

# EyePoint Pharmaceuticals Provides Business Update and Key 2023 Clinical Timelines

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- Topline data for Phase 2 DAVIO 2 clinical trial in wet AMD expected in 4Q 2023 -
- Enrollment remains on-track in Phase 2 DAVIO 2 clinical trial for wet AMD and Phase 2 PAVIA clinical trial for NPDR -
  - Full-year 2022 net product revenue estimated to exceed \$39.5 million versus \$35.3 million in 2021 -
    - Cash and investments of approximately \$144 million as of December 31, 2022 -

WATERTOWN, Mass., Jan. 05, 2023 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders, today announced a business update and key 2023 clinical timelines for its lead product candidate, EYP-1901.

EYP-1901 is an investigational sustained delivery product for serious retinal diseases that uses a bioerodible Durasert<sup>®</sup> micro insert of vorolanib, a selective and patented tyrosine kinase inhibitor (TKI). EYP-1901 represents a potential new mechanism of action and treatment paradigm for retinal diseases by acting as an intracellular vascular endothelial growth factor (VEGF) receptor blocker, which could provide added benefits beyond the traditional large molecule anti-VEGFs. EYP-1901 is currently in Phase 2 clinical trials for wet age-related macular degeneration (wet AMD) and non-proliferative diabetic retinopathy (NPDR).

"EyePoint had a tremendous year executing on the advancement of EYP-1901, including the successful completion of our Phase 1 DAVIO trial for wet AMD, which featured positive safety and efficacy results. In addition, we initiated Phase 2 clinical trials in both wet AMD and NPDR," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "The current standard of care for wet AMD requires monthly or bi-monthly injections and frequent doctor's visits, which is a tremendous treatment burden and often results in skipped treatments. For NPDR, although there are approved agents to treat this disease, this same significant treatment burden translates to the vast majority, 97%, of patients receiving no course of treatment apart from observation by their eye doctor, until their disease progresses to vision loss. Treatment compliance is key in these serious eye disorders, and a missed appointment can result in both vision loss and serious ocular complications. EYP-1901's 'Treat to Maintain' therapeutic approach has the potential to shift this paradigm by providing patients with an efficacious, safe and convenient six to nine month sustained delivery option coupled with the potential benefits of a new mechanism of action to maintain patient vision and reduce treatment burden."

Ms. Lurker continued, "In 2023, we are focused on executing on the ongoing Phase 2 wet AMD and NPDR trials and better understanding the unique benefits that EYP-1901's differentiated TKI mechanism provides patients. EYP-1901 has the potential to transform the way that these serious eye diseases are managed by retina specialists and improve patient outcomes, and we look forward to sharing initial topline data from our Phase 2 DAVIO 2 trial in the fourth quarter of 2023."

### **Anticipated 2023 Milestones:**

- EYP-1901: EYP-1901 is an investigational product and our lead pipeline program deploying a bioerodible Durasert insert containing vorolanib, a selective and patented TKI that brings a new mechanism of action that potentially has clinical benefits beyond current large molecule anti-VEGFs. With the combination of vorolanib and our proprietary bioerodible six to nine month Durasert, EYP-1901 can potentially change the current treatment paradigm for serious eye diseases. Positive twelve-month safety and efficacy data from the DAVIO Phase 1 clinical trial of EYP-1901 showed no reports of ocular or drug-related systemic serious adverse events and no dose limiting toxicities with stable visual acuity and macular thickness on OCT. Further, 53% and 35% of eyes did not require supplemental anti-VEGF injections up to six and twelve months, respectively, following a single dose of EYP-1901. Enrollment in the Phase 2 clinical trials for EYP-1901 in wet AMD and NPDR is ongoing and remains on track.
  - o Topline interim six-month data from the Phase 2 DAVIO 2 clinical trial for wet AMD is anticipated in 4Q 2023.
  - o Complete enrollment in the Phase 2 PAVIA trial for NPDR is expected by 4Q 2023.
  - o Expect to initiate a randomized, controlled Phase 2 clinical trial in diabetic macular edema (DME) in 4Q 2023.
- YUTIQ: YUTIQ is approved for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye, and the Company is commercializing it directly in the U.S. YUTIQ is currently being commercially launched in China by EyePoint's partner OcuMension Therapeutics.

There are currently two Phase 4 trials underway for YUTIQ:

- The CALM study, a Phase 4 multi-center retrospective registry study, in collaboration with the Cleveland Clinic, to collect real-world data on the implant. Efficacy outcomes on individual and combined patient cohorts are planned for presentation during medical conferences in 2023.
- The SYNCHRONICITY study is a prospective, open label study to assess safety and efficacy of YUTIQ in the treatment of chronic, non-infectious posterior segment uveitis and intraocular inflammation. This is a two-year follow up study with an

interim six-month efficacy readout anticipated in 2H 2023.

• **Pipeline Expansion:** EyePoint continues to evaluate molecules for potential use in its Durasert technology for future growth.

### **Corporate Updates**

- Q4 2022 net product revenue estimated to exceed \$9.5 million.
- Q4 2022 customer demand of approximately 980 units of YUTIQ compared to approximately 890 units for Q3 2022.
- Approximately \$144 million in cash and investments at December 31, 2022.
- On November 1, 2022, the Center for Medicare & Medicaid Services ("CMS") published in the Federal Register the calendar year (CY) 2023 Medicare Hospital Outpatient Prospective Payment System and ASC Payment System Final Rule ("Final Rule"). The Final Rule terminated the pass-through related separate payment for DEXYCU, which will no longer be separately reimbursed by Medicare as of January 1, 2023, when furnished in hospital outpatient departments and ASC settings. The Final Rule will reduce the amount of Medicare reimbursement provided to the Company's DEXYCU customers and may result in a significant reduction in the Company's DEXYCU product revenues. Furthermore, the reduction in the Company's DEXYCU product revenues is expected to result in a material impairment of the Company's net intangible asset related to DEXYCU which has a carrying value of \$20.9 million at September 30, 2022.

#### **Financial Outlook**

We expect cash, cash equivalents and investments on hand as of December 31, 2022 and expected net cash inflows from our product sales to enable us to fund our current and planned operations into the second half of 2024.

The preliminary fourth quarter and full-year 2022 revenue results and cash on hand included in this release were calculated prior to the completion of a review by the Company's independent registered public accounting firm and are therefore subject to adjustment.

### **About EyePoint Pharmaceuticals**

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a pharmaceutical 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 Durasert® technology for sustained intraocular drug delivery including EYP-1901, an investigational sustained delivery intravitreal 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.

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 as of January 1, 2023; 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 continued impact of the COVID-19 pandemic on EyePoint's business, the medical community and the global economy and the impact of general business and economic conditions; 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 forwardlooking 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.

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