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Alcon launches the CyPass® Micro-Stent at the American Academy of Ophthalmology (AAO) 2016 annual meeting

- *Alcon to host first live training program on the use of the CyPass® Micro-Stent, a minimally invasive glaucoma surgical device to treat cataract patients with mild to moderate primary open-angle glaucoma*

- *Two-year safety and efficacy data from landmark COMPASS study published in peer reviewed journal* Ophthalmology*; data reinforcing intraocular pressure (IOP)-lowering benefits of the CyPass Micro-Stent to be presented at conference*

Basel, October 17, 2016 – Alcon, the global leader in eye care and a division of Novartis, announced the US launch of the CyPass® Micro-Stent at the annual meeting of the American Academy of Ophthalmology (AAO), October 15-18 in Chicago, where Alcon will host a live training program and present additional data during poster and oral sessions. The CyPass Micro-Stent was approved by the US Food and Drug Administration in July for use in conjunction with cataract surgery to lower intraocular pressure in adult patients with mild to moderate primary open-angle glaucoma.

“We are excited to launch the CyPass Micro-Stent device in a new segment of glaucoma treatment called minimally-invasive glaucoma surgery, or MIGS,” says Sergio Duplan, Region President, North America, Alcon. “This new treatment option for cataract patients with mild to moderate primary open-angle glaucoma has been demonstrated to have a lasting, significant IOP-lowering effect.”

The CyPass Micro-Stent device is implanted during cataract surgery, just below the surface of the eye, into the supraciliary space. It is designed to lower IOP by enhancing aqueous outflow through one of the natural drainage pathways of the eye, with minimal tissue disruption, which allows the excess fluid in the eye to drain. The CyPass Micro-Stent was developed by Transcend Medical, Inc. which Alcon acquired in February 2016.

As part of its activities at AAO, Alcon will present two- and three-year data from COMPASS, the largest study of MIGS to date, as well as three-year data findings from the CYCLE study (a real-world registry study conducted in the EU).

- *Poster presentation. Supraciliary Micro-Stent Implantation for Lowering IOP in Glaucoma Patients Undergoing Cataract Surgery: Randomized, Controlled, 3-Year Results From a Single Center*, presented by Dr. Steven D. Vold. (Mon, Oct 17 from 12:30-2:00PM; Location: Hall A)
    - Key finding: The CyPass Micro-Stent implantation at the time of cataract surgery decreased unmedicated and medicated IOP from baseline and sustained the lower IOP pressure through 36 months.

- *Poster presentation. Prognostic Factors for Lowering IOP in Primary Open-Angle Glaucoma by Combined Supraciliary Micro-Stenting-Phaco Cataract Surgery: COMPASS Randomized Controlled Trial*, presented by Dr. Tsontcho Ianchulev (Sun, Oct 16 from 12:30-2:00pm; Location: Hall A)
    - Key finding: The CyPass Micro-Stent implanted during cataract surgery demonstrated sustained reduction in IOP at 24 months in patients with mild-to-moderate primary open-angle glaucoma.

- *Paper presentation. Minimally Invasive Supraciliary Micro-stent for IOP Control in Combined POAG-cataract Surgery: 2-year COMPASS RCT Results*, presented by Dr. Reay H. Brown. (Mon, Oct 17 from 3:52-3:59pm; Location: S405)
    - Key finding: Supraciliary microstenting in combination with cataract surgery demonstrated sustained benefit after cataract surgery over two years.

- *Paper presentation. Multicenter 3-Year Results After Combined Cataract Surgery and Supraciliary Micro-Stent Implantation for Open-Angle Glaucoma*, presented by Dr. Steven R. Sarkisian. (Mon, Oct 17 from 3:24-3:31pm; (Location: S405)
    - Key finding: Study results showed sustained control of IOP for 3 years postoperatively.

Two-year data from the landmark COMPASS study was also published recently in the online edition of the peer-reviewed journal *Ophthalmology*. The data published in *Ophthalmology* is a follow-up for over 500 mild to moderate glaucoma patients who underwent cataract surgery. The randomized clinical study demonstrated safe and sustained two-year reduction in intraocular pressure and glaucoma medication use after micro-interventional surgical treatment for mild-to-moderate primary open-angle glaucoma.

“Findings from the COMPASS and CYCLE studies are significant and further demonstrate Alcon’s dedication to bringing to market some of the most innovative surgical technologies to effectively treat diseases like glaucoma,” said Franck Leveiller, Head of Global Research & Development, Alcon. “We are proud to be working with glaucoma experts and surgeons in the US and around the world to bring this new treatment option to as many eligible patients as possible.”

About Glaucoma
More than 60 million people globally are affected by glaucoma that can lead to progressive damage of the optic nerve. Early diagnosis of glaucoma is critical to manage the disease, as it is often asymptomatic and therefore can go undetected until it is at an advanced stage. As the disease progresses, patients may experience loss of peripheral (side) vision, tunnel vision or eye spots. Glaucoma can eventually result in gradual, irreversible loss of vision and blindness. The exact cause of glaucoma is unknown. However, elevated pressure in the eye (intraocular pressure, or IOP) is generally present with glaucoma and is the only known modifiable risk factor. As a chronic disease, patients can be treated with eye drops, oral medications, laser surgery, traditional surgery or a combination of these methods.[1,2,3]

About the CyPass Micro-Stent
The CyPass Micro-Stent is a prescription medical device that is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate primary open-angle glaucoma. The use of the CyPass Micro-Stent is contraindicated in eyes with angle closure glaucoma and eyes with traumatic, malignant, uveitic or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle. If IOP is not adequately maintained after implantation of a CyPass Micro-Stent, additional therapy may be needed for IOP control.

In a randomized, multicenter clinical trial comparing cataract surgery with CyPass to cataract surgery alone, the most common post-operative adverse events included: Best Corrected Visual Acuity (BCVA) loss of 10 or more letters at 3 months after surgery (8.8% for CyPass vs. 15.3% for cataract surgery only); anterior chamber cell and flare requiring steroid treatment 30 or more days after surgery (8.6% vs. 3.8%); worsening of visual field mean deviation by 2.5 or more decibels (6.7% vs. 9.9%); IOP increase of 10 or more mmHg 30 or more days after surgery (4.3% vs. 2.3%); and corneal edema 30 or more days after surgery, or severe in nature (3.5% vs. 1.5%). Please refer to the Instructions for Use for the CyPass Micro-Stent for a complete list of contraindications, warnings, precautions and adverse events.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “launches,” “to host,” “to be presented,” “will,” “excited,” “launch,” “dedication,” “can,” or similar terms, or by express or implied discussions regarding potential additional approvals for the CyPass Micro-Stent, or regarding potential future revenues from CyPass Micro-Stent. 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 CyPass Micro-Stent will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that CyPass Micro-Stent will be commercially successful in the future. In particular, management's expectations regarding CyPass Micro-Stent could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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 safety, quality or 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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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2. Quigley and Broman. The Number of People with Glaucoma Worldwide in 2010 and 2020. Br J Ophthalmol 2006;90:262-7.
3. http://myeyes.com/glaucoma.shtml(link is external)

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