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BIOLEX ANNOUNCES PRESENTATION AT EASL OF INTERIM RESULTS FROM EMPOWER PHASE 2b STUDY OF LOCTERON® IN CHRONIC HEPATITIS C

Locteron dosed once every two weeks demonstrated a comparable reduction in viral load compared to once-weekly standard of care with 57% less flu-like adverse events

PITTSBORO, NORTH CAROLINA, April 16, 2010 - Biolex Therapeutics, Inc. announced that interim results from EMPOWER, a prospectively designed analysis of results from two Phase 2b trials of Locteron®, were presented yesterday in a late-breaker session at the 45th 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. In the EMPOWER study, the 480 µg dose of Locteron demonstrated viral kinetics and response rates that were comparable to the PEG-Intron® control while also achieving a 57% reduction in flu-like adverse events.

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. Interim results from SELECT-2 were also presented at EASL yesterday. SELECT-2 contributed a total of 59 Locteron 480 µg and PEG-Intron patients to EMPOWER.
- **The 480 STUDY**, a Phase 2b trial evaluating the 480 µg dose of Locteron versus PEG-Intron. Interim results from the 480 STUDY will be presented in an oral presentation at EASL later today. The 480 STUDY contributed 74 patients to EMPOWER.

All patients 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). All patients in EMPOWER have completed at least six weeks of study, and over 80% of the patients have completed 12 weeks of study.

Through six weeks of treatment, Locteron 480 µg administered once every two weeks demonstrated reductions in viral loads (mean changes in HCV RNA from baseline) that were somewhat more rapid than that achieved with PEG-Intron administered once per week. Rates of undetectable HCV RNA achieved after six weeks of treatment were 31% for Locteron 480



µg and 19% for PEG-Intron. The currently available results after 12 weeks of treatment (a number of patients have not yet reached the 12-week time point) suggest comparable reductions in mean HCV RNA and rates of undetectable HCV RNA for Locteron 480 µg and PEG-Intron.

In EMPOWER, 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 was evident even in the first week of the trial and continued through the 12-week time point available for evaluation. After six weeks of treatment, total flu-like adverse events reported for Locteron 480 µg 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 57% less than the total reported for PEG-Intron.

The EMPOWER results were presented by the lead author, Walker Long, MD, Chief Medical Officer and Vice President, Drug Development, Biolex Therapeutics, in the form of a poster titled “Q2Week Controlled-Release Interferon Alpha2b + Ribavirin Reduces Flu-like Symptoms >50% and Provides Equivalent Efficacy in Comparison to Weekly Pegylated Interferon Alpha2b + Ribavirin in Treatment-Naïve Genotype 1 Chronic Hepatitis C: Results from EMPOWER, a Randomized Open-Label 12-week Comparison in 133 Patients.”

“The EMPOWER study allows us to focus on the activity associated with one specific dose of Locteron and test our hypothesis that equivalent efficacy can be achieved while greatly reducing flu-like adverse events,” said Dr. Long. “These results exceed our expectations. We believe that the importance of reducing flu-like adverse events will grow with the advent of direct-acting virals and the shortening of therapy, due to the prevalence of these side effects during the first three months of treatment.”

Three serious adverse events were reported for Locteron 480 µg and three were reported for PEG-Intron. All events were expected labeled events for interferon alpha. Higher rates of mild or moderate (Grade 2 and Grade 3) reductions in measurements of white blood cell counts, platelets and neutrophils were observed for Locteron 480 µg compared to PEG-Intron, while higher rates of mild or moderate reductions in measurements of hemoglobin were observed for PEG-Intron. There were no Grade 4 reductions in hematological measurements 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 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 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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