

**BIOLEX ANNOUNCES LOCTERON® SVR12 RESULTS AND SAFETY/TOLERABILITY ADVANTAGES IN SELECT-2 HEPATITIS C TRIAL**

**Additional Tolerability Results from Two Phase 2b Trials of Locteron to be Presented in Late-Breaker Session at AASLD Conference on November 1, 2010**

**PITTSBORO, NORTH CAROLINA, October 28, 2010** - Biolex Therapeutics, Inc. announced positive efficacy, safety and tolerability results from its 72-week SELECT-2 Phase 2b dose-finding Phase 2b trial of Locteron®, the Company’s lead product candidate for the treatment of hepatitis C. For each of the three Locteron doses tested in SELECT-2, the percentage of patients who maintained undetectable levels of virus at week 60 of the trial, 12 weeks after completion of 48 weeks of treatment (SVR12), were comparable with or exceeded the response rate for the PEG-Intron® control. As a result of its controlled-release mechanism, Locteron was dosed half as frequently as PEG-Intron. PEG-Intron is one of two currently marketed pegylated interferon products for the treatment of hepatitis C, a market that currently exceeds \$2.5 billion in worldwide sales.

Additional results from SELECT-2 demonstrated the substantial tolerability advantages of Locteron. Patients treated with each of the three Locteron doses in SELECT-2 reported a statistically significant reduction in flu-like adverse events ( $p < 0.001$ ) compared to the PEG-Intron group. Accordingly, Locteron patients in all three dose groups used less concomitant medications (analgesics and antipyretics) than the PEG-Intron patients during the study period. Lastly, patients receiving the two lower doses of Locteron experienced lower rates of depression and discontinuations due to adverse events than patients receiving PEG-Intron.

Response rates and tolerability results for SELECT-2 are outlined in the table below:

	<b>SELECT-2 Interim Results</b>			<b>PEG-Intron</b> (n=30)
	<b>Locteron</b>			
	<u>640 µg</u> (n=29)	<u>480 µg</u> (n=29)	<u>320 µg</u> (n=28)	
Patients Achieving SVR 12 <sup>1</sup>	45%	35%	36%	30%
Reduction in Flu-Like Adverse Events	69% Reduction	68% Reduction	71% Reduction	n/a
Patients Using Analgesics	66%	48%	45%	73%
Discontinuations Due to Adverse Events	21%	14%	14%	23%

<sup>1</sup> Percentage of patients who maintained undetectable levels of virus at week 60 of the trial, 12 weeks after completion of 48 weeks of treatment.



“The strong viral response of Locteron achieved with once-every-two-week dosing is an improvement over current interferons, and I am impressed by the consistency of the flu-like effect across trials and different reporting methodologies,” said Nezam Afdhal, M.D., Chief of Hepatology at Beth Deaconess Medical Center, Harvard Medical School. “The reduction in symptoms of depression is quite promising and needs to be followed up in additional clinical evaluation. The Locteron safety and tolerability results are clearly important as recent clinical results demonstrate that interferon is likely to remain a core component of future treatment regimens that incorporate the new direct-acting anti-virals, highlighting the need for a more tolerable interferon to reduce the side-effect burden on patients from these multi-drug combinations and maximize their adherence to treatment.”

### **SELECT-2 Depression Results**

In SELECT-2, depression was measured in both patient-reported and clinic-reported methods and showed an advantage for Locteron for the dose groups encompassing the expected commercial dose range, the 320 and 480 µg doses. Throughout the 48 weeks of treatment in SELECT-2, patients self-reported their status using the Beck’s Depression Inventory (BDI), one of the most widely used instruments for measuring the severity of depression. Results demonstrated that fewer patients reported scores greater than 16 using the BDI (the threshold for mild depression) in the 320 and 480 µg Locteron dose groups compared to the PEG-Intron group. The patient-reported BDI results were confirmed independently by adverse event assessments performed by the clinical sites as highlighted in the table below:

	<b>SELECT-2 Depression Results</b>			<b>PEG-Intron</b>
	<b>Locteron</b>			
	<b>640 µg</b>	<b>480 µg</b>	<b>320 µg</b>	
Patients Reporting Score Greater than 16 Using BDI (Mild Depression Threshold)	34%	21%	14%	37%
Adverse Events Categorized as Depression Recorded by Clinical Sites	28%	10%	0%	20%

These findings from SELECT-2 are of particular importance as a survey of hepatitis C patients published in the *Journal of Viral Hepatitis* in 2010, showed that depression and flu-like symptoms were cited as the two most important adverse events impacting patient adherence to treatment.

### **AASLD Presentation**

Biolex also announced today that new tolerability data from two Phase 2b trials of Locteron have been accepted for a late-breaker presentation on November 1, 2010 at the 61st Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.



These latest tolerability results include daily patient self-reporting of flu-like adverse events using an electronic patient reported outcome system (ePRO).

“We believe that the efficacy, safety and tolerability results from SELECT-2 support the profile of Locteron as the most combinable interferon for use with direct-acting anti-viral drugs in emerging combination regimens,” said Mr. Jan Turek, Biolex’s President and Chief Executive Officer. “We are pleased that the ePRO results, the newest data supporting the tolerability advantages of Locteron, have been accepted for presentation at the AASLD conference.”

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 SELECT-2 Study**

Biolex’s SELECT-2 Phase 2b trial was designed to identify one or more doses of Locteron that demonstrated viral kinetics and response rates comparable to the PEG-Intron® control while also achieving at least a 50% reduction in flu-like adverse events. SELECT-2 is being conducted in the United States and Europe in 116 treatment-naïve, genotype-1, chronic hepatitis C patients. Patients were randomized into one of four dosing cohorts, the 320, 480 or 640 µg dose of Locteron (administered once every two weeks) or a control arm consisting of PEG-Intron (1.5 µg/kg, administered every week), with all patients receiving weight-based ribavirin. Patients were treated for 48 weeks and are being followed for an additional 24 weeks to determine the sustained virologic response (SVR) rate. All patients in the trial have reached at least the 60-week time point of the study, or 12 weeks of follow-up after completion of the scheduled 48 weeks treatment.

In SELECT-2, all adverse events were recorded during weekly clinic visits by the clinical site personnel. Flu-like adverse events were predefined to include arthralgia, chills, fever, headache, and myalgia. Under the statistical analysis plan for the trial, the reductions in flu-like adverse events were tested after four and 12 weeks of treatment and were statistically significant for all three Locteron doses ( $p < 0.001$  at 12 weeks for each of the 320, 480 or 640 µg doses of Locteron). In addition to the weekly clinic reporting, flu-like adverse events were self reported daily by patients through an electronic patient reported outcome system (ePRO). The ePRO results will be reported at the upcoming AASLD meeting as detailed above.

### **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 (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.

### **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 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.

###

#### Contacts:

Media: Tim Brons, Vida Communication, 415-675-7402, [tbrons@vidacommunication.com](mailto:tbrons@vidacommunication.com)

Investors: Dale Sander, Chief Financial Officer, 858-663-6993, [dsander@biolex.com](mailto:dsander@biolex.com)

Partnering: Bipin Dalmia, Senior Vice President, Business Development and Intellectual Property, 919-923-6616, [bdalmia@biolex.com](mailto:bdalmia@biolex.com)

