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MEDIA & INVESTOR RELEASE

Sandoz launches generic brimonidine tartrate/timolol maleate eyedrop in US for patients with ocular hypertension, expanding leading ophthalmic portfolio

- *Brimonidine tartrate/timolol maleate combination eyedrop is used to treat elevated eye pressure in patients with ocular hypertension*[1]
- *Ocular hypertension affects over 5% of all adults*[2]*; the eye does not properly drain fluid, causing eye pressure to build up*[3]
- *Sandoz manufactures high-impact medicines that bring savings to US patients and support the sustainability of the overall US healthcare system*

Basel, April 14, 2022 — Sandoz, a global leader in generic and biosimilar medicines, today announced the US launch of its generic combination eyedrop brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, an AB-rated generic equivalent to AbbVie's COMBIGAN®*, to lower eye pressure in patients with ocular hypertension (high eye pressure).[1] This prescription eyedrop is immediately available to patients via retail pharmacies.

Anyone can develop ocular hypertension, but certain groups are at higher risk, including but not limited to African Americans and Hispanics, people over age 40, people living with diabetes or high blood pressure, people who are very myopic (near-sighted) and people who take long-term steroid medicines.[4] It is important to treat high eye pressure before it causes damage to the optic nerve and vision loss.[5]

"Fixed combinations of medicines to treat ocular hypertension can offer patients enhanced convenience, improved adherence, reduced exposure to preservatives, and cost savings," said Keren Haruvi, President, Sandoz Inc. "We developed this important generic eye treatment in-house to expand patient access to high-quality, more affordable eye care for millions of US patients."

Sandoz is a leading provider of ophthalmic medicines in the US, with over 36 product families for the treatment of a wide range of eye diseases. The launch of generic brimonidine tartrate/timolol maleate combination eyedrops in the US expands the Sandoz ophthalmology portfolio, helping maintain its #1 position in the US generic ophthalmic space.[6]

* *COMBIGAN® and its design are registered trademarks of Allergan, Inc., an AbbVie company.*

Important Safety Information

Contraindications

- Bronchial asthma, a history of bronchial asthma, severe chronic obstructive pulmonary disease.
- Sinus bradycardia, atrioventricular block, overt cardiac failure, cardiogenic shock.
- Neonates and infants (under the age of 2 years).
- Hypersensitivity to any component of this product.

Warnings and Precautions

- Potential for Severe Respiratory or Cardiac Reactions
- Cardiac Failure
- Obstructive Pulmonary Disease
- Potentiation of Vascular Insufficiency
- Increased Reactivity to Allergens
- Potentiation of Muscle Weakness
- Masking of Hypoglycemic Symptoms in Patients with Diabetes
- Mellitus
- Masking of Thyrotoxicosis
- Ocular Hypersensitivity

Adverse Reactions

Most common adverse reactions occurring in approximately 5 to 15% of patients included allergic conjunctivitis, conjunctival folliculosis, conjunctival hyperemia, eye pruritus, ocular burning, and stinging.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions

- Antihypertensives/cardiac glycosides may lower blood pressure.
- Concomitant use with systemic beta-blockers may potentiate systemic beta-blockade.
- Oral or intravenous calcium antagonists may cause atrioventricular conduction disturbances, left ventricular failure, and hypotension.
- Catecholamine-depleting drugs may have additive effects and produce hypotension and/or marked bradycardia.
- Use with CNS depressants may result in an additive or potentiating effect.
- Digitalis and calcium antagonists may have additive effects in prolonging atrioventricular conduction time.
- CYP2D6 inhibitors may potentiate systemic beta-blockade.
- Tricyclic antidepressants may potentially blunt the hypotensive effect of systemic clonidine.
- Monoamine oxidase inhibitors may result in increased hypotension.

Use in Specific Populations

Not for use in children below the age of 2 years. Use with caution in children ≥2 years of age.

Please see Full Prescribing Information for additional safety information.

Indication and Usage

Brimonidine tartrate and timolol maleate ophthalmic solution, 0.2%/0.5% is an alpha-adrenergic receptor agonist with a betaadrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP; the IOP-lowering of brimonidine tartrate and timolol maleate ophthalmic solution, 0.2%/0.5% dosed twice a day was slightly less than that seen with the concomitant administration of timolol maleate ophthalmic solution, 0.5% dosed twice a day and brimonidine tartrate ophthalmic solution, 0.2% dosed three times per day.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such generic or biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our ambition is to be the world’s leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2021 sales of USD 9.6 billion.

Sandoz on social media:

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Twitter: https://twitter.com/sandoz_global

Facebook: https://www.facebook.com/sandozglobal/
Instagram: https://www.instagram.com/sandozglobal

CEO Richard Saynor on LinkedIn: https://www.linkedin.com/in/richard-saynor/

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