EyePoint Pharmaceuticals Reports First Quarter 2023 Financial Results and Highlights Recent Corporate Developments

May 3, 2023

– Completed enrollment in the oversubscribed Phase 2 DAVIO 2 clinical trial evaluating EYP-1901 in wet age-related macular degeneration (AMD); topline data anticipated in 4Q 2023

– Enrollment ahead of schedule in the Phase 2 PAVIA clinical trial evaluating EYP-1901 in non-proliferative diabetic retinopathy (NPDR); trial size reduced based on robust body of clinical evidence and proof-of-concept for vorolanib and EYP-1901

– YUTIQ net product revenue increased 60% to $7.4 million compared with $4.6 million in 1Q 2022

– Management to host a conference call and webcast today at 8:30 a.m. ET

WATERTOWN, Mass., May 03, 2023 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced financial results for the first quarter ended March 31, 2023 and highlighted recent corporate developments.

“In the first quarter, we continued to successfully execute on our key objectives across all areas of the business. Most importantly, we announced the completion of enrollment in our Phase 2 DAVIO 2 clinical trial evaluating EYP-1901 in wet AMD. We were particularly pleased by the high level of physician and patient interest, which resulted in the oversubscription of the trial to 160 patients compared to the original target of 144 patients. We look forward to announcing topline data from the DAVIO 2 trial in the fourth quarter of this year,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. “Combined with the Phase 1 DAVIO results, the Phase 2 DAVIO 2 data read-out will represent the most robust dataset among tyrosine kinase inhibitors in development for wet AMD. In addition, the body of evidence for EYP-1901 and vorolanib from both the clinical and non-clinical data to-date, combined with the drug’s proven anti-VEGF pharmacological mechanism across VEGF-mediated retinal diseases, support a strong proof-of-concept for EYP-1901 in NPDR. Accordingly, we have modified the trial size to enroll a minimum of 60 patients for the Phase 2 PAVIA clinical trial evaluating EYP-1901 in NPDR, which allows for enrollment completion ahead of schedule in the second quarter of this year, an accelerated path to Phase 2 data in the first half of 2024 and, subsequently, an earlier initiation timeline for the Phase 3 clinical trials. We look forward to providing additional clinical updates in the quarters to come.”

Ms. Lurker continued, “Once again, our commercial team delivered a strong quarter with $7.4 million in YUTIQ net product revenue, a 60% increase over the first quarter of 2022. We remain very pleased with the performance of YUTIQ and the terrific results our commercial team are producing.”

R&D Highlights and Updates

- EyePoint presented preclinical data on the neuroprotective effect of vorolanib, the active drug in EYP-1901, in a mouse model of retinal detachment at ARVO 2023. An encore presentation of the final twelve-month Phase 1 DAVIO results for EYP-1901was also presented.
- The Company announced completion of enrollment in the Phase 2 DAVIO 2 clinical trial evaluating EYP-1901 as a potential six-month maintenance treatment for wet AMD in March 2023. The trial was oversubscribed and exceeded its original target of 144 patients, enrolling a total of 160 patients. All patients were previously treated with a standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of EYP-1901 or to an aflibercept on-label control. Topline data remain on track for the fourth quarter of 2023.
- The size of the Phase 2 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment for moderate to severe NPDR was modified based on the body of evidence and proof-of-concept (POC) data for vorolanib, with enrollment completion now anticipated in the second quarter of 2023. The body of evidence collected on EYP-1901 from both the clinical and non-clinical data to date, combined with vorolanib’s proven anti-VEGF pharmacological mechanism across VEGF-mediated retinal diseases, support a strong POC for EYP-1901 in NPDR. Accordingly, the Phase 2 PAVIA clinical trial size has been reduced to enroll a minimum of 60 patients, allowing for an accelerated path to Phase 2 data and the initiation of Phase 3 clinical trials.
- EyePoint and Rallybio announced a research collaboration to evaluate Rallybio’s complement inhibitor C5 (component 5) using EyePoint’s proprietary Durasert ® technology for sustained intraocular drug delivery. The initial focus of the collaboration will be on developing a potential long-acting treatment for geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss.
- EyePoint was accepted to present an encore presentation of the Phase 1 DAVIO clinical trial twelve-month results at the European Society of Ophthalmology (SOE) Congress 2023 taking place June 15 – 17th in Prague. This presentation marks the first time that EYP-1901 clinical trial results will be presented outside of the U.S.
- At the American Society of Retina Specialists (ASRS) 41st Annual Meeting in July, Rishi Singh, MD, Staff Physician,

Cleveland Clinic Florida and President of the Cleveland Clinic Martin Hospitals, will present pharmacokinetic results from a study evaluating EYP-1901's drug delivery through the Durasert platform. The Company was also accepted to present clinical data at the ASRS Annual Meeting, including a subgroup analysis of the EYP-1901 final twelve-month Phase 1 DAVIO results and an update on the YUTIQ® CALM registry study. The CALM study is a Phase 4, multi-center registry study and a collaboration between EyePoint and the Cleveland Clinic.

- Plans to initiate a Phase 2 trial evaluating EYP-1901 in diabetic macular edema (DME) in the first quarter of 2024 remain on track.

Recent Corporate Highlights

- The Company entered into a lease agreement in January for the construction of a 40,000-square-foot standalone commercial manufacturing facility in Northbridge, Massachusetts to support global product supply of EYP-1901 and YUTIQ. The Company was awarded $1.9 million of state and local grants for the facility with lease payments not commencing until completion of construction, anticipated in the second half of 2024.

- Jay S. Duker, M.D., who served as the Company's Chief Operating Officer (COO) since November 2021, was promoted to the additional role of President in January 2023. In addition to continuing to oversee his duties as COO, in his expanded role, Dr. Duker will also oversee regulatory affairs.

YUTIQ Commercial Performance in First Quarter 2023

Net product revenue for YUTIQ for the first quarter ended March 31, 2023 was $7.4 million compared with $4.6 in the first quarter of 2022, which represents a 60% increase.

Customer demand for YUTIQ in the first quarter of 2023 was approximately 930 units compared with 650 units in the first quarter of 2022, which represents a 43% increase.

Review of Results for the First Quarter Ended March 31, 2023

For the first quarter ended March 31, 2023, total net revenue was $7.7 million compared to $9.3 million for the quarter ended March 31, 2022. Net product revenue for the first quarter was $7.4 million, compared to net product revenues of $9.0 million for the first quarter ended March 31, 2022. The reduction in net product revenues was driven by a significant reduction in DEXYCU revenues due to the discontinuation of pass-through reimbursement for that product effective January 1, 2023.

Net revenue from royalties and collaborations for the first quarter ended March 31, 2023 totaled $0.3 million compared to $0.3 million in the corresponding period in 2022.

Operating expenses for the first quarter ended March 31, 2023 totaled $29.2 million compared with $27.6 million in the prior year period. This increase was primarily driven by continued investment in R&D for EYP-1901 development, offset by a reduction in sales and marketing spend for DEXYCU. Non-operating income, net, for the first quarter of 2023, totaled $0.4 million and net loss was $21.2 million, or ($0.56) per share, compared to a net loss of $21.0 million, or ($0.56) per share, for the prior year period.

Cash and investments at March 31, 2023 totaled $122.5 million compared to $144.6 million at December 31, 2022.

Financial Outlook
The Company expects the cash, cash equivalents and investments on hand at March 31, 2023 and expected net cash inflows from product sales will enable it to fund current and planned operations into the second half of 2024.

Conference Call Information
EyePoint will host a conference call today, at 8:30 a.m. ET to discuss the results for the first quarter ended March 31, 2023 and recent corporate developments. To access the live conference call, please register at https://register.vevent.com/register/BI90ffc1666dc94fd1b3705e1b5ec9157d. A live audio webcast of the event can be accessed via the Investors section of the Company website at www.eyepointpharma.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary erodible Durasert E™ technology for sustained intraocular drug delivery including EYP-1901, an investigational sustained delivery intravitreal anti-VEGF treatment currently in Phase 2 clinical trials. The proven Durasert® drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products, including YUTIQ® for the treatment of posterior segment uveitis, which is currently marketed by the Company. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. For more information visit www.eyepointpharma.com.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the use of proceeds for the offering and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint's actual results to be materially different than those expressed in or implied by EyePoint's forward-looking statements. For EyePoint, this includes uncertainties regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for

EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration and non-proliferative diabetic retinopathy; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the success of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of competition and other developments affecting sales of our commercialized products, YUTIQ® and DEXYCU®; the loss of pass-through reimbursement status for DEXYCU at the end of 2022; market acceptance of our products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; the extent to which the COVID-19 pandemic impacts EyePoint's business, the medical community and the global economy; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; and other factors described in our filings with the Securities and Exchange Commission. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Investors:

Anne Marie Fields
Stern IR
Direct: 332-213-1956
annemarie.fields@sternir.com

Media Contact:

Amy Phillips
Green Room Communications
Direct: 412-327-9499
aphillips@greenroompr.com

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
Product sales, net	$ 7,394	$ 9,010
License and collaboration agreements	34	59
Royalty income	255	225
Total revenues	7,683	9,294
Operating expenses:		
Cost of sales, excluding amortization of acquired intangible assets	640	1,777
Research and development	13,618	9,945
Sales and marketing	5,737	6,693
General and administrative	9,242	8,548
Amortization of acquired intangible assets	-	615
Total operating expenses	29,237	27,578
Loss from operations	(21,554)	(18,284)
Other income (expense):		
Interest and other income, net	1,202	61
Interest expense	(812)	(1,194)
Gain (loss) on extinguishment of debt	-	(1,559)
Total other expense, net	390	(2,692)
Net loss	$ (21,164)	$ (20,976)
Net loss per common share - basic and diluted	$ (0.56)	$ (0.56)
Weighted average common shares outstanding - basic and diluted	37,486	37,253

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 105,765	$ 95,633
Marketable securities	16,718	48,928
Accounts and other receivables, net	10,422	15,503
Prepaid expenses and other current assets	9,081	9,858
Inventory	4,071	2,886
Total current assets	146,057	172,808
Operating lease right-of-use assets	5,777	6,038
Other assets	2,759	1,510
Total assets	$ 154,593	$ 180,356
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,938	$ 22,278
Deferred revenue	1,237	1,205
Short-term borrowings	5,295	10,475
Other current liabilities	772	579
Total current liabilities	27,242	34,537
Long-term debt	29,370	29,310
Deferred revenue - noncurrent	13,270	13,557
Operating lease liabilities - noncurrent	5,721	5,984
Other long-term liabilities	600	600
Total liabilities	76,203	83,988
Stockholders' equity:		
Capital	770,062	766,933
Accumulated deficit	(692,515)	(671,351)
Accumulated other comprehensive income	843	786
Total stockholders' equity	78,390	96,368
Total liabilities and stockholders' equity	$ 154,593	$ 180,356

EYEPOINT PHARMACEUTICALS

Source: EyePoint Pharmaceuticals, Inc.