



EyePoint Pharmaceuticals Presents Positive YUTIQ™ 36-month Follow-up Phase 3 Data at the 2019 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting

May 1, 2019

– 36-month data showed a uveitis eye flare recurrence rate of 56.3% in YUTIQ-treated eyes vs. 92.9% in sham eyes -

– Durability of 36-month data and safety support long-term efficacy of YUTIQ -

WATERTOWN, Mass., May 01, 2019 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ:EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today announced the presentation of 36-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 Glenn J. Jaffe, M.D., Robert Machemer Professor of Ophthalmology at Duke University School of Medicine, at the 2019 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Vancouver, British Columbia, in an oral session entitled "Treatment of Non-infectious Uveitis that Affects the Posterior Segment with a Single Intravitreal Fluocinolone Acetonide Insert (FAi) – 3-year Results".

"The 36-month follow-up data of the Phase 3 clinical trial showed a uveitis recurrence rate of 56.3% for YUTIQ, which was significantly lower than that of sham-treated eyes which was 92.9%. It is critically important to decrease uveitic recurrences to prevent blindness associated with secondary effects of inflammation," said Dr. Jaffe. "Safety results at 36-months were similar to the 24-month update with no unanticipated side effects. Of particular note, the procedure rate to treat glaucoma was no higher in the YUTIQ group than in the sham group. These durable and promising 36-month results continue to reinforce the potential of YUTIQ as a long-acting treatment option for patients suffering from this chronic disease, which is the third leading cause of blindness."

"The positive, long-lasting 36-month data further enhances our differentiated YUTIQ product profile compared to existing therapies for non-infectious posterior segment uveitis," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "We believe YUTIQ addresses the limitations of local corticosteroids, the current standard of care for uveitis, by providing a one-time administration of continuous dosing of fluocinolone acetonide for up to 36 months, which avoids drug peaks and valleys and improves patient compliance. We recently made YUTIQ commercially available and are pleased to be providing YUTIQ as a treatment option for the patients suffering from this devastating ocular disease."

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 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham eyes (56.3% vs. 92.9%, respectively; $p < 0.001$). Visual acuity gains of 3-lines were more common with YUTIQ (33% vs 15%) and losses were more common with sham (9% vs 1%). 19.5% of YUTIQ treated eyes needed the assistance of adjunctive intraocular/periocular injection medication for uveitic inflammation compared to 69.0% for sham treated eyes. 34.5% of YUTIQ treated eyes needed the assistance of an adjunctive systemic steroid or immunosuppressant compared to 50.0% for sham treated eyes.

Macular edema was resolved in 85% of YUTIQ treated eyes and 70% of sham treated eyes that had edema recorded at baseline. Intraocular pressure (IOP) lowering drops were used in 42% of YUTIQ treated eyes and 33% of sham treated eyes with IOP lowering surgeries performed in 6% of YUTIQ treated eyes and 12% of sham treated eyes. Cataracts were extracted from 74% of patients administered YUTIQ with phakic eyes and 24% of patients administered sham with phakic eyes.

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 EyePoint Pharma website at: www.eyepointpharma.com/wp-content/uploads/2019/01/YUTIQ-USPI-20181120.pdf.

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

Non-infectious posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which 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 either local steroid injections, with limited duration of effect, or 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 severe 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 by the FDA on October 12, 2018 of the YUTIQ™ three-year treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, the Company has developed five of the six FDA-approved sustained-release treatments for eye diseases. The most common adverse reactions reported for YUTIQ were cataract development and increases in intraocular pressure. 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. The most common adverse reactions reported by 5-15% of patients were increased intraocular pressure, corneal edema and iritis. DEXYCU employs the Verisome® extended-release drug delivery technology, which encompasses a broad number of related, but distinct drug delivery systems with the

potential 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. ("Alimera"), is currently sold directly in the U.S. and several EU countries. Retisert® (fluocinolone acetonide intravitreal implant), for non-infectious posterior segment uveitis, is licensed to and sold by Bausch & Lomb, Inc. 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 commercialization of YUTIQ and DEXYCU, the potential for our products to alter the treatment landscape for ocular diseases; the expected use of proceeds from our debt refinancing and equity offering and our belief that the amounts available from the CRG credit facility together with our current cash and cash equivalent position are sufficient to fund our operations and debt service obligations through to the generation of positive cash flow in 2020, 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 successfully 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 timing of a line extension application for approval of our next-generation YUTIQ shorter-duration treatment for non-infectious posterior segment uveitis; potential off-label sales of ILUVIEN for non-infectious posterior segment uveitis; consequences of fluocinolone acetonide side effects; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema ("DME"); 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 pricing and reimbursement for ILUVIEN in its licensed territories for non-infectious posterior segment uveitis; potential declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; 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; 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.

Contacts

Investors:

Argot Partners
Kimberly Minarovich
(646) 368-8014
kimberly@argotpartners.com

Joseph Rayne
(617) 340-6075
joseph@argotpartners.com

Media:

Thomas Gibson
(201) 476-0322
tom@tomgibsoncommunications.com



Source: EyePoint Pharmaceuticals, Inc.