Nektar Therapeutics Reports Fourth Quarter and Year-End 2020 Financial Results

February 25, 2021

SAN FRANCISCO, Feb. 25, 2021 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported financial results for the fourth quarter and full year ended December 31, 2020.

Cash and investments in marketable securities at December 31, 2020 were approximately $1.2 billion as compared to $1.6 billion at December 31, 2019.

"This past year, Nektar made significant progress advancing our clinical pipeline of novel cytokine therapeutics," said Howard W. Robin, President and CEO of Nektar. "Our broad registrational program evaluating bempegaldesleukin (BEMPEG) plus nivolumab is progressing well with five registrational studies underway in melanoma, renal cell carcinoma and bladder cancer. We also recently added a sixth study to the registrational program to evaluate BEMPEG in combination with pembrolizumab in head and neck cancer and are pleased to be collaborating with Merck on the study. For our PROPEL study, we look forward to reporting the first data for BEMPEG plus pembrolizumab in patients with metastatic non-small cell lung cancer in the second half of 2021."

"For our second cytokine program, NKTR-255, we were very encouraged by the early signs of clinical activity that we recently reported at the SITC 2020 meeting, and are now advancing two Phase 1 clinical studies in combination with ADCC antibodies, one in hematological malignancies and one in solid tumors," continued Mr. Robin. "Finally, our partner Eli Lilly is conducting a broad Phase 2 program for NKTR-358, our T regulatory cell IL-2 agent, with Phase 2 studies in both lupus and ulcerative colitis and plans to initiate additional Phase 2 studies in immune-mediated diseases over the next 12-18 months."

Summary of Financial Results

Revenue in the fourth quarter of 2020 was $23.5 million as compared to $33.9 million in the fourth quarter of 2019. Revenue for the year ended December 31, 2020 was $152.9 million as compared to $114.6 million in 2019 and was higher primarily due to the recognition of $50.0 million in total milestones from Bristol-Myers Squibb related to the start of two new registrational trials of bempegaldesleukin plus Opdivo® (nivolumab) in adjuvant melanoma and muscle-invasive bladder cancer.

Total operating costs and expenses in the fourth quarter of 2020 were $134.2 million as compared to $143.5 million in the fourth quarter of 2019. Total operating costs and expenses for 2020 were $578.0 million as compared to $554.7 million in 2019. Total operating costs and expenses for full year 2020 increased as compared to 2019 primarily as a result of $45.2 million in impairment charges in the first quarter of 2020 resulting from the discontinuation of the NKTR-181 program, partially offset by a decrease in R&D expense.

R&D expense in the fourth quarter of 2020 was $102.7 million as compared to $110.4 million for the fourth quarter of 2019. R&D expense for the year ended December 31, 2020 was $408.7 million as compared to $434.6 million in 2019. Excluding pre-commercial manufacturing costs for NKTR-181 incurred during 2019, research and development expense increased for the full year 2020 primarily due to the clinical development of bempegaldesleukin in five registrational trials.

G&A expense was $27.1 million in the fourth quarter of 2020 and $27.1 million in the fourth quarter of 2019. G&A expense for 2020 was $104.7 million as compared to $98.7 million in 2019.

Net loss for the fourth quarter of 2020 was $117.2 million or $0.65 basic and diluted loss per share as compared to a net loss of $112.2 million or $0.64 basic and diluted loss per share in the fourth quarter of 2019. Net loss for the year ended December 31, 2020 was $444.4 million or $2.49 basic and diluted loss per share as compared to net loss of $440.7 million or $2.52 basic and diluted loss per share in 2019.

2020 and Year-to-Date 2021 Business Highlights:

- In February 2021, Nektar announced a clinical trial collaboration and supply agreement with Merck for a Phase 2/3 study of bempegaldesleukin, Nektar's investigational IL-2 pathway agent, in combination with Merck's KEYTRUDA® (pembrolizumab) for first-line treatment of patients with metastatic or unresectable recurrent squamous cell carcinoma of the head and neck (SCCHN) whose tumors express PD-L1. The study is planned to start in the second half of 2021.
- In February 2021, Nektar announced a financing and co-development collaboration with SFJ Pharmaceuticals® for the development of bempegaldesleukin plus pembrolizumab in SCCHN. SFJ has agreed to fund up to $150 million to support the planned Phase 2/3 study and manage clinical trial operations for the study. In return, Nektar agrees to pay SFJ success-based annual milestone payments over a period of seven to eight years which are contingent upon receipt of certain U.S. regulatory approvals for specified indications for bempegaldesleukin, and will begin following completion of the SCCHN study, which is projected to be completed in 2024.
- In December 2020, Nektar sold its royalties on future sales of ADYNOVATE® and MOVANTIK® to Healthcare Royalty Management, LLC in exchange for $150 million.
- In December 2020, Nektar announced dosing of the first patient in its Phase 1/2 study of its IL-15 agonist, NKTR-255, in combination with cetuximab in patients with relapsed or refractory head and neck squamous cell carcinoma or colorectal

cancer. The study may enroll up to 80 patients at approximately 15 investigator sites in the United States and European Union.

- In December 2020, Nektar presented preclinical data for NKTR-255 at the American Society of Hematology (ASH) 2020 Annual Meeting, underscoring the potential for NKTR-255 as an innovative immunotherapeutic agent in the treatment of multiple myeloma.
- In November 2020, Nektar presented new data from its immuno-oncology pipeline at the virtual 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting. Updated clinical data from the PIVOT-02 study metastatic melanoma cohort showed that bempegaldesleukin with nivolumab resulted in a durable clinical benefit with median progression-free survival of 30.9 months. NKTR-255 showed biological activity in the first patients treated in the monotherapy dose-escalation phase of the ongoing Phase 1 study in multiple myeloma and non-Hodgkin's lymphoma. In addition, new data showed that the combination of TLR agonist candidate, NKTR-262, plus bempegaldesleukin alters the tumor micro-environment through activation of both the innate and adaptive arms of the immune system.
- In November 2020, Nektar presented new data from its NKTR-358 program at the American College of Rheumatology (ACR) virtual meeting. Data from the Phase 1b study in patients with mild to moderate systemic lupus erythematosus (SLE) showed that NKTR-358 produced a dose-dependent increase in expression of regulatory T cell (Treg) activation markers, providing a rationale for continued development in SLE and other inflammatory indications.
- In October 2020, Nektar initiated a Phase 1b clinical study of bempegaldesleukin in adult patients with mild COVID-19 infection. The randomized, double-blind, placebo-controlled trial is designed to assess the safety, tolerability, and pharmacokinetic and pharmacodynamic profile of bempegaldesleukin in adult patients with mild COVD-19.
- In August 2020, Vaccibody AS and Nektar announced that the first patient had been dosed in the Phase 1/2a study evaluating bempegaldesleukin with VB10.NEO, Vaccibody's personalized neoantigen cancer vaccine, in patients with advanced squamous cell carcinoma of the head and neck.
- In June 2020, Nektar announced the presentation of results from the Phase 1b study evaluating multiple ascending doses of NKTR-358 at the Annual European Congress of Rheumatology (EULAR 2020) virtual meeting. The data showed that treatment with NKTR-358 was safe and well tolerated in patients with mild-to-moderate SLE and led to a marked and selective, dose-dependent expansion of regulatory T cells (Tregs) that was maintained over multiple administrations.
- In May 2020, Nektar announced the publication of clinical data from its PIVOT-02 study evaluating bempegaldesleukin in combination with nivolumab in immunotherapy-naïve patients with advanced solid tumors, including melanoma, renal cell carcinoma (RCC) and non-small cell lung cancer. The data, published in *Cancer Discovery,* a journal of the American Association for Cancer Research, showed that bempegaldesleukin plus nivolumab resulted in encouraging overall response rates across multiple tumor types, independent of baseline PD-L1 expression, with responses continuing to deepen over time.
- In April 2020, Nektar repaid the principal and accrued interest of its senior notes totaling $254.8 million.
- 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 expanded the ongoing registrational program for bempegaldesleukin plus Opdivo® from three ongoing registrational trials in first-line metastatic melanoma, first-line cisplatin-ineligible metastatic urothelial cancer and first-line metastatic RCC to include two additional registrational trials in adjuvant melanoma and muscle-invasive bladder cancer. In addition, the expanded development plan includes a Phase 1/2 study to evaluate bempegaldesleukin plus nivolumab in combination with a tyrosine-kinase inhibitor in first-line RCC in order to support a future registrational trial.
- In January 2020, Nektar made the strategic business decision to withdraw its New Drug Application (NDA) for NKTR-181, an investigational opioid medicine in development for chronic pain and make no further investment into the program.

Conference Call to Discuss Fourth Quarter and Year-End 2020 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 25, 2021.

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 25, 2021.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
Conference ID: 3857247 (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, immunology,

and virology 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," "advance," "plan" 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 and the availability of clinical data 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 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 challenges caused by the COVID-19 pandemic, regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes and competitive factors; (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 6, 2020. 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.

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

ASSETS	December 31, 2020	December 31, 2019 (1)
Current assets:		
Cash and cash equivalents	$ 198,955	$ 96,363
Short-term investments	862,941	1,228,499
Accounts receivable	38,889	36,802
Inventory	15,292	12,665
Advance payments to contract manufacturers	3,908	31,834
Other current assets	18,020	15,387
Total current assets	1,138,005	1,421,550
Long-term investments	136,662	279,119
Property, plant and equipment, net	59,662	65,665
Operating lease right-of-use assets	126,476	134,177
Goodwill	76,501	76,501
Other assets	1,461	344
Total assets	$ 1,538,767	$ 1,977,356
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Senior secured notes, net and interest payable	$ -	$ 252,891
Accounts payable	22,139	19,234
Accrued compensation	14,532	11,467
Accrued clinical trial expenses	44,207	32,626
Accrued contract manufacturing expenses	11,310	7,304

Other accrued expenses	9,585	12,338
Operating lease liability, current portion	13,915	12,516
Deferred revenue, current portion	91	5,517
Total current liabilities	115,779	353,893
Operating lease liability, less current portion	136,373	142,730
Liabilities related to the sales of future royalties, net	200,340	72,020
Deferred revenue, less current portion	2,464	2,554
Other long-term liabilities	6,516	768
Total liabilities	461,472	571,965
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	18	17
Capital in excess of par value	3,388,730	3,271,097
Accumulated other comprehensive loss	(2,295)	(1,005)
Accumulated deficit	(2,309,158)	(1,864,718)
Total stockholders' equity	1,077,295	1,405,391
Total liabilities and stockholders' equity	$ 1,538,767	$ 1,977,356

(1) The consolidated balance sheet at December 31, 2019 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,	
	2020	2019	2020	2019
Revenue:				
Product sales	$ 2,884	$ 5,815	$ 17,504	$ 20,117
Royalty revenue	(412)	12,214	30,999	41,222
Non-cash royalty revenue related to sale of future royalties	20,562	8,718	48,563	36,303
License, collaboration and other revenue	428	7,115	55,849	16,975
Total revenue	23,462	33,862	152,915	114,617
Operating costs and expenses:				
Cost of goods sold	4,323	5,989	19,477	21,374
Research and development	102,724	110,369	408,678	434,566
General and administrative	27,136	27,142	104,682	98,712
Impairment of assets and other costs for terminated program	-	-	45,189	-
Total operating costs and expenses	134,183	143,500	578,026	554,652
Loss from operations	(110,721)	(109,638)	(425,111)	(440,035)
Non-operating income (expense):				
Interest expense	-	(5,428)	(6,851)	(21,310)
Non-cash interest expense on liability related to sale of future royalties	(8,183)	(7,191)	(30,267)	(25,044)
Interest income and other income (expense), net	1,829	10,371	18,282	46,335
Total non-operating expense, net	(6,354)	(2,248)	(18,836)	(19)
Loss before provision for income taxes	(117,075)	(111,886)	(443,947)	(440,054)
Provision for income taxes	128	278	493	613
Net loss	$ (117,203)	$ (112,164)	$ (444,440)	$ (440,667)
Net loss per share:				
Basic	$ (0.65)	$ (0.64)	$ (2.49)	$ (2.52)
Diluted	$ (0.65)	$ (0.64)	$ (2.49)	$ (2.52)

Weighted average shares outstanding used in computing net loss per share:				
Basic	179,684	176,130	178,581	174,993
Diluted	179,684	176,130	178,581	174,993

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

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (444,440)	$ (440,667)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(48,563)	(36,303)
Non-cash interest expense on liability related to sale of future royalties	30,267	25,044
Stock-based compensation	94,261	99,795
Depreciation and amortization	14,182	13,156
Impairment of advance payments to contract manufacturers and equipment for terminated program	20,351	-
Accretion of premiums (discounts), net and other non-cash transactions	3,943	(11,394)
Changes in operating assets and liabilities:		
Accounts receivable	1,913	6,411
Inventory	(2,627)	(1,284)
Operating leases, net	2,743	13,090
Other assets	4,476	1,190
Accounts payable	2,382	12,967
Accrued compensation	4,697	1,530
Other accrued expenses	8,644	4,349
Deferred revenue	(5,516)	(16,565)
Net cash used in operating activities	(313,287)	(328,681)
Cash flows from investing activities:		
Purchases of investments	(987,533)	(1,380,865)
Maturities of investments	1,449,304	1,614,036
Sales of investments	41,700	-
Purchases of property, plant and equipment	(7,258)	(26,285)
Net cash provided by investing activities	496,213	206,886
Cash flows from financing activities:		
Proceeds from sale of future royalties, net of $3.8 million of transaction costs	146,250	-
Repayment of senior notes	(250,000)	-
Proceeds from shares issued under equity compensation plans	23,396	23,355
Net cash provided by (used in) financing activities	(80,354)	23,355
Effect of exchange rates on cash and cash equivalents	20	(102)
Net increase (decrease) in cash and cash equivalents	102,592	(98,542)
Cash and cash equivalents at beginning of year	96,363	194,905
Cash and cash equivalents at end of year	$ 198,955	$ 96,363
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 9,742	$ 19,199
Cash paid for income taxes	$ 539	$ 555
Right-of-use assets recognized in exchange for operating lease liabilities	$ 2,133	$ 57,691

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