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Maxim Pharmaceuticals Reports Data from its Phase 3 Trial of Ceplene in Acute Myeloid Leukemia Patients at American Society of Hematology Annual Meeting

SAN DIEGO, December 6, 2004 – Maxim Pharmaceuticals (Nasdaq: MAXM) (SSE: MAXM) announced today additional data from its randomized and controlled Phase 3 trial (MP-MA-0201) investigating Ceplene plus Interleukin-2 (IL-2) in the treatment of acute myeloid leukemia (AML) patients in complete remission during an oral presentation at the American Society of Hematology 46th Annual Meeting and Exposition. The data presented included the updated p-value (p=0.0096) for the primary endpoint of leukemia free survival, and details of the demographics, risk factors and other baseline characteristics of the patient population, which were all well balanced. The preliminary p-value previously reported (p=0.026) only stratified the patient population by complete remission status and did not additionally stratify by country as set forth in the study protocol.

"The study results suggest that Ceplene plus IL-2 could potentially meet the biggest clinical challenge facing AML patients today – extending the duration of complete remission. The standard of care today for patients in remission is no treatment, or bone marrow transplant for those patients who qualify. Any therapy that can prolong remission, particularly a therapy that is generally well-tolerated and can be self-administered at home like Ceplene and low dose IL-2, could represent a significant medical advance in the treatment of AML," stated Dr. Mats Brune, M.D., Ph.D., of the Hematology Unit, Sahlgrenska University Hospital in Goteborg, Sweden, and principal investigator of the study.

"We are very pleased with the leukemia-free survival benefit demonstrated by this trial. It potentially offers a remission therapy option to AML patients where previously there was none," stated Larry G. Stambaugh, Chairman and CEO of Maxim. "In an effort to make this therapy available to patients as soon as possible, we are having discussions with both the FDA and

EMEA regarding Ceplene's regulatory path. We are working towards submitting regulatory filings by mid 2005."

About MP-MA-0201
MP-MA-0201 was an international, multi-center, randomized, open-label, Phase 3 study evaluating the efficacy and safety of treatment with Ceplene plus IL-2 in patients with AML in their first or subsequent complete remission (CR). Prior to enrollment, patients were treated with induction and consolidation therapy according to institutional practices. Upon enrollment, patients were stratified by country and then by remission status, i.e. first complete remission (CR1) or later complete remission (CR>1). Patients were then randomized to one of two treatment groups, the Ceplene plus IL-2 group or the control group. The control group received the current standard of care, which is no treatment. A total of 320 patients were entered into the study, equally distributed between the two study arms.

Patients in the treatment arm received Ceplene plus IL-2 during ten 3-week treatment periods. After each of the first 3 treatment periods, there was a 3-week rest period, whereas each of the remaining cycles was followed by a 6-week rest period. Treatment duration was approximately 18 months. Patients were followed for relapse and survival until at least 3 years from randomization of the last patient enrolled. IL-2 was administered subcutaneously (sc), 1 µg/kg body weight twice daily (BID) during treatment periods. Ceplene was administered sc 0.5 mg BID after IL-2. After the patient became comfortable at self-injection under the investigator's supervision, both drugs could be administered at home. Patients in the control group followed the same schedule of visits and study procedures as patients in the treatment group.

The primary endpoint of the study was the difference in leukemia-free survival between the treatment group and the control group using an intent-to-treat analysis. Leukemia-free survival is the number of days from randomization to relapse or death, whichever comes first. Secondary endpoints included the difference in leukemia-free survival between the treatment group and the control group for patients in either their first CR or subsequent CR, leukemia-free survival rates at 6, 12, 18, 24, and 36 months, overall survival, remission inversion rate (for CR>1 patients only), and safety.

An analysis of the intent-to-treat population demonstrates that treatment with Ceplene plus IL-2 prolonged the leukemia-free survival of patients with AML in remission compared to patients receiving the standard of care, no treatment. With a minimum follow-up of 3 years, the median leukemia-free survival was 267 days (95% confidence interval [CI], 232 – 341 days) for patients in the control group, and 325 days (95% CI, 266 – 597 days) for patients treated with Ceplene plus IL-2. A stratified log-rank test of the Kaplan-Meier estimate of leukemia-free survival of all randomized patients showed a statistically significant advantage for the treatment group (p =0.0096). At 3 years after randomization of the last patient, 24% of control patients were alive and free of leukemia, compared with 34% of patients treated with Ceplene plus IL-2.

Among patients in CR1 (n = 261), leukemia-free survival was statistically significantly improved (p=0.0136, log-rank test) for patients treated with Ceplene plus IL-2 compared to control

patients. At 36 months after randomization of the last patient, the leukemia-free survival rate was 40% for CR1 patients in the Ceplene plus IL-2 group and 26% in the control group (p = 0.0154). For patients enrolled in CR>1 (n = 59), no significant difference in leukemia-free survival (p = 0.3955) was observed. A statistically significant difference in the secondary endpoint of overall survival was not shown between the 2 treatment groups (p=0.2079), which may be expected since this study was not powered to detect a difference in overall survival at 36 months. However, there is a trend for improved overall survival in the CR1 patients.

Safety and tolerability were consistent with prior clinical experience, and no death was considered treatment related.

About AML
AML is the most common form of acute leukemia in adults. There are approximately 11,900 new cases of AML and 8,900 deaths caused by this cancer each year in the United States. Prospects for long-term survival are poor for the majority of AML patients. Once diagnosed with AML, patients are typically treated with chemotherapy. Although approximately 75% of patients achieve a complete remission, median time in remission before relapse is only 12 months, and only 20% of patients will survive 5 years or more. There are currently no accepted remission maintenance therapies for AML patients. Ceplene has orphan drug status from the U.S. Food and Drug Administration for the treatment of AML, and the Company has applied for orphan drug status in Europe.

About Ceplene
In patients with cancer, including leukemias such as AML, the ability of the immune system to destroy cancer cells is frequently compromised. Ceplene therapy is being developed to maintain the integrity of pivotal immune cells, in particular T cells and natural killer (NK) cells, in patients with cancer. Ceplene treatment aims at facilitating immune-mediated destruction of cancer cells, including leukemic cells, and also at improving the efficiency of T and NK cell-activating agents such as IL-2. Research regarding histamine, the active agent underlying Ceplene, and related clinical results has been the subject of more than 80 presentations at major scientific and clinical meetings, and has been published in more than 300 scientific and clinical articles. More information on Ceplene's mechanism of action, including a short animation, is available on the Company's website at www.maxim.com.

Maxim Overview
Maxim Pharmaceuticals is a global biopharmaceutical company with a diverse pipeline of therapeutic candidates for life-threatening cancers and liver diseases. Maxim's research and development programs are designed to offer hope to patients by developing safe and effective therapeutic candidates that have the potential to extend survival while maintaining quality of life. Ceplene, Maxim's lead drug candidate, is an immune-modulator that reverses immune suppression and protects critical immune cells. Because Ceplene modifies basic immune functions, it has the potential to be used in a range of diseases. Additionally, Maxim is developing small-molecule apoptosis modulators for cancer, cardiovascular disease and degenerative diseases.

Ceplene and the apoptosis compounds are investigational drugs and have not been approved by the U.S. Food and Drug Administration or any international regulatory agency.

This news release contains certain forward-looking statements that involve risks and uncertainties. Such forward-looking statements include statements regarding the efficacy, safety and intended utilization of Ceplene, the conduct and results of the Company's clinical trials, and the Company's plans regarding regulatory filings, future research and clinical trials. Such statements are only predictions and the Company's actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include the risk that products that appeared promising in early research and clinical trials do not demonstrate safety or efficacy in larger-scale or later clinical trials, the risk that the Company will not obtain approval to market its products, and the risks associated with the Company's reliance on outside financing to meet its capital requirements. These factors and others are more fully discussed in the Company's periodic reports and other filings with the Securities and Exchange Commission.

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