

# Alcon receives US FDA approval for AcrySof® IQ ReSTOR® +3.0D Multifocal Toric intraocular lens for cataract patients

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- - New intraocular lens (IOL) combines two technologies that correct for presbyopia and corneal astigmatism simultaneously
- - This IOL is a new option for patients who desire good near, intermediate and distance vision with an increased potential for spectacle independence
- - US commercialization expected to start on a rolling basis in the first quarter of 2017

FORT WORTH, Texas, Dec. 22, 2016 /PRNewswire/ -- Alcon, the global leader in eye care and a division of Novartis, has received approval from the US Food and Drug Administration (FDA) for its AcrySof® IQ ReSTOR® +3.0D Multifocal Toric Intraocular Lens (IOL). The new IOL is designed to address presbyopia and pre-existing corneal astigmatism at the time of cataract surgery in adult patients who desire good near, intermediate and distance vision with an increased potential for spectacle independence. The product is already commercially available in the European Union, Australia, Canada, and many countries in Central and South America and Asia.

"The AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL is an important addition to our market-leading IOL portfolio, and broadens our offering of presbyopia- and astigmatism-correcting lenses to meet the different visual needs of patients," said Sergio Duplan, Alcon Region President for North America. "We are committed to delivering ongoing innovation that enables surgeons to provide the best possible outcome for their patients."

Nearly 4 million cataract surgeries are performed each year in the United States, and more than 50% of those patients have levels of astigmatism that could be addressed with these new IOLs<sup>1,2</sup>. Worldwide, nearly 1.7 billion people experience near vision issues due to presbyopia, an eye condition that involves the gradual loss of the eye's ability to actively focus on close objects. Due to the aging population, this number is expected to soar to more than 2 billion people with presbyopia by 2020<sup>3</sup>.

"Correcting presbyopia and astigmatism, with one lens, at the time of cataract surgery is a great benefit to patients and can improve patient satisfaction," said Dr. Stephen Lane, Medical Director, Associated Eye Care and Adjunct Clinical Professor at the University of Minnesota. "The introduction of this advanced technology IOL gives us an additional treatment option to help reduce dependence on spectacles for patients with astigmatism."

Alcon plans to commercialize AcrySof IQ ReSTOR +3.0D Multifocal Toric IOLs in the United States on a rolling basis starting in the first quarter of 2017.

## About Cataracts

A cataract is a cloudy area in the natural lens of the eye that affects vision. As a cataract develops, the eye's lens gradually becomes hard and cloudy allowing less light to pass through, which makes it more difficult to see. The vast majority of cataracts happen as a result of normal aging but radiation exposure, taking steroids,

diabetes, and eye trauma can accelerate the development of cataracts<sup>4</sup>. Cataracts are the most common age-related eye condition and the leading cause of preventable blindness<sup>5</sup>. Twenty million people in the US age 40 and older have cataracts<sup>6</sup>. Cataracts are treated by removing the eye's cloudy natural lens and surgically replacing it with an intraocular lens or IOL. More than 98% of cataract surgeries are considered successful and patients typically can return to their normal routines within 24 hours<sup>7</sup>.

#### About Astigmatism and Presbyopia

Astigmatism is a variation in the shape or curvature of the cornea and, if left untreated, can cause blurred vision at all distances. Presbyopia is an eye condition that occurs as part of natural aging. It involves the gradual loss of the eye's ability to actively focus on close objects, such as smart phones, computers, books and menus. The first signs of presbyopia are eyestrain, difficulty seeing in dim light and problems focusing on small objects and/or fine print. Once a person is in their 40s, it is likely they will experience presbyopia and will require vision correction such as reading glasses or multifocal contact lenses.

#### Important Information about the AcrySof® IQ ReSTOR® +3.0D Multifocal Toric IOL

Side effects associated with the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL include visual disturbances such as glare, rings around lights, and blurred vision. These side effects may make it more difficult to see while driving at night or completing tasks in low lighting such as at night or in fog, after surgery as compared to before surgery.

The AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL corrects corneal astigmatism only when it is placed in the correct position in the eye. There is a possibility that the IOL could be placed incorrectly or could move within the eye. This may result in less improvement or a reduction in vision because your corneal astigmatism has not been fully corrected, or it may cause visual symptoms.

The safety and effectiveness of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL has not been established in patients with certain eye conditions, such as glaucoma or diabetic retinopathy (an increase in eye pressure or complications of diabetes in the eye).

#### Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "potential," "expected," "to start," "committed," "ongoing," "could," "plans," or similar terms, or by express or implied discussions regarding the expected timing of commercialization of AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL in the United States, or regarding potential additional marketing approvals for AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL, or regarding potential future revenues from AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL. 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 AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL will be commercialized in the United States in any particular time frame, or at all. Neither can there be any guarantee that AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL will be commercially successful in the future. In particular, management's expectations regarding AcrySof IQ ReSTOR +3.0D Multifocal Toric IOL 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; unexpected delays in the US commercialization process; 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 Alcon

Alcon is the global leader in eye care. As a division of Novartis, we offer the broadest portfolio of products to enhance sight and improve people's lives. Our products touch the lives of more than 260 million people each year living with conditions like cataracts, glaucoma, retinal diseases and refractive errors, and there are millions more who are waiting for solutions to meet their eye care needs. Our purpose is reimagining eye care, and we do this through innovative products, partnerships with eye care professionals and programs that enhance access to quality eye care. Learn more at [www.alcon.com](http://www.alcon.com).

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#### 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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