Alcon treatment Travatan® receives EU approval for pediatric glaucoma patients

- New indication to decrease elevated intraocular pressure in patients, aged two months to less than 18 years, with ocular hypertension or pediatric glaucoma

- Pediatric indication complements Alcon’s broad treatment portfolio in glaucoma, providing a new important prostaglandin-based therapy for young patients

- Glaucoma is a life-long, irreversible eye disease that can progressively lead to blindness if left untreated or not adequately managed

Basel, Switzerland, December 23, 2014 – Alcon, the global leader in eye care and second-largest division of Novartis, announced that its treatment for patients with glaucoma, Travatan® (40µg/mL travoprost) Eye Drops Solution, has been granted an additional indication by the European Commission to decrease elevated intraocular pressure (IOP) in pediatric patients, aged two months to less than 18 years, with ocular hypertension or pediatric glaucoma. Travatan® is currently indicated to decrease elevated intraocular pressure in adult patients with ocular hypertension or open-angle glaucoma.

Glaucoma is a progressive eye disease that damages the optic nerve, resulting in gradual, irreversible loss of vision, and eventually blindness if left untreated or not adequately managed. Elevated eye pressure, or IOP, is considered the main risk factor for glaucoma.

“Pediatric glaucoma affects only a small number of children worldwide, so there is little data available about how to manage this sight-threatening disease in pediatric patients,” said Professor Stefano Gandolfi, MD, Head of Eye Clinic, University of Parma, Italy. “The Travatan® approval for this additional indication means that ophthalmologists now have a new medicine to prescribe to help children and adolescents control their IOP level every day.”

Pediatric glaucoma is responsible for 5% of childhood blindness worldwide. Patients suffering from glaucoma have no cure and, if vision is lost, it cannot be restored. Elevated IOP is the only known modifiable risk factor for glaucoma and can typically be controlled with daily administration of eye drops, or in the most severe cases, with surgery.

“We are pleased to receive the new EU pediatric indication of Travatan®, which further strengthens Alcon’s globally-leading glaucoma portfolio. The addition of this indication demonstrates Alcon’s long-term commitment and dedication to alleviating the patient burden of this sight-threatening disease,” said Jeff George, Global Head of Alcon.

The EU approval is based on a 12-week, Phase III, multicenter, double-masked, randomized, parallel-group study (n=152). The primary efficacy endpoint was the IOP change from baseline at Week 12 of the study. The effect on IOP was seen after the second week of treatment and was consistently maintained throughout the 12-week
study period. Mean IOP reductions in the travoprost and timolol groups were similar. Travatan® was shown to be safe and effective for use in children from two months to less than 18 years of age, at the same dose as for adults. No data are available for children below the age of two months. In the clinical study, the most frequently reported adverse drug reactions in pediatric patients were ocular hyperemia and growth of eyelashes.

Travatan®, preserved with POLYQUAD®, is the first and only, multi-dose prostaglandin analogue without benzalkonium chloride (BAK) approved in the EU. In previous clinical studies in adult patients, Travatan® showed strong IOP-lowering efficacy, decreasing IOP by 30% over the course of a day.

Alcon provides a broad spectrum of pharmaceutical and surgical treatment solutions to address the needs of patients at all stages of glaucoma management and care. As a world leader in treatments for glaucoma patients, Alcon is committed to developing solutions for unmet medical needs. Alcon offers a broad range of pharmaceutical treatment options for patients with glaucoma to help lower elevated IOP: Simbrinza®, Travatan®, Duotrac®, Azarga®, Azopt® and Izba®.

**About Glaucoma**

Glucoma is a leading cause of blindness, and affects more than 60 million people worldwide. Glaucoma is a group of eye diseases that lead to progressive damage of the optic nerve and can result in gradual, irreversible loss of vision and eventually blindness. There is no cure for glaucoma and vision lost cannot be restored. Medications can lower eye pressure, the only known modifiable risk factor for glaucoma, but must be taken lifelong and regularly. The exact cause of glaucoma is unknown.

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The foregoing release contains forward-looking statements that can be identified by words such as “commitment,” “dedication,” “committed,” or similar terms, or by express or implied discussions regarding potential additional marketing approvals for Travatan, or regarding potential future revenues from Travatan, Simbrinza, DuoTrav, Azarga, Azopt, Izba, the Ex-press Glaucoma Filtration Device and the other products in the Alcon glaucoma portfolio. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Travatan or any other product in the Alcon glaucoma portfolio will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Travatan or any other product in the Alcon glaucoma portfolio will be commercially successful in the future. In particular, management’s expectations regarding such products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, 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 Novartis**

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified
portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 133,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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