EyePoint Pharmaceuticals Announces U.S. Commercial Launch of DEXYCU (dexamethasone intraocular suspension) 9%

March 12, 2019

DEXYCU indicated for the intraocular treatment of postoperative inflammation

WATERTOWN, Mass., March 12, 2019 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ:EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today announced that it has commercially launched DEXYCU™ (dexamethasone intraocular suspension) 9% in the United States. DEXYCU is the first and only U.S. Food and Drug Administration (FDA) approved intraocular steroid for the treatment of postoperative inflammation and is administered as a single dose at the end of cataract surgery. DEXYCU is intended to replace the use of steroid eyedrops which have a dosing regimen that, depending on the brand, can require self-administration for up to four times a day and titrating down over four weeks. This complicated dosing regimen can often lead to poor patient compliance.

The launch of DEXYCU will be phased, with the initial phase being to leading cataract surgery experts, to ensure proper training on DEXYCU's administration ahead of its wider availability in the ophthalmology community. The Centers for Medicare and Medicaid Services (CMS) has assigned a specific and permanent reimbursement J-code for DEXYCU, J1095, through the Healthcare Common Procedure Coding System (HCPCS) that became effective on January 1, 2019. The J-code will replace the previously issued C-code for DEXYCU (C9034) that became effective on October 1, 2018. EyePoint Assist, the Company-sponsored program designed to ensure access to DEXYCU, is available for eligible patients in need of financial assistance.

"EyePoint is proud to announce the U.S. commercial launch of our second innovative ophthalmic product, DEXYCU, which is now available to cataract surgery patients to treat inflammation that occurs after this common surgical procedure. There are approximately 4.8 million cataract surgeries a year in the US," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "DEXYCU offers a single-dose, sustained release treatment option conveniently administered at the end of cataract surgery which can eliminate the complicated and burdensome steroid eyedrop regimen following surgery."

DEXYCU is the first long-acting intraocular steroid approved by the FDA for the treatment of postoperative inflammation. Cataract surgery is the most frequent surgical procedure in the U.S., with approximately 4.8 million performed annually. DEXYCU employs the Company's Verisome sustained-release drug delivery technology to deliver a biodegradable extended-release formulation of the steroid dexamethasone into the posterior chamber of the eye via a single injection at the end of surgery, eliminating the burden of self-administering steroid eye drops up to four times a day for several weeks on a titrated schedule, in a primarily elderly patient population.

About DEXYCU™

DEXYCU™ (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation and was approved by the FDA on February 9, 2018. A link to the full product label is available at: https://dexycu.com/wp-content/uploads/2019/01/DEXYCU-PI-20181220.pdf.

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 the majority of the 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 intraocular pressure increased, 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., 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. and Vitrasert (ganciclovir implant), for cytomegalovirus retinitis was licensed and sold by Bausch and Lomb until being discontinued in 2013. The Company's development programs are focused on using its core Durasert™ and the Verisome platform technologies to deliver drugs to treat posterior segment uveitis (shorter-duration treatment), 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 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 successful release of our YUTIQ line extension shorter-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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Source: EyePoint Pharmaceuticals, Inc.