EyePoint Pharmaceuticals and OcuMension Therapeutics Announce Approval of New Drug Application by China's NMPA for YUTIQ® for the Treatment of Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

June 21, 2022

WATERTOWN, Mass. and BEIJING, June 21, 2022 (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, and OcuMension Therapeutics (HKSE: 1477), a fast-growing ophthalmology focused pharmaceutical company in China, today announced that China's Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) has approved YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18mg for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. YUTIQ is the first drug approved for commercialization in China based entirely on real-world data, as well as the first drug approved for commercial use in OcuMension's innovative pipeline.

In September 2020, OcuMension launched a real-world study of YUTIQ for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye at Boao Lecheng Super Hospital in Hainan Province through the urgent clinical need channel granted to Boao Lecheng Pilot Zone. In April 2021, the CDE accepted OcuMension's new drug application (NDA) for YUTIQ that was filed with the real-world data collected at Boao Lecheng Super Hospital.

"YUTIQ's approval in China marks an important milestone for EyePoint and OcuMension's shared mission of bringing sustained-release drug delivery treatments to patients with debilitating diseases of the eye," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "Since YUTIQ's U.S. approval over three years ago, EyePoint has been able to deliver this innovative ocular therapy and provide an improved standard of care for patients by providing up to three years of continuous control in chronic, non-infectious uveitis affecting the posterior segment of the eye. We are proud to partner with OcuMension and expand YUTIQ's global reach in the emerging Chinese market as we work together to improve the lives of patients with serious eye disorders."

"We are thrilled to announce the new drug approval for YUTIQ in China. This approval marks the first-ever treatment approved from OcuMension's innovative pipeline and, more importantly, a critical therapeutic advancement for patients suffering from chronic, non-infectious uveitis affecting the posterior segment of the eye," said Ye Liu, Chief Executive Officer of OcuMension Therapeutics. "The OcuMension team has been working diligently to bring this potential best-in-class drug to Chinese patients as soon as possible, and I would like to express my sincerest gratitude to all of our colleagues in R&D, registration and commercialization that contributed diligently to YUTIQ's approval. We would also like to thank Boao Lecheng Super Hospital for helping us execute the real-world study of YUTIQ and our partners at EyePoint for their support in this registration and application. We are committed to bringing YUTIQ to market as soon as possible to benefit Chinese patients in need."

YUTIQ received approval by the U.S. Food and Drug Administration (FDA) on October 18, 2018. The treatment is currently marketed by EyePoint in the U.S., and EyePoint maintains development and commercialization rights for YUTIQ for the treatment of non-infectious uveitis affecting the posterior segment of the eye in the Americas and in Asia.

About Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

Non-infectious uveitis affecting the posterior segment of the eye is a chronic form of uveitis that may cause a variety of complications, including cataracts and glaucoma. When the inflammation is not controlled in a timely manner, it can lead to visual impairment or even permanent vision loss. The complex clinical presentation of non-infectious uveitis and the high degree of similarity between subtypes pose a significant challenge for accurate diagnosis. There are 1.4 million patients with this condition in China.

About YUTIQ®

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye, and was approved by the FDA on October 12, 2018. A link to the full product label is available on the YUTIQ website at: https://yutiq.com/downloads/US-YUT-2100035%20YUTIQ%20Prescribing%20Information-2021.pdf.

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 anti-VEGF treatment initially targeting wet age-related macular degeneration. 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 chronic non-infectious uveitis affecting the posterior segment of the eye, which is currently marketed by the Company. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

About OcuMension

OcuMension is a China-based ophthalmic pharmaceutical platform company dedicated to identifying, developing and commercializing first- or best-in-class ophthalmic therapies. Its vision is to provide a world-class pharmaceutical total solution to address significant unmet ophthalmic medical needs in China. We believe that our ophthalmic pharmaceutical platform with a clear first-mover advantage will secure us a leading position in the ophthalmic industry in China. Up to now, the Company has 22 drug assets in the immediate and posterior segments of the eye, establishing a comprehensive ophthalmic drug pipeline, of which six products have entered Phase III clinical trials. The NDA for OT-401 (fluocinolone acetonide intravitreal implant), our core product, has been accepted by the CDE, and is the first new drug applied for NDA in China based entirely on real world data. On 10 July 2020, OcuMension Therapeutics was listed on the Main Board of The Stock Exchange of Hong Kong Limited (stock code: 01477).

For more information on OcuMension Therapeutics, please visit https://www.ocumension.com/.

EYEPOINT PHARMACEUTICALS 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 six-month treatment for serious eye diseases, including wet age-related macular degeneration; 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®; 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. More detailed information on these and additional factors that could affect EyePoint's actual results are described in EyePoint's filings with the SEC, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as revised or supplemented by its Quarterly Reports on Form 10-Q and other documents filed with the SEC. All forward-looking statements in this news release speak only as of the date of this news release. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

For EyePoint Pharmaceuticals:

Investors:
Christina Tartaglia
Stern IR
Direct: 212-698-8700
christina.tartaglia@sternir.com

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

For OcuMension Therapeutics:
IR@ocumension.com

Source: EyePoint Pharmaceuticals, Inc.