

**FOR IMMEDIATE RELEASE**

**BIOLEX ANNOUNCES PRESENTATION AT EASL OF INTERIM RESULTS FROM 480 STUDY, A PHASE2b TRIAL OF LOCTERON® IN CHRONIC HEPATITIS C**

**Phase 2b Results in Oral Presentation at the 45th Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria**

**PITTSBORO, NORTH CAROLINA, April 19, 2010** - Biolex Therapeutics, Inc. announced that interim results from a Phase 2b trial of Locteron®, the “480 STUDY,” were presented Friday evening at the 45<sup>th</sup> Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria. Locteron, controlled-release interferon alpha 2b, is designed to improve patient care by providing a more convenient once-every-two week dosing schedule and by reducing the flu-like symptoms associated with pegylated interferons, the current standard of care. Through six and 12 weeks of treatment in the trial, Locteron achieved the Company’s objective by demonstrating viral kinetics and response rates that were at least comparable to the PEG-Intron® control while also achieving a reduction in flu-like adverse events.

The Phase 2b trial is being conducted in Europe and Israel and includes 74 treatment-naïve hepatitis C patients with the genotype-1 variant of the virus. The 480 STUDY is designed to provide, in combination with the SELECT-2 Phase 2b trial, patient results for use in the EMPOWER analyses of efficacy and tolerability of the 480 µg dose of Locteron versus PEG-Intron (interim results from SELECT-2 and EMPOWER were also presented at the EASL conference last week). The 480 STUDY includes the first clinical evaluation of the single-injection drug configuration of Locteron planned for use in Phase 3 trials.

In Panel A of the 480 STUDY, 42 patients were randomized in Europe to receive treatment with either the 480 µg dose of Locteron (in the same two-injection configuration as the SELECT-2 trial) or PEG-Intron. In Panel B, 32 patients in Israel were randomized to receive treatment with either the 480 µg dose of Locteron (single-injection format) or PEG-Intron. Participants in the 480 STUDY are treatment-naïve, genotype-1, chronic hepatitis C patients, and all participants also received weight-based ribavirin. All patients in Panel A of the trial have completed 12 weeks of study and all patients in Panel B have completed at least six weeks of study.



In both Panel A and Panel B, the Locteron 480 µg dose administered once every two weeks demonstrated reductions in viral loads (mean changes in HCV RNA from baseline) that were at least comparable to that achieved with PEG-Intron administered once per week. Rates of undetectable HCV RNA achieved in each Panel and on a combined basis are outlined in the table below:

**480 STUDY Interim Results**  
**% of Patients with Undetectable HCV RNA**

	Panel A		Panel B		Combined	
	Locteron 480 µg (n=19)	PEG-Intron (n=23)	Locteron 480 µg (n=16)	PEG-Intron (n=16)	Locteron 480 µg (n=35)	PEG-Intron (n=39)
6 Weeks	42%	22%	38%	6%	40%	15%
12 Weeks	63%	61%	*	*	*	*

\*Majority of patients in Panel B have not yet completed 12 weeks of study.

In the 480 STUDY, flu-like adverse events were predefined to include arthralgia, chills, fever, headache, and myalgia. After six weeks of treatment, total flu-like adverse events reported for Locteron 480 µg for Panel A and Panel B combined were 52% less than the total events reported for PEG-Intron. Available results after 12 weeks of treatment suggest total flu-like adverse events reported for Locteron 480 µg were 58% less than the total reported for PEG-Intron. The majority of the difference occurred in Panel A as the flu-like adverse events reported in Panel B, which is still in process, were low in both cohorts.

The 480 STUDY results were presented by the lead author, Zahariy Krastev, MD, Principal Investigator, University Hospital “St Ivan Rilski,” Sofia, Bulgaria, in an oral presentation titled “Randomized, Open-Label, 12-Week Comparison of Controlled-Release Interferon Alpha2b + Ribavirin Vs. Pegylated-Interferon Alpha2b + Ribavirin in Treatment-Naïve Genotype1 Hepatitis C: 4 Week Results from 480 STUDY (Panel A).”

“We are pleased that the efficacy of Locteron in these interim results is at least comparable to PEG-Intron despite the fact that Locteron was dosed half as frequently,” said Dr. Krastev. “There is a need for a more convenient and more tolerable interferon component of hepatitis C therapy, particularly with the advent of triple-combination therapy, and I look forward to participating in expanded trials of Locteron in the future.”

One serious adverse event has been reported to date for Locteron 480 µg and three were reported for PEG-Intron. All events were expected labeled events for interferon alpha. No Grade 4 reductions in hematological measurements have been reported to date for either Locteron 480 µg or for PEG-Intron. There were no novel toxicities identified in either cohort of the trial.



Locteron is an investigational therapeutic candidate and has not been approved for sale by the United States Food and Drug Administration or by any international regulatory agency.

### **Locteron Overview**

Locteron is a controlled-release interferon alpha designed to improve patient care in the treatment of hepatitis C through a more favorable side-effect profile and dosing convenience compared to existing pegylated interferon products. In contrast to Locteron's controlled-release mechanism, the currently approved products, Pegasys® and PEG-Intron, and the investigational product Zalbin™, are immediate-release products that lack a controlled-release mechanism. Interferon alpha serves as the foundation of current combination therapy for hepatitis C patients. It is estimated that worldwide sales of interferon products for the treatment of hepatitis C will approach \$6 billion by 2016.

Locteron incorporates an advanced controlled-release drug delivery technology that allows dosing once every two weeks, more convenient than Pegasys and PEG-Intron, each of which require dosing every week. More importantly, Locteron's controlled-release mechanism results in the gradual release of interferon alpha 2b to patients over the duration of two weeks and avoids the early peak plasma levels of the active interferon that characterize the pegylated interferons and Zalbin. This controlled-release mechanism is designed to reduce the frequency, duration and severity of flu-like symptoms commonly experienced by patients treated with pegylated interferons and with Zalbin.

### **About Biolex Therapeutics**

Biolex is a biopharmaceutical company that uses its patented LEX System<sup>SM</sup> to develop follow-on biologics, hard-to-make therapeutic proteins and to optimize monoclonal antibodies. The LEX System is a novel technology that genetically transforms the aquatic plant *Lemna* to enable the production of biologic product candidates. The company's product candidates are designed to provide superior efficacy/tolerability profiles and to address large, proven pharmaceutical markets. Biolex's lead product candidate, Locteron®, is in Phase 2b clinical testing for the treatment of chronic hepatitis C. Biolex has also developed two other product candidates that capitalize on the benefits of the LEX System. BLX-301 is a humanized anti-CD20 antibody glyco-optimized for the treatment of non-Hodgkin's B-cell lymphoma and other diseases. BLX-155 is a direct-acting thrombolytic designed to dissolve blood clots in patients.

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