Bausch + Lomb And Nicox Announce PDUFA Date For Novel Glaucoma Candidate Latanoprostene Bunod

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Valeant Pharmaceuticals International, Inc.'s (NYSE: VRX and TSX: VRX) wholly owned subsidiary, Bausch + Lomb, and Nicox S.A. (Euronext Paris: FR0013018124, COX) announced that the US Food and Drug Administration (FDA) has set a PDUFA date of August 24, 2017 for its decision on the New Drug Application (NDA) for latanoprostene bunod ophthalmic solution, 0.024%. Latanoprostene bunod is an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

If approved, latanoprostene bunod would be the first nitric-oxide donating prostaglandin F2α analog for ophthalmic use.

"This is an exciting development in our journey to bring this new treatment option to the more than 3 million patients in the US with open angle glaucoma and ocular hypertension, and address a significant unmet medical need," said Joseph C. Papa, Chairman and CEO of Valeant. "Valeant is committed to delivering therapies that make a difference in patients' lives, and our work on latanoprostene bunod is a strong example of that."

"If granted, the FDA's approval of latanoprostene bunod will allow for the introduction of the first truly novel medication for these patients in many years," said Michele Garufi, Chairman and CEO of Nicox. "Additionally, latanoprostene bunod would represent the first commercially available therapy to use our proprietary nitric oxide-donating R&D platform, which we will continue to apply in the development of future innovative ophthalmic compounds."

Latanoprostene bunod was licensed by Nicox to Bausch + Lomb.