EyePoint Pharmaceuticals Presents Positive YUTIQ™ 24-month Follow-up Data at the American Academy of Ophthalmology (AAO) 2018 Annual Meeting

October 29, 2018

WATERTOWN, Mass., Oct. 29, 2018 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today announced the presentation of 24-month efficacy and safety data supporting the Company's YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg three-year micro-insert for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. The data were presented by Quan Dong Nguyen, M.D., M.Sc., Professor of Ophthalmology, Byers Eye Institute, Stanford University School of Medicine, at the Retina Sub-Specialty Day at the 2018 American Academy of Ophthalmology (AAO) Annual Meeting in Chicago, IL at a Late Breaking Developments presentation entitled, “24-month Evaluation of Fluocinolone Acetonide Intravitreal Insert Treatment for Non-Infectious Posterior Uveitis.”

“Decreasing or eliminating uveitis flares is a critical factor in managing non-infectious posterior-uveitis as recurrences of attacks can lead to blindness if not properly treated. The 24-month follow-up data from the Phase 3 clinical trial of YUTIQ showed a significantly increased likelihood of achieving and maintaining inflammation control for YUTIQ compared to sham, highlighting the potential of YUTIQ to decrease disease recurrences,” said Dr. Nguyen. “Patients treated with YUTIQ were more likely to not need rescue adjunctive therapies for uveitic inflammation at 24-months compared to sham and no unanticipated side effects were seen. These positive long-term efficacy and safety results of YUTIQ are particularly encouraging as treatment options for innovative therapeutics for non-infectious uveitis of the posterior segment are limited, resulting in high unmet medical need for new therapies to treat this devastating, potentially blinding disease.”

Nancy Lurker, EyePoint’s President and Chief Executive Officer, commented, “These promising and durable 24-month clinical results reinforce our belief in the long-lasting potential of a single injection of YUTIQ in patients with noninfectious posterior segment uveitis. YUTIQ has the potential to address the limitations in the current standard of care by providing a consistent, and highly effective three-year long treatment option to prevent posterior segment uveitic flares with convenient administration done in the physician’s office. We continue to build our commercial infrastructure and sales organization in preparation for the planned U.S. launch of YUTIQ in the first quarter of calendar 2019.”

The first double-masked, randomized Phase 3 trial of YUTIQ enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S., with 87 eyes treated with YUTIQ and 42 eyes receiving sham injections. At 24-months of the three-year trial, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham eyes (59.8% vs. 97.6%, respectively; $p<0.001$). 16.1% of YUTIQ treated eyes needed the assistance of adjunctive intraocular/periocular injection medication for uveitic inflammation compared to 66.7% for sham treated eyes. 27.6% of YUTIQ treated eyes needed the assistance of adjunctive systemic steroids or immunosuppressants for uveitic inflammation compared to 50.0% for sham treated eyes.

Macular edema was resolved in 84.1% of YUTIQ treated eyes and 57.1% of sham treated eyes that had edema recorded at baseline. Intraocular pressure (IOP) lowering drops were used in 41.4% of YUTIQ treated eyes and 33.3% of sham treated eyes with IOP lowering surgeries performed in 4.6% of YUTIQ treated eyes and 7.1% of sham treated eyes. Cataracts were extracted from 64.3% of patients administered YUTIQ with phakic eyes (42) and 14.3% of patients administered sham with phakic eyes (21).

YUTIQ was approved by the U.S. Food and Drug Administration (FDA) on October 12, 2018 for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

About Chronic Non-infectious Uveitis Affecting the Posterior Segment of the Eye

Non-infectious posterior segment uveitis is a chronic, inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is believed to be a leading cause of blindness globally. It affects people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior segment uveitis is estimated to affect between 55,000 - 120,000 people, resulting in approximately 30,000 cases of blindness, making it the third leading cause of blindness in the U.S. Today, patients with posterior uveitis are typically treated with systemic steroids, but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have side effects including an increased risk of cancer.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals, Inc. (formerly pSivida Corp.) (www.eyepointpharma.com), headquartered in Watertown, MA, is a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products in indications with high unmet medical need to help improve the lives of patients with serious eye disorders. With the approval of YUTIQ™, the Company has developed five of only six FDA-approved sustained-release treatments for eye diseases. In addition, DEXYCU™ was approved by the FDA on February 9, 2018. DEXYCU, administered as a single intraocular dose at the end of ocular surgery for the treatment of postoperative inflammation, is the first and only FDA-approved intraocular product with this indication. DEXYCU employs the Verisome® extended-release drug delivery technology, which encompasses a broad number of related, but distinct drug delivery systems capable of incorporating an extensive range of active agents, including small molecules, proteins and monoclonal antibodies. ILUVIEN® (fluocinolone acetonide intravitreal implant), a micro-insert for diabetic macular edema, licensed to Alimera Sciences, Inc., is currently sold directly in the U.S. and several EU countries. Retisert® (fluocinolone acetonide intravitreal implant), for posterior uveitis, is licensed to and sold by Bausch & Lomb, Inc. YUTIQ three-year treatment of chronic non-infectious uveitis affecting the posterior segment of the eye was approved by the FDA on October 12, 2018. The Company's pre-clinical development program is focused on using its core Durasert™ and the Verisome platform technologies to deliver drugs to treat wet age-related macular degeneration, glaucoma, and other diseases. To learn more about the Company, please visit www.eyepointpharma.com and connect on Twitter, LinkedIn, Facebook and Google+.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: Various statements made in this release are

forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our plans to commercialize YUTIQ and DEXYCU, the expected timing of release of the 24-month and 36-month patient follow-up data for YUTIQ and our expectations regarding the timing of a filing of an application for approval of a next-generation, shorter-duration treatment for posterior segment uveitis, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements include uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce commercial supply of YUTIQ and DEXYCU and commercialize YUTIQ and DEXYCU in the U.S.; our ability to successfully build a commercial infrastructure and enter into and maintain commercial agreements for the launch of DEXYCU and YUTIQ; the development of our next-generation YUTIQ short-acting treatment for uveitis; potential off-label sales of ILUVIEN for non-infectious posterior segment uveitis ("NIPU"); consequences of fluocinolone acetonide side effects; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema ("DME") which depends on the ability of Alimera Sciences, Inc. ("Alimera") to continue as a going concern; Alimera's ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; Alimera's ability to obtain marketing approval for ILUVIEN in its licensed territories for NIPU; potential declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, contract sales organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential exit of the United Kingdom from the European Union; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements in light of these risks. 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. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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