

Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

PALO ALTO, Calif., March 10, 2022 /PRNewswire/ --

- Phase 3 COVID-19 TOGETHER (Lambda) Study Data in March 2022
- Phase 3 HDV D-LIVR (Lonafarnib) Study Topline Data Planned by End of 2022
- Phase 3 HDV LIMT-2 (Lambda) Study Enrolling
- Strong Cash Position of Approximately \$106 Million as of 12/31/21
- Company to Host Conference Call Today at 4:30 PM ET

Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious diseases, today reported financial results for fourth quarter and full year 2021 and provided a business update.

"We expect 2022 to be a transformational year for Eiger with topline data planned from two Phase 3 studies," said David Cory, President and CEO of Eiger. "The Phase 3 *TOGETHER* study of Peginterferon Lambda for COVID-19 is expected to readout later this month and the Phase 3 *D-LIVR* study of Lonafarnib for HDV is planned to readout by end of year. We look forward to reporting results from these potentially registration enabling studies as well as progress across our other late-stage pipeline programs with multiple catalysts this year."

Program Highlights

Lonafarnib: Oral Prenylation Inhibitor for HDV

- D-LIVR Phase 3 multi-center, global study
 - o Two Lonafarnib-based regimens, both with potential for registration
 - Lonafarnib oral and Lonafarnib / peginterferon alfa combination
 - o Fully enrolled N=407, with topline data planned by end of 2022
 - *D-LIVR* study design includes conservative powering assumptions, modeling response rates well below what was demonstrated in Phase 2
 - Ukraine and Russia Update
 - Ukraine:
 - Eiger continues to closely assess this evolving situation, prioritizing patient care and patient monitoring to ensure continuity in the study
 - Eiger believes the study remains more than adequately powered to demonstrate statistical significance over placebo even if these patients discontinue from study
 - Russia:
 - To date, no interruption to patient visits, safety monitoring, or drug supply; contingency plans in place to ensure continuity of drug supply, sample storage and analysis to preserve integrity of results

Peginterferon Lambda: Well-tolerated Interferon for HDV

- LIMT-2 Phase 3 multi-center, global study
 - o Peginterferon Lambda monotherapy for registration
 - Enrolling patients, targeting N=150

Peginterferon Lambda and Lonafarnib Combination for HDV

- LIFT-2 Phase 2 study at National Institutes of Health
 - Initiating 1H22, targeting N=30
- Potential to be interferon of choice in HDV combination therapies

Peginterferon Lambda for Non-hospitalized COVID-19 Infection

- Novel mechanism of action, agnostic to variants and mutations
- TOGETHER Phase 3 study fully enrolled, N>1,800

- o Includes unvaccinated and vaccinated patients across multiple variants
- Topline data planned in March 2022

Avexitide for Rare Metabolic Disorders

- Granted Breakthrough Therapy Designation for Congenital Hyperinsulinism (HI)
- Granted Rare Pediatric Disease Designation for HI; PRV eligible
- Phase 3 ready in 2022

Zokinvy® for Progeria and Processing-Deficient Progeroid Laminopathies

- Successful U.S. commercial launch
 - Approximately 80% of identified U.S. patients converted to commercial supply
- EMA review of MAA
 - CHMP opinion expected in first half of 2022

Corporate

• Cash, cash equivalents and investments of \$106.1 million to begin 2022 expected to fund planned operations through Q3 2023

Fourth Quarter and Full Year 2021 Financial Results

Cash, cash equivalents, and total investments as of December 31, 2021 totaled \$106.1 million compared to \$128.8 million on December 31, 2020.

Net product sales of Zokinvy were \$3.4 million for fourth quarter 2021, as compared to \$3.0 million for third quarter 2021. The increase reflects shipment of product under a reimbursed early access program approved in France, partially offset by fewer shipments to the U.S. specialty pharmacy due to timing of patient refills. The Company commercially launched Zokinvy in the U.S. in January 2021 and reported full year 2021 net sales of \$12.1 million.

Cost of Sales was \$0.1 million and \$0.7 million for fourth quarter and full year 2021, respectively, and related to certain manufacturing, shipping, and distribution costs associated with Zokinvy that were incurred after FDA approval.

Research and Development expenses were \$18.2 million and \$64.4 million for fourth quarter and full year 2021, respectively, as compared to \$12.5 million and \$41.6 million for the same periods in 2020. The increases in fourth quarter and full year 2021 expenses were primarily due to contract manufacturing and clinical trial related expenses for increased clinical development activities and personnel related expenses, including stock-based compensation, due to an increase in headcount.

Selling, General and Administrative expenses were \$6.0 million and \$23.9 million for fourth quarter and full year 2021, respectively, as compared to \$5.4 million and \$20.6 million for the same periods in 2020. The increases in fourth quarter and full year 2021 were primarily due to an increase in personnel related expenses attributed to an increase in headcount and an increase in outside services, including consulting and advisory services to support the growth of the Company.

Total operating expenses include non-cash expenses of \$2.8 million and \$10.7 million for fourth quarter and full year 2021, respectively, as compared to \$2.1 million and \$7.8 million for the same periods in 2020.

The Company reported net losses of \$21.8 million, or \$0.64 per share, and \$33.9 million, or \$1.00 per share, for fourth quarter and full year 2021, respectively, as compared to \$18.8 million, or \$0.58 per share, and \$65.1 million, or \$2.31 per share, for the same periods in 2020.

As of December 31, 2021, the company had 34.6 million of common shares outstanding.

CONFERENCE CALL

At 4:30 PM Eastern Time today, March 10, 2022, Eiger will host a conference call to discuss its financial results and provide a business update. The live and replayed webcast of the call will be available through the company's website at <u>www.eigerbio.com</u>. To participate in the live call by phone, dial (844) 743-2495 (U.S.) or (661) 378-9529 (International) and enter conference ID 4338659. The webcast will be archived and available for replay for at least 90 days after the event.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases. The Eiger HDV platform includes two first-in-class therapies in Phase 3 that target critical host processes involved in viral replication. All five Eiger rare disease programs have been granted FDA Breakthrough Therapy Designation. 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 within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our anticipated significant milestones in 2022; the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; expectations regarding the timing and availability of topline data from our Phase 3 D-LIVR study in HDV; the ability to fully enroll the Phase 3 LIMT-2 study; initiating a Phase 3 study for avexitide in congenital hyperinsulinism; the approval of Zokinvy in jurisdictions outside of the U.S., including the EU; and the potential of peginterferon lambda to be an effective therapy for newly diagnosed outpatients with COVID-19; and the possibility of success of any of our product candidates. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the "Risk Factors" sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and Eiger's subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

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Total liabilities and stockholders' equity

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

		Year Ended December 31, 2021	Year Ended December 31, 2020 ⁽¹⁾	
		2021	2020(*/	
ASSETS				
Cash and cash equivalents	\$	22,221\$	28,864	
Short-term debt securities		66,594	99,976	
Accounts receivable		2,576	-	
Inventories		2,612	93	
Prepaid expenses and other current assets		9,361	8,873	
Total current assets		103,364	137,806	
Long-term debt securities		17,262	-	
Property and equipment, net		613	709	
Operating lease right-of-use assets		653	1,176	
Other assets		4,510	3,903	
Total assets	\$	126,402\$	143,594	
LIABILITIES AND STOCKHOLDERS' EQUIT	ΓY			
Current liabilities	\$	29,901\$	16,627	
Other liabilities		24,102	31,932	
Stockholders' equity		72,399	95,035	
	-			

126,402\$

143,594

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,	
		2021	2020	2021	2020
Product revenue, net	\$	3,360 \$	—\$	12,142 \$	_
Costs and operating expenses:					
Cost of sales		104	_	745	_
Research and development ⁽¹⁾		18,186	12,545	64,436	41,590
Selling, general and administrative ⁽¹⁾		5,984	5,418	23,900	20,559
Total operating expenses		24,274	17,963	89,081	62,149
Loss from operations		(20,914)	(17,963)	(76,939)	(62,149)
Interest expense		(900)	(913)	(3,559)	(3,594)
Interest income		39	75	158	704
Other income (expense), net		25	(5)	46,487	(12)
Income(loss) before provision for taxes		(21,750)	(18,806)	(33,853)	(65,051)
Provision for income taxes		18	_	64	
Net loss	\$	(21,768)\$	(18,806)\$	(33,917)\$	(65,051)
Net income (loss) per common share:					
Basic and diluted	\$	(0.64)\$	(0.58)\$	(1.00)\$	(2.31)
Weighted-average common shares outstanding: Basic and diluted	3	4,010,405 3	2,701,820 3	3,944,342_2	8,143,391

⁽¹⁾Includes stock-based compensation expense of:

	Three Months Ended December 31,			Year Ended December 31,	
		2021	2020	2021	2020
Research and development	\$	625 \$	340 \$	2,252 \$	1,494
General and administrative		1,339	1,097	5,649	4,479
Total stock-based compensation expense	\$	1,964 \$	1,437 \$	7,901 \$	5,973

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