Egalet Announces Positive Top-Line Results from Oral Human Abuse Liability Study of Abuse-Deterrent Morphine, Egalet-001

Egalet-001 met primary endpoint of reduced drug liking compared to MS Contin®

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Wayne, Penn. – January 22, 2015 – Egalet Corporation (Nasdaq: EGLT) ("Egalet") today announced positive results from a Category 3 human abuse liability (HAL) study of Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate. The clinical HAL study demonstrated that in nondependent, recreational opioid users, the abuse potential of manipulated Egalet-001 taken orally was significantly lower than that for manipulated MS Contin (morphine sulfate controlled-release).

"This is the first Category 3 clinical human abuse liability study for Egalet's Guardian™ Technology," said Jeffrey Dayno, MD, chief medical officer at Egalet. "The study results demonstrate the robustness of Egalet's differentiated technology, which is based not only on the principles of formulation and matrix design, but also on its unique manufacturing process that employs injection molding. These clinical data expand the abuse-deterrent profile of Egalet-001 which, in Category 1 studies, has shown strong abuse-deterrent characteristics by demonstrating resistance to common and rigorous methods of physical and chemical manipulation in a differentiated approach without introducing an additional pharmacologic agent."

This Category 3 abuse-deterrent HAL study was conducted in accordance with the FDA draft guidance on Abuse-Deterrent Opioids: Evaluation and Labeling (January 2013). It was a single-center, randomized, double-blind, double-dummy, four-way crossover study which assessed the abuse potential of Egalet-001 versus MS Contin in 38 nondependent, recreational opioid users when taken orally. The primary objective was to compare the relative abuse potential of intact and manipulated formulations of Egalet-001 versus manipulated MS Contin. Since Egalet-001 is extremely hard and difficult to chew, the manipulation of the product involved a series of maneuvers using different household tools to try and reduce the particle size to maximally defeat the tablet. This procedure was based on the outcome of the first phase, physical tampering, of the Category 1 abuse-deterrent studies for Egalet-001.

A few highlights from the study include:

- On the primary endpoint of drug liking as measured by Emax, the score for manipulated Egalet-001 was significantly lower than the Emax for manipulated MS Contin ($p < 0.007$);
- There was no statistical difference on drug liking scores (Emax) between intact and manipulated Egalet-001, indicating that even after significant manipulation, Egalet-001 retains its abuse-deterrent characteristics;
- The corresponding pharmacokinetic (PK) data from this study demonstrated a higher maximum plasma concentration (Cmax) and shorter time to maximum plasma concentration (Tmax) for manipulated MS Contin compared to manipulated Egalet-001; and,
- The 'Abuse Quotient,' which is defined as the Cmax/Tmax, for each of the treatment arms, was as follows:
    - 5.7 for intact Egalet-001

- 16.4 for manipulated Egalet-001 and
- 45.9 for manipulated MS Contin

“The data from this oral human abuse liability study demonstrate a clinically relevant decrease in drug liking for Egalet-001 compared to MS Contin when manipulated and taken orally,” said Lynn Webster, MD, principal investigator of the study and vice president scientific affairs, PRA International. “These clinical results, plus the difficulty that I have observed trying to defeat the Egalet-001 tablets in preparation for the study, suggest that Egalet-001 shows real promise as an abuse-deterrent, extended-release morphine product candidate to help address the ongoing challenge of opioid misuse, abuse, overdose and death.”

In addition to this Category 3 HAL study, Egalet presented positive results from Category 1 studies for Egalet-001 last year at PainWeek and will share the results from additional abuse-deterrent studies later this year.

About Egalet

Egalet, a fully integrated commercial specialty pharmaceutical company, is focused on developing, manufacturing and marketing innovative pain treatments. The Company has two approved products: OXAYDO (oxycodone HCI, USP) tablets for oral use only -CII, the first and only approved immediate-release oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate, and SPRIX® (ketorolac tromethamine) Nasal Spray, a non-steroidal anti-inflammatory drug (NSAID), indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. In addition, using Egalet’s proprietary Guardian™ Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. The lead programs, Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation, and Egalet-002, an abuse-deterrent, extended-release, oral oxycodone formulation, are in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate. Egalet’s Guardian Technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple active pharmaceutical ingredients with similar or different release profiles. Full prescribing information for OXAYDO and SPRIX and additional information on Egalet can be found at www.egalet.com.

Safe Harbor

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management’s current expectations, and are subject to known and unknown uncertainties and risks. Actual results could differ materially from those discussed due to a number of factors, including, but not limited to: the success of our clinical trials; our ability to obtain regulatory approval of our product candidates; competitive factors; general market conditions; and other risks factors described in Egalet's filings with the United States

Securities and Exchange Commission. Egalet assumes no obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by law.

For further information: BiotechComm E. Blair Clark-Schoeb Tel: 917-432-9275 Email: blair@biotechcomm.com