Nektar Therapeutics Reports Fourth Quarter and Year-End 2019 Financial Results

February 27, 2020

SAN FRANCISCO, Feb. 27, 2020 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported financial results for the fourth quarter and full year ended December 31, 2019.

Cash and investments in marketable securities at December 31, 2019 were approximately $1.6 billion as compared to $1.9 billion at December 31, 2018.

"Nektar's progress over the past year has established a strong foundation for growth, with a robust portfolio of clinical-stage immuno-oncology and immunology candidates addressing multiple therapeutic areas," said Howard W. Robin, President and CEO of Nektar. "Our amended joint development plan with Bristol-Myers Squibb for bempegaldesleukin in combination with Opdivo expands the active registrational program for the doublet to five indications, including new Phase 3 studies in the adjuvant melanoma setting and muscle invasive bladder cancer. It also provides a path forward in first-line lung cancer and enhances our ability to pursue new combinations in additional indications."

Mr. Robin continued, "We also advanced NKTR-255, a novel IL-15 agonist that stimulates NK cells and memory T cells, into the clinic in combination with ADCC therapies. With NKTR-358, we have an opportunity to address the underlying immune imbalance associated with multiple autoimmune and chronic inflammatory diseases. Our partner Eli Lilly is on track to initiate a Phase 2 study in lupus, advance ongoing Phase 1b clinical trials in psoriasis and atopic dermatitis, and start an additional Phase 2 study in a new autoimmune indication this year."

Summary of Financial Results

Revenue in the fourth quarter of 2019 was $33.9 million as compared to $39.8 million in the fourth quarter of 2018. Revenue for the year ended December 31, 2019 was $114.6 million as compared to $1.2 billion in 2018 and was lower primarily due to the recognition of $1.06 billion of license revenue from the Bristol-Myers Squibb collaboration agreement in the second quarter of 2018.

Total operating costs and expenses in the fourth quarter of 2019 were $143.5 million as compared to $140.1 million in the fourth quarter of 2018. Total operating costs and expenses for 2019 were $554.7 million as compared to $505.4 million in 2018. Total operating costs and expenses increased primarily as a result of increases in research and development (R&D) expense and general and administrative (G&A) expense.

R&D expense in the fourth quarter of 2019 was $110.4 million as compared to $108.9 million for the fourth quarter of 2018. R&D expense for the year ended December 31, 2019 was $434.6 million as compared to $399.5 million in 2018. R&D expense was higher in 2019 as compared to 2018 primarily because of the continued clinical development of bempegaldesleukin, including the registrational studies in melanoma, bladder cancer and renal cell carcinoma, and manufacture of Phase 2 drug supply for NKTR-358, which were partially offset by lower bempegaldesleukin and NKTR-181 manufacturing costs.

G&A expense was $27.1 million in the fourth quarter of 2019 as compared to $23.8 million in the fourth quarter of 2018. G&A expense for 2019 was $98.7 million as compared to $81.4 million in 2018. G&A expense was higher in the fourth quarter and full year 2019 as compared to the same periods in 2018 primarily due to non-cash stock based compensation expense, limited commercialization readiness activities for NKTR-181, as well as other costs related to personnel, facilities and outside services.

Net loss for the fourth quarter of 2019 was $112.2 million or $0.64 basic and diluted loss per share as compared to a net loss of $98.2 million or $0.57 basic and diluted loss per share in the fourth quarter of 2018. Net loss for the year ended December 31, 2019 was $440.7 million or $2.52 diluted loss per share as compared to net income of $681.3 million or $3.78 diluted earnings per share in 2018.

2019 and Year-to-Date Business Highlights:

- In February 2020, Nektar announced the publication of preclinical bempegaldesleukin data in two manuscripts in *Nature Communications* showing how bempegaldesleukin works synergistically with multiple immune-based therapies to enhance T-cell-mediated tumor control.
- In January 2020, Nektar and Bristol-Myers Squibb announced a new joint development plan that expands the ongoing registrational program for bempegaldesleukin plus Opdivo (nivolumab) from three ongoing registrational trials in first-line metastatic melanoma, first-line cisplatin-ineligible metastatic urothelial cancer and first-line metastatic renal cell carcinoma (RCC) to include two additional registrational trials in adjuvant melanoma and muscle-invasive bladder cancer. In addition, a Phase 1/2 study will be initiated to evaluate bempegaldesleukin plus nivolumab in combination with axitinib in first-line RCC in order to support a future registrational trial. Bristol-Myers Squibb will also independently conduct and fund a Phase 1/2 study in first-line non-small-cell lung cancer with bempegaldesleukin and nivolumab.
- In January 2020, Nektar made the strategic business decision to withdraw its New Drug Application (NDA) for NKTR-181, an investigational medicine in development for chronic pain and make no further investment into the program.
- In December 2019, Nektar presented results from preclinical studies of NKTR-255, its IL-15 agonist, at the 61st American Society of Hematology Annual Meeting highlighting the candidate's potential in the treatment of hematological malignancies by restoring both NK cell and memory CD8 T cell compartments in patients.

- In November 2019, Nektar presented updated results from the first-in-human Phase 1a study of NKTR-358 at the 2019 Annual Meeting of the American College of Rheumatology supporting development of the candidate as a first-in-class T regulatory cell stimulator for the treatment of autoimmune and other chronic inflammatory conditions.
- In November 2019, Nektar presented new data from the Stage IV front-line melanoma cohort in the PIVOT-02 study at the 2019 Society for Immunotherapy of Cancer Annual Meeting. At a median time of follow-up of 18.6 months, median progression free survival had not yet been reached.
- In October 2019, Nektar announced that its partner Eli Lilly initiated two Phase 1b studies of NKTR-358, one in patients with psoriasis and one in patients with atopic dermatitis.
- In October 2019, Nektar announced the initiation of a first-in-human, Phase 1 clinical study evaluating NKTR-255 as monotherapy for patients with relapsed or refractory non-Hodgkin lymphoma or multiple myeloma.
- In September 2019, Nektar presented clinical data from its PIVOT-02 study for bempegaldesleukin in combination with Opdivo (nivolumab) at the 2019 CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference demonstrating the promising clinical activity of the combination in patients with advanced or metastatic triple-negative breast cancer, particularly in patients with PD-L1 negative baseline tumors.
- In August 2019, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for bempegaldesleukin in combination with Opdivo (nivolumab) for the treatment of patients with previously untreated unresectable or metastatic melanoma.
- In June 2019, Nektar presented biomarker and clinical data from the ongoing PIVOT-02 study for bempegaldesleukin in combination with Opdivo (nivolumab) at the 2019 ASCO Annual Meeting. Clinical data presented included 12-month follow-up for the Stage IV first-line melanoma patient cohort and showed a deepening and durability of response over time.
- In April 2019, Nektar presented positive preclinical data on its immuno-oncology pipeline candidates, bempegaldesleukin and NKTR-255, at the 2019 AACR Annual Meeting.
- In March 2019, Nektar presented preliminary immune activation, safety and clinical activity data from the ongoing dose-escalation stage of the REVEAL study at the 2019 ASCO-SITC Meeting. The REVEAL Phase 1/2 study is evaluating the safety and efficacy of NKTR-262, a novel TLR agonist, in combination with bempegaldesleukin.
- In February 2019, Nektar presented clinical data from first-line Stage IV urothelial carcinoma patients enrolled in the PIVOT-02 study of bempegaldesleukin with Opdivo (nivolumab) at the 2019 ASCO Genitourinary Cancers Symposium.

The company also announced upcoming presentations at the following scientific congresses:

Society of Toxicology (SOT) 59th Annual Meeting, Anaheim, CA

- **Presentation:** *"Bempegaldesleukin (NKTR-214), a novel IL-2 based immunotherapy, demonstrates superior nonclinical safety compared to that reported for recombinant human IL-2 (rhIL-2)",* Leung, S., et al.
    - **Session:** Safety Assessment: Pharmaceutical—Drug Development
    - **Date:** Wednesday, March 18th, 10:45 a.m. – 12:30 p.m.
- **Presentation:** *"Toxicology Species Selection for Preclinical Safety Assessment of TLR7/8 Prodrug Agonist"*, Gunther, J., et al.
    - **Session:** Safety Assessment: Pharmaceutical—Drug Development
    - **Date:** Wednesday, March 18th, 10:45 a.m. – 12:30 p.m.

American Chemical Society National Meeting

- **Presentation:** *"NKTR-262: Discovery of a novel TLR 7/8 agonist prodrug that demonstrates synergistic anti-tumor effect in combination with NKTR-214, a CD-122 preferential IL-2 pathway agonist"*, Anand, N., et al.
    - **Session:** MEDI: Tissue Specific Delivery: TLR Agonists
    - **Date**: Tuesday, March 24th, 10:10 a.m. – 10:45 a.m.

Conference Call to Discuss Fourth Quarter and Year-End 2019 Financial Results
Nektar management will host a conference call to review the results beginning at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time, Thursday, February 27, 2020.

This press release and a live audio-only Webcast of the conference call can be accessed through a link that is posted on the home page and Investors section of the Nektar website: https://ir.nektar.com/. The web broadcast of the conference call will be available for replay through March 27, 2020.

To access the conference call, follow these instructions:
Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
Passcode: 2507828 (Nektar Therapeutics is the host)

In the event that any non-GAAP financial measure is discussed on the conference call that is not described in the press release, or explained on the conference call, related information will be made available on the Investors page at the Nektar website as soon as practical after the conclusion of the conference call.

About Nektar
Nektar Therapeutics is a biopharmaceutical company with a robust, wholly-owned R&D pipeline of investigational medicines in oncology and

immunology as well as a portfolio of approved partnered medicines. 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 which can be identified by words such as: "may," "design," "potential" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of, and future development plans for, bempegaldesleukin, NKTR-358 and NKTR-255, and the timing of the initiation of clinical studies for our drug candidates. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Because forward-looking 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 forward-looking statements include, among others: (i) our statements regarding the therapeutic potential of bempegaldesleukin, NKTR-358 and NKTR-255 are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) bempegaldesleukin, NKTR-358 and NKTR-255 are an investigational agents and continued research and development for these drug candidates is subject to substantial risks, including negative safety and efficacy findings in ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) bempegaldesleukin, NKTR-358 and NKTR-255 are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval; (iv) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (v) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2019. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. 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.

Contact:
For Investors:
Vivian Wu of Nektar Therapeutics
628-895-0661

For Media:
Dan Budwick of 1AB
973-271-6085
dan@1abmedia.com

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

ASSETS	December 31, 2019	December 31, 2018 (1)
Current assets:		
Cash and cash equivalents	$ 96,363	$ 194,905
Short-term investments	1,228,499	1,140,445
Accounts receivable	36,802	43,213
Inventory	12,665	11,381
Advance payments to contract manufacturers	31,834	26,450
Other current assets	15,387	21,293
Total current assets	1,421,550	1,437,687
Long-term investments	279,119	582,889
Property, plant and equipment, net	64,999	48,851
Operating lease right-of-use assets	134,177	-
Goodwill	76,501	76,501
Other assets	1,010	4,244
Total assets	$ 1,977,356	$ 2,150,172
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 19,234	$ 5,854
Accrued compensation	11,467	9,937
Accrued clinical trial expenses	32,626	14,700
Accrued contract manufacturing expenses	7,304	23,841
Other accrued expenses	11,414	9,087
Senior secured notes, net	248,693	-
Interest payable	4,198	4,198
Lease liability, current portion	12,516	-
Deferred revenue, current portion	5,517	13,892

Other current liabilities	924	493
Total current liabilities	353,893	82,002
Senior secured notes, net	-	246,950
Lease liability, less current portion	142,730	-
Liability related to the sale of future royalties, net	72,020	82,911
Deferred revenue, less current portion	2,554	10,744
Other long-term liabilities	768	9,990
Total liabilities	571,965	432,597
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	17	17
Capital in excess of par value	3,271,097	3,147,925
Accumulated other comprehensive loss	(1,005)	(6,316)
Accumulated deficit	(1,864,718)	(1,424,051)
Total stockholders' equity	1,405,391	1,717,575
Total liabilities and stockholders' equity	$ 1,977,356	$ 2,150,172

(1) The consolidated balance sheet at December 31, 2018 has been derived from the audited financial statements at that date but does not include all of the information and notes required by generally accepted accounting principles in the United States for complete financial statements.

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share information)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenue:				
Product sales	$ 5,815	$ 4,360	$ 20,117	$ 20,774
Royalty revenue	12,214	12,078	41,222	41,976
Non-cash royalty revenue related to sale of future royalties	8,718	8,971	36,303	33,308
License, collaboration and other revenue	7,115	14,417	16,975	1,097,265
Total revenue	33,862	39,826	114,617	1,193,323
Operating costs and expenses:				
Cost of goods sold	5,989	7,461	21,374	24,412
Research and development	110,369	108,883	434,566	399,536
General and administrative	27,142	23,777	98,712	81,443
Total operating costs and expenses	143,500	140,121	554,652	505,391
Income (loss) from operations	(109,638)	(100,295)	(440,035)	687,932
Non-operating income (expense):				
Interest expense	(5,428)	(5,415)	(21,310)	(21,582)
Non-cash interest expense on liability related to sale of future royalties	(7,191)	(6,388)	(25,044)	(21,196)
Interest income and other income (expense), net	10,371	12,048	46,335	37,571
Total non-operating income (expense), net	(2,248)	245	(19)	(5,207)
Income (loss) before provision for income taxes	(111,886)	(100,050)	(440,054)	682,725
Provision for income taxes	278	(1,838)	613	1,412
Net income (loss)	$ (112,164)	$ (98,212)	$(440,667)	$ 681,313
Net income (loss) per share:				
Basic	$ (0.64)	$ (0.57)	$ (2.52)	$ 4.02
Diluted	$ (0.64)	$ (0.57)	$ (2.52)	$ 3.78
Weighted average shares outstanding used in computing net income (loss) per share:				
Basic	176,130	173,271	174,993	169,600
Diluted	176,130	173,271	174,993	180,119

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net income (loss)	$ (440,667)	$ 681,313
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Non-cash royalty revenue related to sale of future royalties	(36,303)	(33,308)
Non-cash interest expense on liability related to sale of future royalties	25,044	21,196
Stock-based compensation	99,795	88,101
Depreciation and amortization	13,156	10,870
Accretion of discounts, net and other non-cash transactions	(11,394)	(10,952)
Changes in operating assets and liabilities:		
Accounts receivable	6,411	(25,505)
Inventory	(1,284)	(655)
Operating lease right-of-use assets, net of operating lease liabilities	13,090	-
Other assets	1,190	(31,652)
Accounts payable	12,967	971
Accrued compensation	1,530	1,674
Other accrued expenses	3,816	27,947
Deferred revenue	(16,565)	(15,331)
Other liabilities	533	3,545
Net cash provided by (used in) operating activities	(328,681)	718,214
Cash flows from investing activities:		
Purchases of investments	(1,380,865)	(2,271,250)
Maturities of investments	1,614,036	890,957
Sales of investments	-	11,963
Purchases of property, plant and equipment	(26,285)	(14,239)
Sales of property and plant	-	2,633
Net cash provided by (used in) investing activities	206,886	(1,379,936)
Cash flows from financing activities:		
Payment of capital lease obligations	-	-
Proceeds from shares issued under equity compensation plans	23,355	61,735
Issuance of common stock to Bristol-Myers Squibb	-	790,231
Net cash provided by financing activities	23,355	851,966
Effect of exchange rates on cash and cash equivalents	(102)	(101)
Net increase (decrease) in cash and cash equivalents	(98,542)	190,143
Cash and cash equivalents at beginning of year	194,905	4,762
Cash and cash equivalents at end of year	$ 96,363	$ 194,905
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 19,199	$ 19,471
Cash paid for income taxes	$ 555	$ 618
Right-of-use assets recognized in exchange for operating lease liabilities	$ 57,691	$ -

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