EyePoint Pharmaceuticals Presents Positive Data Showcasing YUTIQ® at the 37th Annual Scientific Meeting of the American Society of Retina Specialists

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WATERTOWN, Mass., July 30, 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 data supporting the Company's YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg three-year micro-insert for chronic, non-infectious uveitis affecting the posterior segment of the eye. The data were presented in three oral sessions at the 37th Annual Scientific Meeting of the American Society of Retina Specialists (ASRS) in Chicago, Illinois.

“The supportive, 36-month follow-up data of YUTIQ continues to reinforce our confidence in its long-lasting potential for this difficult to treat ocular disease, as well as its favorable safety and tolerability profile,” said Nancy Lurker, President and Chief Executive Officer. “Uveitis specialists have shared our enthusiasm regarding YUTIQ’s commercial launch, which is supported by these positive data, with several of these physicians specifically highlighting the consistent dosing and one-time administration of YUTIQ compared to local corticosteroids. We look forward to further expanding the commercial reach and adoption of YUTIQ across the U.S. for patients with non-infectious uveitis affecting the posterior segment of the eye.”

Data included in all three presentations at ASRS are from the first double-masked, randomized Phase 3 trial of YUTIQ, which enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. 87 eyes were treated with YUTIQ and 42 eyes received sham injections.

Summaries of the ASRS presentations are as follows:

Title: Best Corrected Visual Acuity at 36 Months in Study of Fluocinolone Acetonide Intravitreal (FAi) Insert for Non-Infectious Posterior Uveitis (NIPU)
Presenter: Sumit Sharma, M.D., Assistant Professor of Ophthalmology, Vitreoretinal Surgeon and Uveitis Staff Physician, Cleveland Clinic Lerner College of Medicine, Case Western Reserve University
Session Title: Inflammatory and Infectious Diseases Symposium

Results at the 36-month follow up of the Phase 3 trial of YUTIQ demonstrated that visual acuity gains of 3-lines or more were more common with YUTIQ (33.3% vs 14.7%) and losses were more common with sham (8.8% vs 1.4%). Change (ETDRS letters, mean±SD) in best corrected visual acuity (BCVA) for YUTIQ at 36-months showed an increase of 9.1±13.0 letters compared to an increase of 2.5±14.2 letters in sham treated eyes. In the subset of patients with greater central subfield foveal thickness (CSFT) at baseline, the proportion of eyes gaining 3 or more lines of vision was higher for YUTIQ eyes compared to sham eyes (46.3% vs 16.7%). Similarly, 3 or more lines of vision gains were seen in the subset of patients with macular edema at baseline (50.0% for YUTIQ vs. 21.7% for sham) and patients with ≥ 1+ vitreous haze at baseline (55.9% for YUTIQ vs. 26.7% for sham). The proportion of eyes gaining 3 or more lines of vision was similar for the YUTIQ and sham eyes regardless of whether or not intraocular pressure (IOP) lowering drops were used at any time during the study.

Title: Cumulative Recurrences with the Fluocinolone Acetonide Intravitreal (FAi) Insert for Non-Infectious Posterior Uveitis (NIPU): 36-Month Results
Presenter: David Callanan, M.D., Texas Retina Associates, Vitreoretinal Surgery, Medical Retina, Uveitis, Carver College of Medicine, University of Iowa
Session Title: Inflammatory and Infectious Diseases Symposium

At the 36-month follow up, the number of eyes with at least 1 recurrence was 49 for YUTIQ and 39 for sham treated eyes. The median time to the first recurrence was 1,051 days for YUTIQ (95% CI 686, 1,125) and 95 days for sham-treated eyes (95% CI 71, 117). Through 36 months, a total of 103 recurrences were reported in YUTIQ treated eye (mean 1.2 ± 2.0/eye) compared to 166 recurrences in the sham treated eye (mean 4.0 ± 3.3/eye). Multiple (>1) recurrences were observed in 21.8% of YUTIQ treated eyes compared to 73.8% of sham treated eyes. Safety data showed 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.

Title: 36-Month Outcomes of Injectable Fluocinolone Acetonide Intravitreal Insert on Recurrences of Non-infectious Posterior Segment Uveitis
Presenter: Quan Nguyen, M.D., M.Sc., Professor of Ophthalmology, Byers Eye Institute, Stanford University
Session Title: Late Breakers

At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (56.3% vs. 92.9%, respectively; p<0.001). Macular edema was resolved in 85.0% of YUTIQ treated eyes and 69.6% of sham treated eyes that had edema recorded at baseline. IOP lowering drops were used in 42.5% of YUTIQ treated eyes and 33.3% of sham treated eyes with IOP lowering surgeries performed in 5.7% of YUTIQ treated eyes and 11.9% of sham treated eyes. Cataracts were extracted from 73.8% of patients administered YUTIQ with phakic eyes and 23.8% of patients administered sham with phakic eyes. Additional data previously provided in the other two ASRS presentations were also included.

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. (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 and LinkedIn.

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 optimism that our existing cash and cash equivalents at April 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our operations 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 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; 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; 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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