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Alembic’s Bimatoprost gets USFDA approval

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It is used for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension

Alembic Pharmaceuticals Limited recently announced that the company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Bimatoprost Ophthalmic Solution, 0.03%.

The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Lumigan, 0.03% of Allergan Sales, LLC (Allergan). Bimatoprost Ophthalmic Solution, 0.03% is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

Bimatoprost Ophthalmic Solution, 0.03% have an estimated market size of US$ 10 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 90 ANDA approvals (78 final approvals and 12 tentative approvals) from USFDA.