

**BIOLEX PRESENTS AT AASLD MEETING SIGNIFICANT TOLERABILITY
ADVANTAGES OF LOCTERON®, ITS NEXT-GENERATION INTERFERON FOR
HEPATITIS C**

**Locteron Phase 2b Results Include Statistically Significant Reduction of Flu-Like
Adverse Events Confirmed by Two Independent Reporting Methods**

**Locteron's Tolerability and Dosing Advantages and Strong Efficacy Make it a Highly
Combinable Interferon for Use with Future Direct-Acting Anti-Viral Combinations**

PITTSBORO, NORTH CAROLINA, November 1, 2010 - Biolex Therapeutics, Inc. today announced positive results from two Phase 2b trials further demonstrating the strong anti-viral response and tolerability advantages of the 480 µg dose of Locteron® in the treatment of hepatitis C. In the Phase 2b trials, patients directly reported flu-like adverse events on a daily basis through an electronic patient-reported outcome (ePRO) system, and the results demonstrated a statistically significant reduction in the frequency and severity of flu-like adverse events and reduced use of concomitant (analgesic/antipyretic) medications for patients treated with Locteron compared to patients treated with the PEG-Intron® control. Locteron, controlled-release interferon alpha 2b, is designed to offer key advantages compared to currently marketed interferons as a core component of combination therapies for the treatment of hepatitis C. These advantages include reduced flu-like symptoms, reduced rates of depression, and a less frequent dosing regimen with half the number of injections. The "EMPOWER" Phase 2b ePRO results will be presented today in a late-breaker session at the 61st Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

EMPOWER is a prospectively designed analysis of the combined results from two Phase 2b hepatitis C trials focusing on the 480 µg dose of Locteron (the middle dose of three Locteron doses evaluated in the two trials). Through 12 weeks of treatment, 50% of the patients in the Locteron 480 µg group achieved cEVR (undetectable HCV RNA) compared to 46% of the patients in the PEG-Intron group. As a result of its controlled-release mechanism, Locteron achieved strong efficacy results while being dosed half as frequently as PEG-Intron.

The AASLD presentation today includes for the first time results from the ePRO adverse-event reporting system where patients directly recorded their flu-like adverse events on a daily basis, providing greater insight into the patients' real world experiences with these side effects and the impact on their daily activities. In addition to the self-reporting by patients with the ePRO system, flu-like adverse events were also recorded using traditional weekly adverse event assessments performed by the clinical sites. Flu-like adverse events were predefined to include arthralgia, chills, fever, headache, and myalgia.



A substantial reduction in flu-like adverse events for patients treated with Locteron compared to PEG-Intron was evident even in the first week after initiation of treatment and continued through the 12-week time point through which the ePRO system was utilized. The reduction in flu-like adverse events during the week after the first injection supports the hypothesis that the slower rise to Cmax provided by the controlled-release mechanism of Locteron contributes to the tolerability advantages seen in multiple clinical trials. A comparison of the flu-like adverse event reporting by the clinical sites and by ePRO provide independent confirmation of the substantial benefits Locteron provided in reducing these side effects as outlined in the table below:

	<u>Locteron Reduction in Flu-Like Adverse Events (Week 1)</u>			
	<u>Total Events</u>		<u>Moderate and Severe Events</u>	
	<u>Clinical Site Reporting</u>	<u>Patient (ePRO) Self-Reporting</u>	<u>Clinical Site Reporting</u>	<u>Patient (ePRO) Self-Reporting</u>
Locteron Reduction In Flu-Like Adverse Events Compared to PEG-Intron	50% Reduction	51% Reduction	70% Reduction	39% Reduction

“The ePRO results being presented for the first time today are robust and provide important insight into the impact that flu-like adverse events have on patients’ daily lives,” said Patrick Marcellin, MD, PhD, Professor of Hepatology at the University of Paris and Head of the Viral Hepatitis Research Unit in Hôpital Beaujon, Clichy. “Treatment of hepatitis C is likely to progress to triple and quad therapies in which interferons are combined with one or more direct-acting anti-viral drugs. Locteron’s advantages with regards to flu-like adverse events, depression and dosing frequency have the potential to enhance the overall tolerability of, and patient adherence to, these future combinations.”

Consistent with the reduction in flu-like adverse events, less than half as many Locteron patients used concomitant medications (analgesics and antipyretics) compared to the usage of these medications by PEG-Intron patients during the study period as detailed below.

	<u>Percentage of Patients Using Concomitant Medications</u>	
	<u>Locteron 480 µg</u>	<u>PEG-Intron</u>
Patients Using Analgesics	27%	59%
Patients Using Antipyretics	23%	49%

A comparison of the ePRO and clinic site reporting highlights the fact that flu-like adverse events may even be more important to patients than historically believed. The total flu-like adverse events reported directly by the patients using the ePRO system during the first 12



weeks of EMPOWER was more than four times greater than the total flu-like adverse events recorded by the clinical sites. Also of importance, patients rated 80% of their flu-like adverse events as moderate or severe in their ePRO reports, compared to the clinical site reporting in which only 13% of flu-like adverse events were rated as moderate or severe. Despite the apparent differences in sensitivity in the two adverse event reporting methods, the results from both the ePRO and weekly clinic visits independently confirm the reduction in flu-like adverse events for patients treated with Locteron compared to patients treated with PEG-Intron. Through the 12-weeks, the difference in flu-like adverse event counts was statistically significant when measured by both the ePRO and clinical site reporting methods ($p < 0.001$ for each).

The relevance of flu-like adverse events was highlighted in a survey of hepatitis C patients published in the *Journal of Viral Hepatitis* in June 2010 in which depression and flu-like symptoms were cited as the two most important adverse events impacting patient adherence to treatment. Last week Biolex reported 48-week results from its SELECT-2 Phase 2b trial of Locteron demonstrating substantial reductions in depression compared to PEG-Intron.

AASLD Presentation

The EMPOWER ePRO and clinical-site tolerability results will be presented today by the lead author, Walker Long, MD, Chief Medical Officer and Vice President, Drug Development, Biolex Therapeutics, in the form of a poster titled “Adverse Event Reporting During HCV Treatment Via Weekly Clinic Visits Substantially Underestimates Flu Frequency & Severity Compared to Daily ePRO: Results From 133 Patients in EMPOWER.”

“The EMPOWER results are notable in that they show a statistically significant reduction of flu-like adverse events for Locteron confirmed by two sources, the clinical site assessments and the daily patient reporting of side effects through the ePRO System. The reductions in the percent of patients using analgesics and in overall analgesic use observed in the Locteron group provide additional support for improved tolerability on Locteron,” said Dr. Long. “These results complement the positive results released last week from our SELECT-2 Phase 2b trial in which we showed statistically significant reductions in flu-like adverse events for three different Locteron doses, and substantial reductions in depression for the Locteron 480 and 320 µg doses.”

About EMPOWER Study

The objective of the EMPOWER study was to test the hypothesis that the 480 µg dose of Locteron dosed once every two weeks reduces flu-like symptoms but retains equivalent efficacy compared to PEG-Intron (1.5 µg/kg, administered every week). The 133 patients in the EMPOWER study were enrolled in two contributing Phase 2b trials:

- SELECT-2, a Phase 2b dose-finding trial evaluating the 320, 480 or 640 µg doses of Locteron versus PEG-Intron.
- The 480 STUDY, a Phase 2b trial evaluating the 480 µg dose of Locteron versus PEG-Intron.



All patients in both trials were treatment-naïve-genotype-1 subjects with chronic hepatitis C, and all patients were also treated with weight-based ribavirin. A total of 30 sites participated in the two trials (14 sites in the US, 11 in Europe, and five in Israel).

Locteron Overview

Locteron, controlled-release interferon alpha 2b, is designed to offer key advantages compared to currently approved products, including reduced flu-like symptoms and rates of depression, and cutting in half the number of injections required. In contrast to Locteron, the currently approved products, Pegasys® and PEG-Intron, are immediate-release products that lack a controlled-release mechanism. The two-drug combination of interferon alpha and ribavirin serves as the current standard of care for the treatment of hepatitis C. The launch of the first direct-acting anti-viral (DAA) product, projected for 2011, will transform treatment of genotype-1 patients to a triple-drug therapy (interferon plus ribavirin plus DAA) and substantially raise cure rates. Other recent triple or quad drug combinations with interferon (including interferon plus ribavirin plus two DAA agents) have shown promise in early clinical testing, further solidifying the continued role of interferon in the treatment of hepatitis C. 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. This controlled-release mechanism is designed to reduce the frequency and severity of flu-like symptoms and depression commonly experienced by patients treated with pegylated interferons.

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.

About Biolex Therapeutics

Biolex is a biopharmaceutical company that uses its patented LEX SystemSM 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 best-in-class efficacy/tolerability profiles while incorporating proven mechanisms of action. 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-155 is a direct-acting thrombolytic designed to dissolve blood clots in patients. BLX-301 is a humanized anti-CD20 antibody glyco-optimized for the treatment of non-Hodgkin's B-cell lymphoma and other diseases.



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