EyePoint Pharmaceuticals Announces Positive Topline 36-month Follow-up Data for Second Phase 3 Study of YUTIQ®

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36-month data showed uveitis eye flare recurrence rate of 46.5% in YUTIQ-treated eyes vs. 75.0% in sham eyes, a 40% reduction

WATERTOWN, Mass., March 02, 2020 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing innovative ophthalmic products, today announced positive topline 36-month follow-up data from the second Phase 3 trial of 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 durable 36-month follow-up data from the second Phase 3 trial of YUTIQ highlight its long-term ability to reduce uveitic flares, consistent with the findings from the first Phase 3 trial. Reduction of uveitic flares is a key component in the treatment of this devastating disease leading to progressive vision loss and blindness, thus the recurrence rate of 46.5% at 36-months is compelling,” said Dr. Thomas Albini, Professor of Clinical Ophthalmology at Bascom Palmer Eye Institute in Miami, Florida. “Safety data showed no unanticipated side effects at each follow-up timepoint at 12-, 24-, and 36-months. These promising efficacy and safety data, coupled with a one-time administration, further position YUTIQ as a new, innovative treatment alternative for patients suffering from chronic non-infectious uveitis affecting the posterior segment of the eye.”

“We continue to believe YUTIQ is a differentiated treatment option compared to existing therapies because of its highly efficacious and solid safety profile, coupled with its convenient, single administration and long-term consistent dosing of drug,” said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. “The 36-month results provide additional support in its long-acting potential, a characteristic consistently regarded by treating physicians as a critical treatment advantage. Our commercial efforts are yielding increased reception and adoption from uveitis specialists across the U.S., as well as positive patient feedback on the YUTIQ product profile.”

The second double-masked, randomized Phase 3 trial of YUTIQ enrolled 153 patients in 15 clinical centers in India, with 101 eyes treated with YUTIQ and 52 eyes receiving sham injections. At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (46.5% vs. 75.0%, respectively; p=0.001). Visual acuity gains or losses of 3-lines or more were both similar between treatment groups. Considerably fewer YUTIQ-treated eyes (8.9%) needed the assistance of adjunctive intraocular/periocular injection medication for uveitic inflammation compared to sham treated eyes (51.9%); 31.7% of YUTIQ treated eyes needed the assistance of an adjunctive systemic steroid or immunosuppressant compared to 32.7% for sham treated eyes.

Macular edema was resolved in 75.8% of YUTIQ treated eyes and 53.8% of sham treated eyes that had edema recorded at baseline. Mean intraocular pressure (IOP) at 36 months was 14.8 mmHg and 13.4 mmHg in the YUTIQ treated eyes and sham treated eyes, respectively. Intraocular pressure lowering drops were used in 74.3% of YUTIQ treated eyes and 73.1% of sham treated eyes. IOP lowering surgeries were performed in 2.0 % of YUTIQ treated eyes and in none in the sham treated eyes. In patients with phakic eyes when enrolled in the study cataracts were extracted from 70.5% of patients administered YUTIQ and 26.5% of patients administered sham by the final 36-month time point of the study.

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 Pharmaceutical 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. is a pharmaceutical 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. The Company currently has two commercial products: DEXYCU®, the first approved intraocular product for the treatment of postoperative inflammation, and YUTIQ®, a three-year treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. The Company's pipeline leverages its proprietary bioerodible Durasert® technology for extended intravitreal drug delivery including EYP-1901, a VEGF inhibitor, targeting wet age-related macular degeneration, diabetic retinopathy and retinal vein occlusion. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts with offices in Basking Ridge, New Jersey.

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 expected financial results for the fourth quarter and full fiscal year ended December 31, 2019 and longer-term financial and business goals are forward-looking statements. Our preliminary fourth quarter and full year 2019 revenue results are preliminary and subject to adjustment in the ongoing review procedures by our independent registered public accounting firm. In addition, any financial projections and other estimates contained herein are

forward-looking statements with respect to the anticipated performance of the Company. Such financial projections and estimates are as to future events and are not to be viewed as facts, and reflect various assumptions of management of the Company and are subject to significant business, financial, economic, operating, competitive and other risks and uncertainties and contingencies (many of which are difficult to predict and beyond the control of the Company) that could cause actual results to differ materially from the statements included herein. 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 are risks and uncertainties inherent in our business including, without limitation: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for YUTIQ and DEXYCU; the regulatory approval and successful release of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; potential off-label sales of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye; consequences of fluocinolone acetonide side effects for YUTIQ; consequences of dexamethasone side effects for DEXYCU; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema, or 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 commercialize ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the territories in which Alimera is licensed to do so; 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; volatility of stock price; possible dilution; absence of dividends; 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. 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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