

BIOLEX PRESENTS FINAL PHASE 2B RESULTS AT EASL HIGHLIGHTING TOLERABILITY ADVANTAGES OF LOCTERON® IN TREATMENT OF HCV

Presentation Highlights Strong Antiviral Activity and SVR Rates, Significant Reductions in Flu-Like Adverse Events and Reduced Rates of Depression

Significant Tolerability Advantages and a 50% Reduction in Dosing Frequency Support Locteron’s Attractiveness for Use in New Triple- and Quad-Combination Regimens

PITTSBORO, NORTH CAROLINA, March 31, 2011 - Biolex Therapeutics, Inc. announced that final 72-week results from its SELECT-2 Phase 2b trial of Locteron® for the treatment of hepatitis C are being presented today at the 46th Annual Meeting of the European Association for the Study of the Liver (EASL) in Berlin, Germany. Data presented today show that Locteron achieved the SELECT-2 study objectives by demonstrating viral kinetics and response rates that were comparable with or exceeded the PEG-Intron® control while also achieving a statistically significant reduction in flu-like adverse events, reduced rates of depression, lower use of concomitant medications and a reduced rate of discontinuation due to adverse events. Locteron, the only controlled-release interferon alpha, is designed to offer key tolerability and dosing advantages over currently marketed interferons and serve as a core component of new combination therapies as the treatment of hepatitis C evolves to triple- and quad-drug regimens.

Locteron Dosing Convenience and Efficacy

Locteron is administered once every other week and requires half as many injections as the currently marketed interferons, each of which are injected once per week. In SELECT-2, the sustained virologic response rate (SVR) for each of the three Locteron doses studied was comparable with or exceeded the response rate for the PEG-Intron control as outlined in the table below.

	SELECT-2 SVR Results			
	<u>Locteron</u> (Administered Once Every Two Weeks)			<u>PEG-Intron</u> (Administered Every Week)
	<u>640 µg</u> (n=29)	<u>480 µg</u> (n=29)	<u>320 µg</u> (n=28)	
Patients Achieving SVR ¹	41%	34%	36%	33%

Locteron Tolerability Advantages

A major objective of the SELECT-2 trial was to further demonstrate the ability of Locteron’s controlled-release mechanism to improve patient tolerability. In SELECT-2, patients treated with Locteron experienced a significant reduction in the frequency and severity of flu-like

¹Percentage of patients who maintained undetectable levels of virus at week 72 of the trial, 24 weeks after completion of 48 weeks of treatment (includes all patients who were dosed at least once in the trial).



adverse events, reduced use of concomitant (analgesic/antipyretic) medications and reduced rates of depression compared to patients treated with the PEG-Intron control.

The SELECT-2 results were presented by the lead author, Eric Lawitz, MD, Medical Director and Principal Investigator, Alamo Medical Research, in a poster titled “SVR for Controlled-Release Interferon Alpha-2b (CR2b) + Ribavirin Compared to Pegylated Interferon Alpha-2b (Peg2b) + Ribavirin in Treatment-Naïve Genotype-1 (G1) Hepatitis C: Final Results from SELECT-2.”

“The results from the SELECT-2 trial are certainly consistent with the promise of this drug candidate as a next-generation interferon,” said Dr. Lawitz. “The ability of Locteron to contribute to the achievement of comparable viral cure rates with once-every-two-week dosing is a major improvement over current interferons. I am also impressed by the consistency of the Locteron tolerability advantages seen across different outcome measures and reporting methodologies. I look forward to seeing the development of Locteron expanded to testing in combination with direct-acting anti-viral agents.”

In SELECT-2, flu-like adverse events were predefined to include arthralgia, chills, fever, headache, and myalgia and were captured in two ways:

- Traditional weekly adverse event assessments performed by medical personnel at the clinical sites during the entire 48 weeks of treatment.
- Daily electronic patient reported outcome (ePRO) system where patients directly reported their flu-like adverse events each day for the first 12 weeks of the trial.

Locteron substantially reduced flu-like side effects under both measures as shown below:

	Locteron		
	640 µg	480 µg	320 µg
Weekly Clinic Reports:	(% reduction versus PEG-Intron)		
Through 12 Weeks	53%	55%	59%
	p<0.001 ²	p<0.001 ²	p<0.001 ²
Through 48 Weeks	65%	65%	65%
Daily ePRO Reports (Through 12 Weeks):			
Flu-Like AEs	41%	39%	56%
Severe Flu-Like AEs	31%	69%	73%

² The reductions in flu-like adverse events were tested after four and 12 weeks of treatment and were statistically significant at both time points for all three Locteron doses.



As the ePRO results were reported in real-time directly by the patients, they provide important insight into the patients' real-world experiences with these side effects and the impact on their daily activities. A comparison of the ePRO and clinic site reporting highlights the fact that flu-like adverse events may be even 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 SELECT-2 were almost five times greater than the total flu-like adverse events recorded by the clinical sites. Also of importance, patients rated 77% of their flu-like adverse events as moderate or severe in their ePRO reports, compared to the clinical site reporting in which only 16% 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 complement each other and each demonstrates the substantial reduction in flu-like adverse events for patients treated with Locteron compared to patients treated with PEG-Intron.

“The ePRO results underscore the impact that flu-like adverse events have on patients' daily lives and highlight the potential contribution of Locteron to the future success of multi-drug treatment combinations,” said Zobair Younossi, MD, Professor of Medicine and Executive Director of the Center for Liver Diseases at Inova Fairfax Hospital. “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. If confirmed in phase III clinical trials, Locteron's potential 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, fewer Locteron patients used concomitant medications (analgesics and antipyretics) compared to PEG-Intron patients during the study period. Furthermore, Locteron patients had reduced rates of discontinuation due to adverse events versus the PEG-Intron patients.

SELECT-2 Final Results
Patients Using Analgesics and Discontinuations Due to Adverse Events

	<u>Locteron</u>			<u>PEG-Intron</u>
	<u>640 µg</u>	<u>480 µg</u>	<u>320 µg</u>	
	(During 48 Weeks of Study)			
Patients Using Analgesics	59%	45%	46%	77%
Patients Discontinuing Due to Adverse Events	21%	14%	14%	23%

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. These results will be presented at the EASL conference today in a separate presentation titled “Timing and Frequency of



Depression During HCV-Treatment with Controlled-Release INF α 2b (CR2b) vs. Pegylated INF α 2b (PEG2b): Results from SELECT-2, a Randomized Open-Label 72-week Comparison in 116 Treatment-Naïve Patients with Genotype-1 HCV.”

About the 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 was 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 μ g dose of Locteron (administered once every two weeks) or a control arm consisting of PEG-Intron (1.5 μ g/kg, administered every week), with all patients receiving weight-based ribavirin. Patients were treated for 48 weeks and were followed for an additional 24 weeks to determine the SVR rate. All results reported include all patients who were dosed at least once in the trial.

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. However, the launch of the first direct-acting anti-viral (DAA) product, projected to occur this year, 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. This is considerably more convenient than Pegasys and PEG-Intron, each of which requires 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 *Lemma* 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[®], has completed two Phase 2b clinical trials 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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