# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## FORM 8-K CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 14, 2014

# NEKTAR THERAPEUTICS (Exact Name of Registrant as Specified in Charter)

Delaware 0-24006 94-3134940 (State or Other Jurisdiction of Incorporation) (Commission File Number) (IRS Employer Identification No.)

455 Mission Bay Boulevard South San Francisco, California 94158 (Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: (415) 482-5300

Check ( provisio	the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following ons:
	☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
	☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
	☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events.

On January 14, 2014, Nektar Therapeutics, a Delaware Corporation ("Nektar"), issued a press release announcing that the first subjects were dosed in a Phase 1 clinical study for NKTR-171. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On January 14, 2014, Nektar also issued a press release announcing that etirinotecan pegol (NKTR-102) passes interim efficacy analysis for the BEACON pivotal Phase 3 clinical study in patients with metastatic breast cancer. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "First Subjects Dosed in Phase 1 Clinical Study of NKTR-171, A New Peripherally-Restricted Sodium Channel Blocker
	to Treat Neuropathic Pain" issued by Nektar Therapeutics on January 14, 2014.
99.2	Press Release titled "Etirinotecan Pegol (NKTR-102) Passes Interim Efficacy Analysis for BEACON Pivotal Phase 3 Clinical Study in
	Patients with Metastatic Breast Cancer" issued by Nektar Therapeutics on January 14, 2014.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEKTAR THERAPEUTICS

By: /s/ Gil M. Labrucherie

Gil M. Labrucherie General Counsel and Secretary

Date: January 14, 2014

# EXHIBIT INDEX

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	Patients with Metastatic Breast Cancer" issued by Nektar Therapeutics on January 14, 2014.



### First Subjects Dosed in Phase 1 Clinical Study of NKTR-171, A New Peripherally-Restricted Sodium Channel Blocker to Treat Neuropathic Pain

San Francisco, Calif, January 14, 2014 – Nektar Therapeutics (Nasdaq: NKTR) today announced that the first subjects were dosed in a Phase 1 clinical study for NKTR-171, a new sodium channel blocker being developed as an oral therapy for the treatment of peripheral neuropathic pain. The single-ascending dose Phase 1 clinical study of NKTR-171 will assess its pharmacokinetics, tolerability, and safety in up to 50 healthy subjects. NKTR-171 is a new molecular entity that is specifically designed to treat neuropathic pain by blocking hyperactive neuronal sodium channels associated with damaged nerves in the peripheral nervous system.

Chronic neuropathic pain arises from nerves injured or damaged by systemic disease, infection, toxins, or physical trauma that are in a continuous state of hyper-excitability, often due to aberrant sodium channel firing. This hyper-excitability results in transmission of abnormal pain signals from the periphery to the central nervous system (CNS). Existing therapies that block sodium channels have been shown to provide effective pain relief but are typically associated with significant unwanted CNS side effects, including dizziness, ataxia and somnolence. NKTR-171 is designed to be a peripherally-restricted molecule which selectively blocks hyper-excitable sodium channels without causing the CNS side effects that limit usage of existing therapies.

"Neuropathic pain is estimated to affect more than 20 million people in the US alone and is characterized by symptoms of burning pain and painful hypersensitivity," said Robert Medve, MD, Nektar's Chief Medical Officer. "While conventional sodium channel blockers have demonstrated efficacy in addressing peripheral nerve pain, the CNS-mediated side effects associated with these medicines make the treatment intolerable for many patients. A peripherally-restricted sodium channel blocker with good efficacy and low CNS side effects would be an important advance in the treatment of patients with debilitating neuropathic pain."

#### **About NKTR-171**

In preclinical studies, NKTR-171 demonstrated an improved efficacy and CNS side effect profile when compared to pregabalin (Lyrica®), the most highly prescribed therapy in the treatment of neuropathic pain. <sup>2,3</sup> NKTR-171 also exhibited significantly reduced CNS penetration versus currently-approved sodium channel blockers. NKTR-171 did not significantly impair motor coordination at doses demonstrating analgesia, suggesting that the therapeutic index, or the ability to provide analgesia at doses that do not cause significant CNS side effects, may be greater for NKTR-171 than for currently available therapies. <sup>2,3</sup> In pre-clinical *in vitro* data, NKTR-171 was shown to produce frequency-dependent blockade of inactivated sodium channels, meaning NKTR-171 preferentially blocks the abnormal, rapidly-firing neurons associated with neuropathic pain and spares normal nerve function in unaffected tissues. <sup>2,3</sup>

#### **About Neuropathic Pain**

Neuropathic pain, also known as nerve pain or peripheral neuropathy, is the result of nerve damage and can be caused by such diverse conditions as diabetes, shingles, cancer, HIV, multiple sclerosis and fibromyalgia, as well as injury or trauma to the nerves. According to the Neuropathy Association, an estimated 1 in 15 Americans suffer from peripheral neuropathy<sup>4</sup>. Its prevalence is particularly high among diabetes patients and incidence increases with age<sup>4</sup>. Though neuropathic pain is a very common condition, the symptoms of it can be highly variable, including numbness, tingling, and pricking sensations, sensitivity to touch, or burning sensations, making diagnosis difficult. If left untreated, peripheral neuropathy can lead to permanent nerve damage<sup>5</sup> and significant disability.

Today, medicines that act by blocking sodium or calcium channels such as the gabapentinoids and anti-epileptic medications, are used in the treatment of neuropathic pain but are known to cause significant CNS-related side effects, such as sedation and dizziness. The sodium channel blocker lidocaine is known to be effective in addressing peripheral nerve pain, however it is not selective and blocks both normal and abnormal nerve conduction. The lack of an oral form further limits its utility<sup>5</sup>. In spite of the shortcomings of medications currently prescribed for neuropathic pain, total U.S. sales in 2011 were \$2.5 billion<sup>6</sup>.

#### **About Nektar**

Nektar Therapeutics (NASDAQ: NKTR) is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar has a robust R&D pipeline of potentially high-value therapeutics in oncology, pain and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for naloxegol (NKTR-118), an investigational drug candidate, which has been filed in the U.S., Europe and Canada as a once-daily, oral tablet for the treatment of opioid-induced constipation. This agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of fixed doses of naloxegol and opioids. NKTR-181, a novel mu-opioid analgesic candidate for chronic pain conditions, has completed Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-opioid analgesic in development to treat acute pain is in Phase 1 clinical development. In oncology, etirinotecan pegol (NKTR-102) is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer and is also in Phase 2 studies for the treatment of ovarian, colorectal, lung and brain cancers. In anti-infectives, Amikacin Inhale is in Phase 3 studies being conducted by Bayer Healthcare to treat patients with Gram-negative pneumonia. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a longer-acting PEGylated rFVIII therapy, which is in Phase 3 clinical development.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia<sup>®</sup> for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS<sup>®</sup> for hepatitis C and Amgen's Neulasta<sup>®</sup> for neutropenia.

Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at http://www.nektar.com

#### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "could," "potential," "may" and similar references to future periods. Examples of forward-looking statements include our current views as to the potential of NKTR-171 to be new treatment of peripheral neuropathic pain; the potential of NKTR-171 to exhibit reduced CNS-related side effects that are associated with existing sodium channel blocker therapies; the value of our pegylation and polymer conjugate technology platform; and the potential of certain of our other drug candidates and those of our collaboration partners. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, observations and assumptions regarding the potential of our business, drug candidates, and our technology. Because forwardlooking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forwardlooking statements include, among others: (i) the statements regarding the therapeutic potential of NKTR-171 are based on preclinical data only and data from clinical studies may not confirm these potential therapeutic benefits; (ii) NKTR-171 is in early stage clinical development and could fail at any time due to numerous unpredictable and significant risks related to safety, efficacy and other important findings that can negatively impact clinical development; (iii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of Nektar's technology platform to potential new drug candidates such as NKTR-171 is therefore very uncertain and unpredictable and could unexpectedly fail at any time; (iv) patents may not issue from our patent applications for NKTR-171 or additional intellectual property licenses from third parties may be required; and (v) the outcome of any potential intellectual property or other litigation related to our proprietary drug candidates. Other important risks and uncertainties are detailed in our filings with the Securities and Exchange Commission ("SEC"), including without limitation, those risks and uncertainties set forth in our Form 10-Q filed with the SEC on November 7, 2013. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

# **Nektar Investor Inquiries:**

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# **Nektar Media Inquiries:**

*Brianne Cannon* 415-512-0770

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- 1) Devor et. al., The Journal of Pain, Vol 7, No 1S (January), Supplement 1, 2006: pp S3-S12
- 2) Gursahani et. al., 2013 American Pain Society 32nd Annual Meeting
- 3) Gursahani et. al., 2013 Fourth International Congress on Neuropathic Pain
- 4) Neuropathy Association; Facts (http://www.neuropathy.org/site/PageServer?pagename=About\_Facts)
- $5)\ NINDS\ Peripheral\ Neuropathy\ Fact\ Sheet\ (http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail\_peripheralneuropathy.htm)$
- 6) IMS Health 2011



# Etirinotecan Pegol (NKTR-102) Passes Interim Efficacy Analysis for BEACON Pivotal Phase 3 Clinical Study in Patients with Metastatic Breast Cancer

SAN FRANCISCO, January 14, 2014 -- Nektar Therapeutics (NASDAQ:NKTR) announced today that the Independent Data Monitoring Committee (DMC) created to provide safety oversight for the Company's pivotal clinical study for etirinotecan pegol (NKTR-102) has recommended continuation of the BEACON phase 3 trial, based upon the completion of a planned interim efficacy analysis in accordance with the DMC charter. The BEACON trial is evaluating NKTR-102 versus an agent of physician's choice for the treatment of locally recurrent or metastatic breast cancer, with a primary efficacy endpoint of overall survival. NKTR-102 is the first long-acting topoisomerase I-inhibitor designed to concentrate in tumor tissue, provide sustained tumor suppression throughout the entire chemotherapy cycle, and to reduce the peak exposures that are associated with toxicities of other cytotoxics.

The independent DMC performed the pre-defined interim efficacy analysis, which consisted of a review of ongoing efficacy and safety data, including 50% of patient events necessary to evaluate the primary endpoint of overall survival. In August 2013, the BEACON study completed enrollment of 852 patients with advanced breast cancer whose disease has progressed following treatment with anthracycline, taxane and capecitabine therapies (ATC).

"While the results of BEACON remain blinded to Nektar, we are very pleased that the NKTR-102 trial has successfully passed this important interim efficacy analysis," said Howard Robin, President and CEO of Nektar Therapeutics. "We expect final results from the study at the end of 2014 or early 2015, and if positive, we plan to submit filings in the U.S. and Europe in the second half of 2015. There is a high unmet need for new treatment options for patients with advanced breast cancer, particularly for patients with HER2-negative breast cancer and triple-negative breast cancer."

Positive Phase 2 data for NKTR-102 were recently published in Lancet Oncology in November 2013. (1) Etirinotecan pegol achieved a confirmed objective response rate by RECIST of 29 percent. NKTR-102 demonstrated a high clinical benefit rate (CR+PR+SD greater than six months) of 37 percent (13/35) in the 14-day group and 49 percent (17/35) in the 21-day group. Six patients experienced 100 percent resolution of all target lesions, with two complete RECIST responses and four near-complete responses. Patients treated exhibited low rates of alopecia, neuropathy and neutropenia, which are significant adverse events associated with existing breast cancer therapies. Side effects were generally manageable; the most common Grade 3 toxicity was diarrhea (17-23%) typically occurring after three months of therapy.

#### About the BEACON Study

BEACON is a Phase 3, open-label, randomized, multicenter study of NKTR-102 which enrolled 852 women with locally recurrent or metastatic breast cancer, who have previously been treated with ATC. The trial is being conducted at approximately 150 sites worldwide including North America, Western Europe, Russia and the Republic of Korea. Nearly half of the patients enrolled in BEACON were located in North America. Patients were randomized on a 1:1 basis to receive 145 mg/m2 of single-agent NKTR-102 once every three weeks or a single agent of physician's choice. The physician's choice agents include: ixabepilone, vinorelbine, gemcitabine, eribulin, or a taxane. Randomization was stratified by geographic region, prior use of eribulin and receptor status

The primary endpoint of the BEACON study is overall survival; secondary endpoints include progression-free survival, objective tumor response rates (ORR), clinical benefit rate, duration of response, pharmacokinetics, safety, quality-of-life measurements, and pharmacoeconomic implications. The study is also evaluating specific biomarker data to assess correlation with objective tumor response rates, progression-free survival, overall survival and selected toxicities.

#### **About Etirinotecan Pegol (NKTR-102)**

NKTR-102 is a new therapeutic option in development for advanced breast cancer. It is the first long-acting topoisomerase I inhibitor with a non-overlapping mechanism of action with other agents used to treat breast cancer, which may mitigate potential cancer cross-resistance and reduce overlapping toxicities. In November 2012, etirinotecan pegol was designated a Fast Track development program by the U.S. FDA for the treatment of patients with locally recurrent or metastatic breast cancer progressing after treatment with ATC.

NKTR-102 is believed to penetrate the vasculature of the tumor environment more readily than normal vasculature, increasing the concentration of active drug within tumor tissue to enhance anti-tumor activity. The unique PK profile of etirinotecan pegol provides continuous exposure of active drug throughout the entire chemotherapy cycle, with reduced peak exposures that can be associated with toxicities. In addition to metastatic breast cancer, etirinotecan pegol is also being evaluated for the treatment of ovarian, colorectal, glioma and lung cancers.

#### **About Metastatic Breast Cancer**

More than one million women worldwide are diagnosed with breast cancer globally every year. (2) The chance of developing invasive breast cancer at some time in a woman's life is a little less than one in eight (12%). There are approximately 200,000 new cases of breast cancer in the United States and 430,000 in Europe each year. (3) Metastatic breast cancer refers to cancer that has spread from the breast to distant sites in the body.

Anthracyclines and taxanes (AT) are the most active and widely used chemotherapeutic agents for breast cancer, but the increased use of these agents at an early stage of disease often renders tumors resistant to these drugs by the time the disease recurs, thereby reducing the number of treatment options for metastatic disease. Drugs used to treat patients who progress following AT treatment can have response rates as high as 20-30%; however, resistance develops rapidly and new agents with different mechanisms of action, such as topoisomerase I inhibitors, are needed to allow novel ways to overcome the problem of drug resistance. (4) There are currently no FDA-approved topoisomerase I inhibitors to treat breast cancer.

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- (1) Awada et al, Lancet Oncology 2013 Nov;14 (12):1216-25.
- (2) American Cancer Society, 2007 Global Cancer Facts and Figures Report.
- (3) American Cancer Society, 2009 Global Cancer Facts and Figures Report.
- (4) Moreno-Aspitia and Perez, Mayo Clin Proc. 2009; 84(6):533-545