Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

- Progeria MAA Submission Completed and Accelerated Assessment Granted by EMA
- Progeria NDA Submission Complete by End of March 2020
- Phase 3 HDV Global D-LIVR Study Enrolling and Dosing

PALO ALTO, Calif., March 13, 2020 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today reported financial results for the fourth quarter and full year 2019 and provided a business update.

"We are pleased to announce the submission of the MAA for lonafarnib in Progeria and Progeroid Laminopathies and look forward to completing the NDA submission by end of the month as planned," said David Cory, President and CEO of Eiger. "Site activations, enrollment, and dosing are ongoing in our global Phase 3 HDV study, D-LIVR, and we expect to complete enrollment in 2020. We are closely monitoring the potential impact of COVID-19 on the timing and conduct of D-LIVR. We will remain responsive to any developments and take necessary steps to protect our patients and the integrity of the study."

Recent Highlights and Upcoming Milestones

Lonafarnib in Hepatitis Delta Virus (HDV)

- *Enrollment of Phase 3 D-LIVR study (N=400) planned to complete in 2020*

Lonafarnib in Progeria and Progeroid Laminopathies

- *Marketing Authorization Application (MAA) to EMA completed*
- *Accelerated Assessment for MAA granted by EMA*
- *New Drug Application (NDA) to FDA on-track for completion by end of March 2020*

Peginterferon Lambda (lambda) in HDV

- *Positive End of Phase 2 meeting with FDA with agreement on single Phase 3 study*
- *Plan to finalize Scientific Advice with EMA*
- *End-of-Treatment data from LIFT (lambda combo with lonafarnib) at EASL 2020*

Corporate

- *Appointed Eldon Mayer as Executive Vice President and Chief Commercial Officer*

Fourth Quarter and Full Year 2019 Financial Results

Cash, cash equivalents, and short-term investments as of December 31, 2019 totaled $95.0 million compared to $100.4 million at December 31, 2018, a decrease of $5.4 million.

The Company reported net losses of $16.9 million, or $0.69 per share, and $70.3 million, or $3.08 per share, for the fourth quarter and full year 2019, respectively, as compared to $16.5 million, or $0.93 per share, and $52.4 million, or $3.84 per share, for the same periods in 2018.

Research and Development expenses were $11.9 million and $51.8 million for the fourth quarter and full year 2019, respectively, as compared to $12.0 million and $37.1 million for the same periods in 2018. The increase in full year 2019 expenses was primarily due to costs associated with the Phase 3 D-LIVR HDV study, including drug supply costs, which ramped-up in 2019, employee-related costs from increased headcount and an increase in regulatory related expenses.

General and Administrative expenses were $4.6 million and $17.1 million for the fourth quarter and full year 2019, respectively, as compared to $4.1 million and $14.0 million for the same periods in 2018. The increases in fourth quarter and full year 2018 were primarily due to increases in employee-related costs, including stock-based compensation, from increased headcount and outside services for legal, consulting, advisory and accounting services.

Total operating expenses include total non-cash expenses of $1.6 million and $6.6 million for the fourth quarter and full year 2019, respectively, as compared to $1.6 million and $5.7 million for the same periods in 2018.

As of December 31, 2019, the company had 24.5 million of common shares outstanding.

About Eiger
Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs, for which no approved therapies exist.

Eiger has completed an MAA submission for lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies and plans to complete a New Drug Application (NDA) submission by end of March 2020. The company's lead program is in Phase 3, developing lonafarnib, a first-in-class oral prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also advancing peginterferon lambda, a first-in-class interferon, toward registration for the treatment of HDV. For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements that involve substantial risks and uncertainties. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward-looking statements. These forward-looking statements include terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our anticipating significant milestones in 2020, the timing of our ongoing and planned clinical development, including planned NDA submission in first quarter 2020 for Progeria and Progeroid Laminopathies; the potential for approval of our lonafarnib product candidate in the US and EU for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our announcement of data from the trial of lambda and lonafarnib boosted with ritonavir for HDV (LIFT); our plans to advance Peginterferon Lambda in HDV in the US and EU; our plans for continued advancement of avexitide in registration trials; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; that the company's expectations regarding the effects of COVID-19 on the Company's trials and development may be incorrect, and the potential for success of any of our product candidates.

These statements concern product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). No representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks described in the "Risk Factors" sections in the Annual Report on Form 10-K for the year ended December 31, 2019 to be filed March 13, 2020 and Eiger's subsequent filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

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Eiger BioPharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	Year Ended December 31, 2019	Year Ended December 31, 2018[1]
ASSETS		
Cash and cash equivalents	$ 39,373	$ 61,262

Debt securities, available-for-sale	55,621	39,091
Prepaid expenses and other current assets	5,390	1,492
Total current assets	100,384	101,845
Property and equipment, net	590	167
Operating lease right-of-use assets	1,654	—
Other assets	2,511	436
Total assets	$ 105,139	$ 102,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 16,949	$ 10,024
Other liabilities	31,710	25,832
Stockholders' equity	56,480	66,592
Total liabilities and stockholders' equity	$ 105,139	$ 102,448

(1)Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Eiger BioPharmaceuticals Inc.
Condensed Consolidated Statements of Operations Financial Data
(in thousands, except per share and share amounts)

	Three Months Ended December 31, (unaudited)		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development[(1)]	$ 11,928	$ 12,011	$ 51,791	$ 37,091
General and administrative[(1)]	4,584	4,082	17,113	13,956
Total operating expenses	16,512	16,093	68,904	51,047
Loss from operations	(16,512)	(16,093)	(68,904)	(51,047)
Interest expense	(888)	(755)	(3,406)	(2,329)
Interest income	475	343	2,073	997
Other income (expense), net	5	4	(15)	(12)
Net loss	$ (16,920)	$ (16,501)	$ (70,252)	$ (52,391)
Net loss per common share:				
Basic and diluted	$ (0.69)	$ (0.93)	$ (3.08)	$ (3.84)
Shares used to compute net loss per common share:				
Basic and diluted	24,492,117	17,821,295	22,785,611	13,634,152

[(1)]Includes stock-based compensation expense of:

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Research and development	$ 184	$ 362	$ 1,550	$ 1,500
General and administrative	1,164	1,149	4,129	3,507
Total stock-based compensation expense	$ 1,348	$ 1,511	$ 5,679	$ 5,007

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