



EyePoint Pharmaceuticals Secures Pass-through Payment Status and Assignment of C-Code for DEXYCU™

September 5, 2018

WATERTOWN, Mass., Sept. 05, 2018 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals (NASDAQ:EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today announced that the Centers for Medicare and Medicaid Services (CMS) has approved transitional pass-through status and reimbursement through a C-code for DEXYCU™ (dexamethasone intraocular suspension) 9%. DEXYCU is the Company's U.S. Food and Drug Administration (FDA) approved product for the treatment of postoperative inflammation that is administered as a single intraocular dose at the end of ocular surgery. The code, C9034, will become effective on October 1, 2018.

"The receipt of pass-through status and the assignment of a C-code from CMS marks another important step forward in our commercialization preparation for DEXYCU," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "Our team continues to make progress on our commercialization strategy, hiring and scale-up initiatives in support of our planned commercial launch expected in the first half of 2019. We believe DEXYCU has the potential to address the unmet need and limitations of steroid drops, the current standard of care available for patients to treat inflammation following eye surgery, by providing DEXYCU as a convenient and long-acting single injection alternative therapy."

Approximately 40% of patients who undergo cataract surgery are covered by Medicare Part B. Drugs that are administered as part of the cataract surgery procedure can be covered under a CMS administered transitional-pass-through payment. The pass-through payment was established by the U.S. government to help foster innovative drug development. Drug applications must meet certain qualifications for inclusion. The transitional pass-through status is temporary for three years and products are reimbursed under a C-code, which are issued quarterly by CMS.

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. The Company has developed three of only four FDA-approved sustained-release treatments for back-of-the-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. The New Drug Application (NDA) for EyePoint's lead product candidate, YUTIQ™ three-year treatment of non-infectious uveitis affecting the posterior segment of the eye, has been accepted for filing by the FDA and is currently under standard review with a Prescription Drug User Fee Act (PDUFA) date of November 5, 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 REFORM 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 or believe may occur in the future 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; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema, which depends on Alimera's ability 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; the number of clinical trials and data required for marketing approval for YUTIQ™ in the U.S.; our ability to use data in promotion for YUTIQ which includes clinical trials outside the U.S.; our ability to successfully commercialize DEXYCU™ in the U.S.; our ability to successfully build a commercial infrastructure and enter into commercial agreements for the launch of DEXYCU and YUTIQ, if approved; our ability to successfully commercialize YUTIQ, if approved, in the U.S.; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; the development of our next-generation Durasert shorter-duration treatment for uveitis; 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, 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 U.K. exit from the EU; 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.