



NKTR-102 Has High Response Rate and Sustained Clinical Benefit in 48 Percent of Women with Platinum-Resistant/Refractory Ovarian Cancer

Phase 2 Data Highlighted in Oral Abstract Session of 2010 American Society of Clinical Oncology Annual Meeting

CHICAGO, June 6, 2010 /PRNewswire via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced positive results from a Phase 2 clinical study evaluating single-agent NKTR-102 in women with platinum-resistant/refractory ovarian cancer. A total of 68 patients were enrolled with platinum-resistant disease, half of whom were platinum refractory. All 68 patients were evaluable for the primary endpoint of objective response rate using Gynecologic Cancer InterGroup (GCIG) criteria, which is a combination of response by tumor imaging (RECIST) and/or ovarian cancer biomarker (CA-125) criteria(1). GCIG (confirmed and unconfirmed) response rates were 41 percent (14/34) in the once every 14 days (q14d) dose schedule and 41 percent (14/34) for the once every 21 days (q21d) dose schedule. Confirmed objective GCIG response rates were 29 percent (10/34) and 38 percent (13/34) in the q14d and q21d dose schedules, respectively. Confirmed and unconfirmed objective response rates using RECIST were 24 percent (8/33) and 29 percent (9/31) for the q14d and q21d dose schedules, respectively. Confirmed objective response rates using RECIST were 21 percent (7/33) and 23 percent (7/31) for each dose schedule, respectively.

"NKTR-102 has an exceptionally high response rate compared to what would be expected in this group of heavily pre-treated women with platinum-resistant and refractory ovarian cancer," said Prof. Dr. Ignace Vergote, Head of the Department of Obstetrics and Gynaecology and Gynaecologic Oncology at the Catholic University of Leuven, European Union and Lead Investigator of the NKTR-102 study. "The impressive and rapid-onset treatment effect is particularly significant considering 71 percent of platinum-resistant patients had progressed within three months of their last platinum dose with a median of three prior cancer treatments. Based upon data from the GINECO cooperative group studies, RECIST response rates are typically below 10 percent for patients such as these. In addition, the median progression-free survival of eighteen weeks is considerably longer than would be expected in women with a median platinum-free interval of only one month. These results demonstrate that NKTR-102 holds great therapeutic potential for women battling ovarian cancer."

Approximately 48 percent (31/64) of the women in the study showed clinical benefit with single-agent NKTR-102, with a clinical benefit rate of 52 percent (17/33) in the q14d regimen and 45 percent (14/31) in the q21d regimen. [Table 2.] Confirmed response rates for women that failed prior pegylated liposomal doxorubicin (PLD) therapy were 20 percent (3/15) for the q14d regimen and 29 percent (4/14) for the q21d regimen. [Table 4.] NKTR-102 demonstrated a median progression-free survival of eighteen weeks as compared to a prior median platinum-free interval of four weeks. Confirmed CA-125 response rates were 38 percent (11/29) for both dose schedules.

"NKTR-102's clinical performance in platinum-refractory patients is particularly notable and provides a compelling rationale for accelerated development in this patient population," commented Robert L. Coleman, M.D., a leading ovarian cancer specialist and Director of Clinical Research, Department of Gynecologic Oncology, at The University of Texas M. D. Anderson Cancer Center, Houston, TX. "Rapid entry of NKTR-102 into Phase 3 development in women with less heavily pre-treated recurrent ovarian cancer is of great interest to the gynecologic cancer community."

NKTR-102 was generally well tolerated, particularly at the q21 dose schedule. The most common Grade 3 and 4 side effects were diarrhea, dehydration, hypokalemia, fatigue, nausea and neutropenia, with most side effects being Grade 3 in severity. [Table 5.]

NKTR-102 Phase 2 Study Results

P2 Study of NKTR-102 in Women with Platinum Resistant/Refractory Ovarian Cancer (Abstract #5013) - Sunday, June 6, 2010, 11:15 a.m. - 11:30 a.m. CT, E Arie Crown Theater

The NKTR-102 Phase 2 Study was an international, multicenter, open-label, randomized, two-stage study to evaluate NKTR-102 when given either on a q14d or q21d regimen in women with platinum-resistant/refractory disease to any line of platinum-based chemotherapy (platinum-free interval <6 months). Median lines of prior therapy for women enrolled in the study were three, with 47 percent of the women having failed prior treatment with pegylated liposomal doxorubicin (PLD). Of the 71 patients enrolled, 68 were platinum-resistant, and of these 34 were platinum-refractory (3 patients had platinum-sensitive

disease and were excluded from efficacy results). The primary endpoint of the study was objective response rate (based on RECIST and GCIG response criteria). Secondary endpoints were safety, progression-free survival and overall survival. Three patients in the study remain on NKTR-102 treatment.

TABLE 1. Patient Demographics: Prior Therapies

	NKTR-102 145 mg/m(2) q14d (N=36)	NKTR-102 145mg/m(2) q21d (N=35)	Total (N=71)
Prior Lines of Therapy (median)	3	3	3
Previous Platinum Regimens			
1	33%	31%	32%
2	44%	40%	42%
3	17%	14%	16%
4+	6%	14%	10%
Prior PLD	44%	49%	47%
Prior bevacizumab	11%	14%	13%
Prior gemcitabine	39%	46%	42%
Prior taxane	97%	94%	96%

TABLE 2. Efficacy Results: Objective Response Rates

	NKTR-102 145 mg/m(2) q14d	NKTR-102 145 mg/m(2) q21d
RECIST		
N (evaluable)	33	31
Confirmed + Unconfirmed	8 (24%)	9 (29%)
Confirmed	7 (21%)	7 (23%)
GCIG		
N (evaluable)	34	34
Confirmed + Unconfirmed	14 (41%)	14 (41%)
Confirmed	10 (29%)	13 (38%)
CA-125		
N (evaluable)	29	29
Confirmed	11 (38%)	11 (38%)

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Clinical Benefit Rate (CR+PR+[SD>3 months])		

N (evaluable)	33	31
Confirmed RECIST	17 (52%)	14 (45%)
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TABLE 3. Objective Response Rates by Platinum-Free Interval
NKTR-102 NKTR-102

Platinum-free interval (PFI)	145 mg/m(2) q14d			145 mg/m(2) q21d		
	< 30 days	< 91 days	31-182 days	< 30 days	< 91 days	31-182 days
RECIST						
N(evaluable)	14	19	19	18	25	13
Confirmed + Unconfirmed	0	4 (21%)	8 (42%)	4 (22%)	5 (20%)	5 (39%)
Confirmed	0	3 (16%)	7 (37%)	3 (17%)	4 (16%)	4 (31%)
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GCIG						
N(evaluable)	14	20	20	20	28	14
Confirmed + Unconfirmed	4 (29%)	8 (40%)	10 (50%)	7 (35%)	10 (36%)	7 (50%)
Confirmed	1 (7%)	5 (25%)	9 (45%)	7 (35%)	10 (36%)	6 (43%)
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TABLE 4. Objective RECIST Response Rates by Prior PLD Treatment

RECIST	NKTR-102	NKTR-102
	145 mg/m(2) q14d	145 mg/m(2) q21d
Prior PLD		
N (evaluable)	15	14
Confirmed + Unconfirmed	4 (27%)	6 (43%)
Confirmed	3 (20%)	4 (29%)
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No Prior PLD		
RECIST		
N (evaluable)	18	17
Confirmed +		

Unconfirmed	4 (22%)	3 (18%)
Confirmed	4 (22%)	3 (18%)

TABLE 5. NKTR-102

Safety Profile

Most Common* Drug-
related Grade 3 and
4 AEs*
->5% overall

	NKTR-102 q14d (N = 36)		NKTR-102 q21d (N = 35)	
	Grade 3	Grade 4	Grade 3	Grade 4
Diarrhea	25%	0%	14%	0%
Dehydration	22%	0%	6%	0%
Hypokalemia	17%	3%	9%	0%
Fatigue	6%	0%	14%	0%
Nausea	14%	0%	3%	0%
Vomiting	11%	0%	3%	0%
Abdominal pain	6%	0%	6%	0%
Hyponatremia	8%	0%	3%	0%
Neutropenia	6%	0%	6%	3%

*One patient in each dose regimen died due to neutropenic sepsis (q21d) and pre-renal azotemia (q14d).

About Ovarian Cancer

Nearly all ovarian cancers will become resistant or refractory to platinum-based therapy over time. Ovarian cancer is the fifth leading cause of cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system(2). Approximately 22,000 new cases of ovarian cancer will be diagnosed and 15,000 deaths are expected to be caused by ovarian cancer in the United States this year(2). Initial response rates to treatment with platinum-based agents are typically around 80 percent, but recurrence rates are very high. Treatment options following relapse are limited and overall long-term survival among ovarian cancer patients has not changed significantly in nearly 40 years(3). Agents currently approved by the U.S. Food & Drug Administration to treat women with platinum-resistant ovarian cancer have modest overall response rates of between 6.5 to 13.8 percent(4,5).

About NKTR-102

Nektar is developing NKTR-102, a topoisomerase I inhibitor-polymer conjugate with reduced peak concentrations and a continuous concentration profile. NKTR-102 was invented by Nektar using its advanced polymer conjugate technology platform, and is the first oncology product candidate to leverage Nektar's releasable polymer technology platform.

In addition to the fully-enrolled Phase 2 study currently underway in platinum-resistant/refractory ovarian cancer, NKTR-102 is also being tested in two separate Phase 2 clinical trials in patients with metastatic breast cancer and second-line colorectal cancer.

Analyst and Investor Event Webcast Information

Nektar's management team will host an investor and analyst breakfast on Monday, June 7, 2010 in conjunction with the ASCO Annual Meeting to discuss results from the Phase 2 clinical trial with leading independent clinical thought leaders in the ovarian cancer field.

. The panel of speakers at the event include:

- Lorianne Masouka, M.D., Senior Vice President and Chief Medical Officer of Nektar Therapeutics;
- Prof. Dr. Ignace Vergote, Lead Investigator for the Phase 2 clinical trial of NKTR-102 and Head of the Department of Obstetrics and Gynaecology and Gynaecologic Oncology at the Catholic University of Leuven, European Union;
- J. Tate Thigpen, M.D., Professor of Medicine and Director, Division of Medical Oncology at University of Mississippi Medical Center;
- Robert Coleman, M.D., Director of Clinical Research, Department of Gynecologic Oncology, The University of Texas MD Anderson Cancer Center, Houston, Texas; and
- Daniel Von Hoff, M.D., Chief Scientific Officer, TGen Clinical Research Services at Scottsdale Healthcare and U.S. Oncology.

This event will be webcast on Monday, June 7, 2010 from 8:00 to 9:00 am CT and may be accessed in the Events Calendar section on the homepage of the company's website at www.nektar.com. The webcast will be available on the Nektar website until July 15, 2010.

About Nektar

Nektar Therapeutics is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar's technology and drug development expertise have enabled nine approved products in the U.S. or Europe for leading biopharmaceutical company partners, including UCB's Cimzia(R) for Crohn's disease and rheumatoid arthritis, Roche's MIRCERA(R) for renal anemia and Amgen's Neulasta(R) for neutropenia.

Nektar has created a robust pipeline of potentially high-value therapeutics to address unmet medical needs by leveraging and expanding its technology platforms to improve and enable molecules. In addition to the releasable polymer technology, Nektar is the first company to create a permanent small molecule-polymer conjugate with enhanced oral bioavailability and restricted entry into the CNS. Nektar is currently conducting clinical and preclinical programs in oncology, pain and other therapeutic areas. Nektar recently entered into an exclusive worldwide license agreement with AstraZeneca for its oral NKTR-118 program to treat opioid-induced constipation and its NKTR-119 program for the treatment of pain without constipation side effects. NKTR-102 is being evaluated in Phase 2 clinical studies for the treatment of ovarian, breast and colorectal cancers. NKTR-105 is in a Phase 1 clinical study in cancer patients with refractory solid tumors.

Nektar is headquartered in San Carlos, California, with additional R&D 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>.

This press release contains forward-looking statements that reflect Nektar's current views regarding the potential of Nektar's technology platform, the potential of NKTR-102 for ovarian cancer patients, future development of NKTR-102, and results from the Phase 2 clinical trial of NKTR-102 in ovarian cancer. These forward-looking statements involve substantial risks and uncertainties, including but not limited to one or more of the following: (i) NKTR-102 is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the cancer indications being studied (i.e. ovarian cancer, breast cancer, and colorectal cancer) prior to regulatory approval due to efficacy, safety or other factors; (ii) the data package required and the timing for regulatory approval of a new drug application is very uncertain and difficult to predict due to broad regulatory discretion, changing standards of care, available approved therapies, the size of the completed clinical trials and the statistical significance of the results, the potential need for comparative clinical studies against approved therapies, and other important factors that are not within the control of Nektar; (iii) the timing or success of the commencement or end of clinical trials and commercial launch of new drugs may be delayed or unsuccessful due to regulatory delays, clinical trial design, slower than anticipated patient enrollment, drug manufacturing challenges, changing standards of care, clinical outcomes, or delay or failure in obtaining regulatory approval in one or more important markets; (iv) the Phase 2 results for NKTR-102 in ovarian cancer patients described in this press release remain subject to final data gathering and analysis review and confirmation procedures and the final results could be materially and adversely different; (v) the data from clinical studies in Nektar-102 for ovarian cancer is not necessarily predictive of the outcomes for other cancer indications for which NKTR-102 is being studied by Nektar (i.e. breast and colorectal cancers); (vi) Nektar's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may not be enforceable, or additional

intellectual property licenses from third parties may be required in the future; (vii) the uncertain outcome of any future intellectual property, commercial or other litigation related to Nektar's proprietary product candidates, including without limitation NKTR-102; (viii) if Nektar is unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer; and (ix) certain other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 filed on May 6, 2010, and the most recent Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 3, 2010. Actual results could differ materially from the forward-looking statements contained in this press release. Nektar undertakes no obligation to update forward-looking statements, including but not limited to any clinical, FDA or other regulatory information, whether as a result of new information, future events or otherwise.

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(1) 2008 International Gynecologic Cancer Society. Gynecological Cancer Intergroup, <http://www.gcig.igcs.org/CA-125.html>

(2) *American Cancer Society*, 2009.

(3) Ovarian Cancer National Alliance

(4) Gordon et al., *Journal of Clinical Oncology* 2001, 19: 3312-3322

(5) Doxil US Package Insert, 2008. <http://www.doxil.com/>

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