

EyePoint Pharmaceuticals Announces Assignment of Permanent J-Code for DEXYCU™ by the Center for Medicare and Medicaid Services (CMS)

November 12, 2018

WATERTOWN, Mass., Nov. 12, 2018 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (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 assigned a specific and permanent reimbursement J-code through the Healthcare Common Procedure Coding System (HCPCS) for DEXYCUTM (dexamethasone intraocular suspension) 9%. DEXYCU is the first and onlyFDA-approved, single dose, sustained-release, intracameral steroid for the treatment of postoperative inflammation.

"The issuance of a specific and permanent J-code for DEXYCU is another key milestone for the Company that allows for a convenient and simplified reimbursement process that is familiar to administering physicians and the greater insurance community," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "The addition of a permanent and specific J-code is also important to our commercial strategy as such codes are utilized by CMS and commercial insurers enabling us to address the entire population of patients requiring postoperative ocular inflammation treatment in the U.S. We continue to expect to commercially launch DEXYCU in the U.S. in the first half of calendar 2019 following the completion of a successful commercial supply scale-up."

The code, J1095, will become effective on January 1, 2019, and will replace the previously issued C-code for DEXYCU (C9034) that became effective on October 1, 2018. The Company still retains transitional pass-through status for DEXYCU from CMS for approximately three years.

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 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 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. 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.co

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 plans to commercialize 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 development of our next-generation YUTIQ short-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 forwardlooking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forwardlooking 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@argotpartner

kimberly@argotpartners.com

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

Media:

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



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