TearClear

TearClear Announces Successful Completion of Pre-IND Meeting with the FDA for a Preservative Free Multi-Dose Delivery of Latanoprost for the Treatment of Glaucoma

Prepared to file an IND in mid-2021 via the 505(b)(2) NDA pathway

Boston, MA, US, Dec 1, 2020 — TearClear, an emerging ophthalmic pharmaceutical company, today announced the successful completion of pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding the development plan for the preservative-free multi-dose delivery of a proprietary Latanoprost formulation, including the clinical study design for the registration study.

"We are pleased with the outcome of the Pre-IND meeting and look forward to preparing the IND filing and commencing our pivotal registration trial in 2021," said Robert Dempsey, Chief Executive Officer, TearClear. "The successful completion of this engagement with the FDA is an important milestone for the company and provides clarity and confidence as we advance our lead clinical program in the U.S."

About the 505(b)(2) Pathway

Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act permits the FDA to approve a New Drug Application (NDA) in part on the basis of published literature and/or a previous agency finding as to the safety or effectiveness of a drug. A 505(b)(2) NDA can be utilized for new chemical entities or for changes to previously approved drugs. This pathway potentially allows for a more rapid development and approval timeline compared to new chemical/molecular entities, based in part by referencing this information.

About Preservative-free

Preservatives, such as benzalkonium chloride (BAK), are necessary in ophthalmic solutions to maintain sterility. However, on the ocular surface, they have been reported to be associated with adverse effects like hyperemia, tear film instability and conjunctival inflammation potentially leading to meibomian gland dysfunction (MGD). By removing preservatives from the ocular surface, the potential for long term deleterious effects on the eye are reduced. TearClear's technology offers the only means of delivering a preservative-free dose directly from preserved solutions.

About TearClear

TearClear is an emerging ophthalmic pharmaceutical company with the goal of disrupting the way current topical medications are delivered to the ocular surface. Our lead product candidates in glaucoma will pave the way for future indications across multiple programs in development. This first in class platform of drugs enables medication delivery to ultimately enhance patient safety and compliance by capturing preservatives before they reach the ocular surface. TearClear is based in Boston, MA. For more information, visit TearClear (https://tearclear.com) and connect with us on LinkedIn (https://www.linkedin.com/company/tearclear/?viewAsMember=true).

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