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## MAXIM REPORTS RESULTS FROM HEPATITIS C PILOT STUDY OF CEPLENE TRIPLE-DRUG THERAPY AT AASLD CONFERENCE

Researchers Make Three Presentations Regarding Ceplene at the 52<sup>nd</sup> American Association for the Study of Liver Disease (AASLD) Conference

San Diego, CA, November 12, 2001 - Maxim Pharmaceuticals (Nasdaq NM: MAXM, SSE: MAXM) announced that 72-week results were presented yesterday from its completed pilot study evaluating Ceplene™ (histamine dihydrochloride) in combination with interferon-alpha (IFN-alpha) and ribavirin in the treatment of chronic hepatitis C patients who were nonresponsive to previous therapy. The study is one of three Ceplene presentations being made by independent researchers at the 52nd meeting of the American Association for the Study of Liver Diseases (AASLD) in Dallas, Texas. The results from the completed studies described in the three presentations provide the foundation for the more advanced clinical testing of Ceplene in hepatitis C planned to commence before the end of the year.

In the study, chronic hepatitis C patients who did not respond to or relapsed from previous therapy were treated for 48 weeks with the Ceplene/IFN-alpha/ribavirin triple-drug combination, and followed for an additional 24 weeks after completion of therapy. At 72 weeks, sustained complete viral response was observed in 28 percent (5/18) of patients who entered the study, and in 38 percent (5/13) of evaluable patients (patients who completed at least four weeks of therapy). A complete viral response was defined by virus levels that are below the limit of detection using a validated PCR-RNA technique (Cobas Amplicor HCV Monitor<sup>TM</sup> Test). No serious adverse events and no unexpected or irreversible side effects were reported in the Ceplene study. The results were presented yesterday at the AASLD conference by Yoav Lurie, M.D., principal investigator in the study and Head, Hepatitis Clinic, Liver Unit, Institute of Gastroenterology and Hepatology, Tel Aviv Souraski Medical Center, Israel. Patients that have failed prior therapy for hepatitis C represent a substantial population in need of more effective treatments.

"This study met its objective by demonstrating that Ceplene can be safely administered in this triple-drug combination, and clearly shows that this triple-drug therapy is feasible in nonresponder patients," said Dr. Lurie. "Although this study was not designed to demonstrate efficacy due to the small number of patients involved, the end-of-study results are promising and I look forward to more advanced studies."

Dr. Lurie will also present today previously reported results from a 129-patient Phase 2 study evaluating the treatment of therapy-naïve, chronically infected hepatitis C patients with the combination of Ceplene and IFN-alpha. In the study, 40 percent of evaluable hepatitis C patients treated with the combination of Ceplene and IFN-alpha achieved a sustained complete viral response at 72 weeks. Published research suggests a 16 percent sustained complete response commonly observed for patients treated with IFN-alpha alone.

In addition, Avidan Neumann, Ph.D., Bar-Ilan University, Ramat-Gan, Israel, will make a presentation today at the AASLD conference related to the 129-patient Phase 2 study entitled "Early Hepatitis C Viral Kinetics During Combination Therapy with Histamine Dihydrochloride and Interferon-Alpha and its Prediction of Sustained Viral Response." The presentation will show that an early rapid viral response for patients treated with the Ceplene/IFN-alpha combination was achieved in 63 percent of patients with the genotype 1 variant of the virus and in 76 percent of patients with the genotype 2 /3 variants of the virus. Dr. Neumann's report concludes that these early rapid viral response rates are higher than those commonly reported for treatment with either IFN-alpha or the combination of IFN-alpha and ribavirin.

"The data emerging from the two clinical trials reported at this important liver disease conference supports our further development plans for Ceplene," said Kurt R. Gehlsen, Ph.D., Maxim's Senior Vice President, Development and Chief Technical Officer. "Ceplene has shown a broad potential in different hepatitis C-infected patient populations using multiple treatment regimens. We look forward to combining Ceplene with the current standard of care, pegylated interferon and ribavirin, in our upcoming Phase 2 triple-drug study in nonresponder patients."

The Company recently announced that it plans to commence this fall a 280-patient randomized, controlled, triple-drug Phase 2 trial of Ceplene in combination with pegylated interferon (peginterferon alfa-2b) and ribavirin for the treatment of patients infected with hepatitis C who failed to respond to prior therapy.

Ceplene is an investigational drug and has not been approved by the U.S. Food and Drug Administration or any international regulatory agency.

## **Hepatitis C Overview**

Hepatitis C is now the leading blood-borne infection in the United States. The U.S. Center for Disease Control and Prevention estimates that over 4.5 million Americans are infected with the hepatitis C virus. The World Health Organization and other sources estimate that more than 200 million people are infected worldwide.

Hepatitis is a disease characterized by inflammation of the liver and, in many cases, permanent cirrhosis (scarring) of the liver tissues and mortality. The progress of disease from infection to significant liver damage can take 20 years or more. Some experts estimate that without

substantial improvements in treatment, deaths from hepatitis C will surpass those from HIV. Hepatitis C is the leading cause of liver cancer and the primary reason for liver transplantation in many countries.

## **Ceplene and Maxim Overview**

Maxim Pharmaceuticals is a global biopharmaceutical company with a diverse pipeline of therapeutic candidates for life-threatening cancers and hepatitis. Maxim's research and development programs are designed to offer hope to patients by developing safe and effective therapeutic candidates that extend survival while maintaining quality of life. Maxim has attracted an experienced international management group and a team of employees dedicated to commercializing life-enhancing product candidates. Joining this motivated team in its mission are world-leading scientific and clinical investigators and major pharmaceutical development partners.

Ceplene, based on the naturally occurring molecule histamine, is designed to prevent or inhibit oxidative stress, thereby reversing immune suppression and protecting critical immune cells. Ceplene is administered in combination with cytokines such as IFN-alpha and interleukin-2, a class of proteins that stimulate these same immune cells.

Ceplene is currently being tested in Phase 3 cancer clinical trials for advanced metastatic melanoma and acute myelogenous leukemia. Phase 2 trials of Ceplene are also underway for the treatment of hepatitis C and advanced renal cell carcinoma. More than 1,300 patients have participated in the Company's completed and ongoing clinical trials.

Maxim is also developing small-molecule inhibitors and activators of programmed cell death, also known as apoptosis, that may serve as drug candidates for cancer, cardiovascular disease and other degenerative diseases. Lastly, the Company's MaxDerm technology is designed for the treatment of medical conditions for which topical therapy is appropriate such as oral mucositis, herpes, decubitus ulcers, shingles, burns and related conditions.

This news release contains certain forward-looking statements that involve risks and uncertainties. Such forward-looking statements include statements regarding the efficacy and intended utilization of Ceplene, the apoptosis modulator compounds and MaxDerm, and regarding the Company's 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 clinical trials, the risk that the Company will not obtain approval to market its products, the risk that clinical trials may not commence when planned, and the risks associated with the dependence upon collaborative partners. These factors and others are more fully discussed in the Company's periodic reports and other filings with the Securities and Exchange Commission.

Note: Ceplene<sup>TM</sup>, MaxDerm<sup>TM</sup> and the Maxim logo are trademarks of the Company. Editor's Note: This release is also available on the Internet at http://www.maxim.com.