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Egalet Acquires/Licenses Two Innovative Approved Pain Products

--Transactions transform Egalet into a commercial specialty pharmaceutical company paving the way for commercialization of late-stage pipeline of abuse-deterrent opioids --

-- Company has entered into a debt financing of \$15 million with Hercules Technology Growth Capital to fund the transactions and commercial expansion --

-- Egalet to host conference call today at 9:00 AM EST --

WAYNE, Pa., Jan. 8, 2015 (GLOBE NEWSWIRE) -- Egalet Corporation (Nasdaq:[EGLT](#)) ("Egalet") today announced the licensing and acquisition of two innovative approved pain products transforming Egalet into a fully integrated specialty pharmaceutical company focused on developing and commercializing products indicated to treat patients living with moderate to severe pain. Egalet has agreed to license worldwide rights to OXAYDO™ (oxycodone HCl, USP) tablets for oral use only -CII, the first and only approved immediate-release oxycodone product formulated to deter abuse via snorting from Acura Pharmaceuticals. OXAYDO is approved in the United States and indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. In addition, Egalet has acquired SPRIX® (ketorolac tromethamine) Nasal Spray from Luitpold Pharmaceuticals. SPRIX is 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. With the addition of these two products, Egalet plans to build a commercial infrastructure that will help pave the way for the launch of Egalet's late-stage pipeline of abuse-deterrent opioids.

"The license and acquisition of OXAYDO and SPRIX, two approved innovative pain treatments, helps transform Egalet into a fully integrated specialty pharmaceutical company in advance of the approval of our highly differentiated, late-stage pipeline of abuse-deterrent, extended-release products," said Bob Radie, president and chief executive officer of Egalet. "These products, an immediate-release opioid formulated to deter abuse and a nasal spray NSAID delivering pain relief at an opioid level, are natural fits given our focus on providing patients treatment options for pain that may help deter abuse and misuse as well as accelerate our path to revenue generation and profitability."

To fund these transactions, Egalet has consummated a debt financing with [Hercules Technology Growth Capital](#) of \$15 million. Terms of the debt financing include an interest rate equal to the greater of either 9.4 percent or 9.4 percent plus the prime rate as reported in the *Wall Street Journal* minus 3.25 percent. Payments under the loan agreement are interest only for 12 months, followed by 30 equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2018. As part of the financing, Egalet issued Hercules a warrant to purchase \$600,000 of its common stock.

The transactions are expected to benefit Egalet in the following ways:

- Transform Egalet into a commercial-stage specialty pharmaceutical company with revenue generation two years ahead of plan;
- Establish commercial presence to ensure successful launch of Egalet-001 and Egalet-002 if and when approved;
- Augment the Company's pain portfolio by adding approved treatment options for pain care specialists to prescribe their patients living with moderate to severe pain; and
- Use primarily non-dilutive source of capital to fund transactions.

OXAYDO™ (previously known as OXECTA™) is the first and only immediate-release opioid analgesic formulated to discourage abuse associated with snorting. This single-agent product developed using Acura's Aversion® Technology has no acetaminophen and therefore does not carry the risk of liver toxicity associated with APAP combination products. The most common adverse reactions with OXAYDO are nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia and somnolence. SPRIX® is the first and only NSAID nasal spray for patients who require pain relief at the opioid level.

"With OXAYDO, physicians now have an immediate-release opioid product designed to discourage abuse via snorting," said Jeffrey Dayno, MD, chief medical officer at Egalet. "This is an important addition to extended-release opioids with abuse-deterrent properties to help address the broader public health challenge of opioid misuse and abuse. With SPRIX we can offer patients and physicians a non-opioid treatment option for the short-term management of pain requiring analgesia at the opioid level. These products complement Egalet 001 and Egalet-002, our product candidates which use Egalet's Guardian™ Technology, and are in the final stage of development."

Under the terms of the agreement with Acura Pharmaceuticals, Egalet has licensed worldwide rights to OXAYDO for an upfront payment of \$5 million, a milestone payment of \$2.5 million upon first commercial sale, a payment of \$12.5 million when the product has achieved \$150 million in net sales in a calendar year and a tiered royalty of single-digit to double-digit percent based on sales thresholds.

Under the terms of the agreement with Luitpold Pharmaceuticals, Egalet acquired all intellectual property and certain other assets required to commercialize SPRIX. Egalet agreed to pay Luitpold \$7 million. In addition, Egalet entered into a six-month transition services agreement with Luitpold.

During the transition period Egalet will assume responsibility of SPRIX® and begin promotional efforts in the first quarter of 2015. Egalet plans to launch OXAYDO in the third quarter of 2015. Egalet will provide updates on commercial activities for both products in the first quarter of 2015.

Advisors

Aquilo Partners L.P. advised Egalet on the SPRIX transaction.

About Acute Pain

Acute pain is pain that comes on quickly, can be severe, but lasts a relatively short time.¹ Acute pain has many different causes including surgery, broken bones and dental work, among others. Acute pain can be mild and last for just seconds or it might be severe and come and go over weeks or months. In most cases, acute pain does

not last longer than six months, and it resolves when the underlying cause of pain has been treated or has healed. Unrelieved acute pain, however, might lead to chronic pain.ⁱⁱ

About Chronic Pain

There are approximately 100 million Americans—more than those affected by heart disease, cancer, and diabetes combined—who suffer from chronic pain that is often undertreated according to the Institute of Medicine. It is also the most common reason patients seek medical care, resulting in \$635 billion annually in both medical costs and decreased work productivity. Chronic pain is typically defined as pain that lasts beyond the healing of an injury or that persists beyond three months. Common types of chronic pain include low back pain, arthritis, headache and face and jaw pain. Severe pain typically stops an individual from participating in activities and causes patients to change their behavior to avoid such activities. According to an article in the *New England Journal of Medicine*, chronic pain is associated with functional loss and disability, reduced quality of life, high health care costs, and premature death. Chronic pain also can result in isolation, depression, sleep disorders and other issues that have a negative impact not only on patients but family members as well.

It is important that these patients whose chronic pain often interrupts their daily lives gain and maintain access to adequate pain relief. Opioids analgesics play an important role in the management of moderate to severe pain and are the most widely prescribed products for pain, with prescriptions exceeding 200 million in 2013.

Important Safety Information for OXAYDO™ (oxycodone HCl, USP) Tablets for oral use only - CII

OXAYDO is an immediate-release oral formulation of oxycodone HCl indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.

OXAYDO is contraindicated in patients with respiratory depression, paralytic ileus, acute or severe bronchial asthma or hypercarbia, or known hypersensitivity to oxycodone or any components of the product.

Respiratory depression is the primary risk of OXAYDO and it must be used with extreme caution in patients with chronic obstructive pulmonary disease or cor pulmonale, in patients with decreased respiratory reserve, hypoxia, hypercapnia or pre-existing respiratory depression.

OXAYDO contains oxycodone HCl, an opioid agonist and a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. OXAYDO can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing in situations where there is concern about an increased risk of misuse or abuse. OXAYDO may be abused by crushing, chewing, snorting or injecting the product and these practices pose a significant risk to the abuser that could result in overdose and death.

Patients receiving central nervous system depressants concomitantly with OXAYDO may exhibit an additive central nervous system depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced. Patients should not consume alcoholic beverages, or any medications containing alcohol while taking OXAYDO.

OXAYDO may cause severe hypotension in patients whose ability to maintain blood pressure has been compromised. OXAYDO may produce orthostatic hypotension in ambulatory patients. OXAYDO must be administered with caution in patients in circulatory shock.

Serious adverse reactions that may be associated with OXAYDO include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension and/or shock. The most common adverse reactions are nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia and somnolence.

In opioid naïve patients, start dosing OXAYDO with five to 15 mg every four to six hours as needed for pain. OXAYDO should not be given to anyone other than the individual for whom it was prescribed. Keep OXAYDO in a locked cabinet, drawer or medicine safe so that it will not be stolen.

Please see full prescribing information for OXAYDO at

http://www.egalet.com/products/oxaydo/pi/USPI_OXAYDO_Oxycodone_HCl_Tablets_120814.pdf

Important Safety Information for SPRIX[®] (ketorolac tromethamine) Nasal Spray

SPRIX is a non-steroidal anti-inflammatory drug (NSAID) indicated in adult patients for the short-term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level. Do not exceed a total combined duration of use of SPRIX and other ketorolac formulations (IM/IV or oral) of 5 days. SPRIX is not indicated for use in pediatric patients or for minor or chronic painful conditions.

SPRIX is contraindicated as follows: in patients with peptic ulcer disease or a history of GI bleeding; in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis, or at high risk of bleeding; for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery; in patients with advanced renal impairment and those at risk for renal failure due to volume depletion; use as a prophylactic analgesic before any surgery; use in labor and delivery; use in patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs; and, known hypersensitivity to ketorolac, aspirin, other NSAIDs or EDTA.

SPRIX should be used with caution in patients with a prior history of ulcer disease or GI bleeding, coagulation disorders, in patients taking diuretics or ACE inhibitors, or those with compromised cardiac function. NSAIDs can cause serious anaphylactoid reactions and serious dermatologic adverse reactions; SPRIX should be discontinued immediately in patients with allergic reactions or skin reactions.

The most common adverse reactions (incidence \geq 2%) in patients treated with SPRIX and occurring at a rate at least twice that of placebo are nasal discomfort, rhinalgia, increased lacrimation, throat irritation, oliguria, rash, bradycardia, decreased urine output, increased ALT and/or AST, hypertension, and rhinitis.

SPRIX is not an inhaled product. SPRIX nasal spray should be discarded within 24 hours of taking the first dose, even if the bottle still contains some medication.

Please see full prescribing information for SPRIX at www.sprix.com.

Conference Call Information

Egalet's management will host a conference call to discuss the business update:

Date: January 8, 2015

Time: 9:00 a.m. EST

Webcast (live and archive): <http://egalet.investorroom.com/eventsandwebcasts>

Dial-in numbers: 1-888-346-2615 (domestic)
1-412-902-4253 (international)
Replay dial-in numbers: 1-877-344-7529 (domestic)
1-412-317-0088 (international)
Conference Number: 10058204

About Egalet

Egalet, a fully integrated specialty pharmaceutical company, is focused on developing, manufacturing and marketing innovative pain treatments. The Company has two approved products: OXAYDO (oxycodone HCl, 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 has a pipeline of clinical late-stage, opioid 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 design combination products that include multiple active pharmaceutical ingredients with similar or different release profiles. For more information please visit 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 integrating recent acquisitions; our ability to obtain regulatory approval of our product candidates; our ability to successfully commercialize SPRIX and OXAYDO, 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.

ⁱ <http://www.theacpa.org/search.aspx?term=acute%20pain>

ⁱⁱ <http://my.clevelandclinic.org/services/anesthesiology/pain-management/diseases-conditions/hic-acute-vs-chronic-pain>

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