; and other risks detailed from time-to-time in our ongoing quarterly filings, annual information forms, annual reports and annual filings with Canadian securities regulators and the United States Securities and Exchange Commission.

Should one or more of these risks or uncertainties materialize, or should the assumptions set out in the section entitled "Risk Factors" in our Annual Information Form underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this press release and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. We cannot assure you that such statements will prove to be accurate as actual results and future events could differ materially from those anticipated in such statements. Investors are cautioned that forward-looking statements are not guarantees of future performance and accordingly investors are cautioned not to put undue reliance on forward-looking statements due to the inherent uncertainty therein.

Lorus Therapeutics Inc.'s recent press releases are available through the Company's website at [www.lorusthera.com](http://www.lorusthera.com). For Lorus' regulatory filings on SEDAR, please go to [www.Sedar.com](http://www.Sedar.com). For SEDAR filings prior to July 10, 2007 you will find these under the company profile for Global Summit Real Estate Inc. (Old Lorus).

## **Enquiries:**

For further information, please contact: Dr. Saeid Babaei, 416-798-1200 ext. 490; [ir@lorusthera.com](mailto:ir@lorusthera.com)