Alcon receives FDA Approval for pre-loaded intraocular lens delivery system to treat patients undergoing cataract surgery

- AcrySof® IQ Aspheric Intraocular Lens (IOL) with UltraSert™ Pre-loaded Delivery System helps maintain integrity of incision while facilitating smooth IOL delivery
- Follows earlier FDA approval of AcrySof® IQ ReSTOR® +2.5 Diopter (D) Intraocular Lens (IOL) further expanding Alcon’s lens portfolio for cataract surgery

Basel, October 5, 2015 – Alcon, the global leader in eye care and a division of Novartis, has received US Food and Drug Administration (FDA) approval for its AcrySof® IQ Aspheric IOL with the UltraSert™ Pre-loaded Delivery System for patients undergoing cataract surgery. This new delivery system combines the control of a manually loaded device with the safety and convenience of a disposable, pre-loaded injector to optimize the implantation of the AcrySof IQ Aspheric IOL into the cataract patient’s eye. Nearly four million cataract surgeries are performed each year in the US. The UltraSert™ Pre-loaded Delivery System received the European CE mark in June 2015.

“The introduction of the UltraSert Pre-loaded Delivery System further reinforces our commitment to advancing cataract surgery through innovation,” said Sergio Duplan, Region President, United States and Canada. “We are addressing a distinct need of cataract surgeons for a single-use system that maximizes their control during surgery and helps them streamline procedures to enable improved patient outcomes.”

In cataract surgery, controlling the speed of delivery of the IOL when inserted into the eye is an important factor in achieving a successful cataract procedure. Alcon has addressed this critical factor in the UltraSert Pre-loaded Delivery System with the TensionGlide™ Plunger, a spring-controlled mechanism designed for a smooth, controlled delivery of the AcrySof IQ IOL into the capsular bag. In addition, the UltraSert Pre-loaded Delivery System features a plunger tip which is designed to support consistent IOL folding and precise placement into the capsular bag of the eye.

The design of the new UltraSert Pre-loaded Delivery System also helps to create a less invasive corneal incision during cataract surgery. The smaller nozzle tip allows for a corneal incision down to 2.2 mm for insertion of the IOL while the Depth Guard™ nozzle of the delivery system prevents the device from being inserted deeper into the incision than necessary, preserving the size of the original corneal incision.

“In testing this device, I was immediately impressed with its smooth control and single hand delivery,” said Dr. Robert Lehmann, M.D., F.A.C.S, a practicing ophthalmologist at the Lehmann Eye Center of Nacogdoches, Texas, USA. “I believe it will give the surgeon excellent control during the procedure to ensure a consistent delivery of the IOL into the eye.”
eye. There are many surgeons who are highly interested in pre-loaded devices, and UltraSert represents a major step forward in pre-loaded delivery system technology."

**About Cataracts**
A cataract is a clouding of the natural lens of the eye that affects vision. As a cataract develops, the eye’s lens gradually becomes harder and cloudy which scatters light rays and allows less light to pass through it, thus reducing the patient’s ability to see. The vast majority of cataracts occur as part of normal aging but radiation exposure, taking steroids, diabetes, and eye trauma can accelerate the development of cataracts. Additionally, cataracts can be hereditary and congenital and can present shortly after birth. Cataracts are the most common age-related eye condition and the leading cause of preventable blindness. Cataracts are treated by surgically removing the eye’s cloudy natural lens and replacing it with an intraocular lens (IOL). More than 98 percent of cataract surgeries are considered successful and patients can usually return to their normal routines within 24 hours.

**Important Information about the UltraSert Pre-loaded Delivery System**
As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include corneal endothelial damage, endophthalmitis, retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, and transient or persistent glaucoma. Only Alcon qualified viscoelastic(s) should be used with the UltraSert Pre-loaded Delivery System. The use of an unqualified viscoelastic may cause damage to the lens and potential complications during the implantation process.

**Disclaimer**
The foregoing release contains forward-looking statements that can be identified by words such as “commitment,” “designed,” “will,” “risk,” “potential,” or similar terms, or by express or implied discussions regarding potential additional marketing approvals for the UltraSert Pre-loaded Delivery System or the AcrySof IQ ReSTOR +2.5 Diopter IOL, or regarding potential future revenues from these products. 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 the UltraSert Pre-loaded Delivery System or the AcrySof IQ ReSTOR +2.5 Diopter IOL will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that these products will be commercially successful in the future. In particular, management’s expectations regarding these 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 safety issues; 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
Novartis is innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 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 120,000 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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3. AcrySof® IQ UltraSert™ Preloaded Delivery System Directions for Use.

Novartis Media Relations

Central media line: +41 61 324 2200
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Elizabeth Harness Murphy
Novartis Alcon Communications
+1 817 551 8696 (direct)
+1 585 435 7379 (mobile)
elizabeth.murphy@alcon.com
e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone: +41 61 324 7944
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America:
Richard Pulik +1 212 830 2448
Sloan Pavsner +1 212 830 2417
e-mail: investor.relations@novartis.com