Abbott Announces Positive Results From Pivotal Study Of Tecnis® Symfony IOL For Cataract Surgery

- Results presented today at The American Society of Cataract and Refractive Surgery (ASCRS) annual meeting in New Orleans

- Study showed the Tecnis Symfony IOL improved intermediate and near visual acuity compared to a standard monofocal lens, while maintaining comparable distance visual acuity

NEW ORLEANS, May 8, 2016 /PRNewswire/ -- Today Abbott (NYSE: ABT) announced that its pivotal clinical trial of the company's Tecnis® Symfony 1-Piece Acrylic Intraocular Lens (IOL) met its primary endpoint of improved intermediate vision. Data from this study showed that people who received the Tecnis Symfony lens achieved significantly improved intermediate, as well as near, vision compared to those who received a monofocal IOL. The data were presented today at the American Society of Cataract and Refractive Surgery (ASCRS) in New Orleans by Jason Jones, M.D., Jones Eye Clinic, Sioux City, Iowa.

"Many people with cataracts are asking for an option that will help them perform near activities like reading, use their computers and tablets at intermediate distance, as well as see objects that are far away," said Dr. Jones, an investigator on the study. "The data from this study showed that patients who received the Symfony lens were more likely to achieve improved intermediate and near vision, while maintaining similar distance vision compared with patients who received a standard IOL."

A cataract is a condition in which the lens inside the eye becomes cloudy. Many patients notice the symptoms of a cataract as cloudy or blurred vision, faded color patterns, poor night vision, doubling of images or frequent need to change their glasses prescription.

Cataract surgery is one of the safest and most common surgeries performed by eye surgeons, with almost 4 million surgeries performed in the U.S. every year. That number is expected to grow significantly as the population ages and as new lens choices are introduced that provide people more options for improving their vision and maintaining their active lifestyle after cataract surgery. Though common in older adults, demographics are changing among cataract patients. In 2016 it was estimated that 900,000 cataract procedures would be performed on people in the United States younger than 65 years old.[1]

Unlike monofocal IOLs that provide a fixed focus point at one particular distance, the Tecnis Symfony IOL has proprietary optical features designed to elongate the range of focus of the eye and provide a continuous range of vision at near, intermediate and distance. The Symfony IOL has been widely studied, with data from more than seven studies in over 2,000 eyes being collected. The Symfony IOL is approved in more than 50 countries around the world. In the U.S., it is an investigational lens and is not available for commercial use.

"Today, people with cataracts want the ability to choose a lens that is likely to give them the vision they want so they can continue to be active and lead fulfilling lives," said Thomas Frinzi, senior vice president of Abbott's vision business. "The existing Tecnis family of IOLs offers personalized options for patients. The Symfony data presented at ASCRS will be used to support our regulatory application for the lens in the U.S., potentially providing even more choices to doctors and patients."

About the study

The clinical trial was a prospective, multicenter, bilateral, randomized, subject- and evaluator-masked clinical investigation conducted at 15 U.S. sites. It evaluated the safety and effectiveness of the Tecnis Symfony 1-Piece Acrylic IOL in 148 patients compared with 150 patients who received a Tecnis 1-piece Aspheric Acrylic (monofocal) IOL. The study had two primary endpoints: uncorrected intermediate visual acuity (monocular UCIVA) in one eye, which is a measurement of how well the eye can focus at intermediate distances without the aid of glasses or contacts; and distance corrected intermediate visual acuity (monocular DCIVA) at 66 cm in one eye, which is a measurement of the best possible vision at 66 cm with the use of distance glasses or contacts. Both of these primary endpoints were met, and these data will be used to support the regulatory application of the Tecnis Symfony IOL in the U.S.

Key findings from the trial reported by Dr. Jones at ASCRS include:

- At 6 months of follow-up, patients in the Symfony group achieved 1.7 more lines of UCIVA and 2.4 additional lines of DCIVA at 66 cm than patients in the monofocal group.
- With and without correction for distance vision, Symfony IOL patients achieved an average binocular intermediate visual acuity of 20/20.
- People who received the Symfony lens gained 2.2 more lines of distance-corrected near visual acuity (DCNVA) compared with those in the monofocal group.
- People who received the Symfony lens achieved significantly better monocular near vision compared to those in the monofocal group. When testing both eyes together, mean visual acuity at near without correction was between 20/25 and 20/30.
- Rates of adverse events did not differ between the Symfony IOL and monofocal group.

Data were also presented at ASCRS by James Loden, M.D., Loden Vision Center, Nashville, Tenn., from four prospective, multicenter clinical studies, for a total of 1,464 eyes (of 735 individuals) from 69 sites in Europe, New Zealand and the U.S. These results showed that the Symfony lens was associated with low levels of glare, halo and starburst. High levels of patient satisfaction were also achieved in Symfony clinical trials: More than 91 percent of patients (N=589) in the studies said they

would choose the Symfony lens again, and more than 93 percent (N=557) recommend the lens to a friend or family member.

About The Tecnis Family of IOLs:

The Tecnis Multifocal Family of 1-Piece IOLs are currently available in three add powers: +4.0, +3.25 and +2.75. In addition, the Tecnis Family of IOLs also includes a monofocal 1-Piece IOL and the Tecnis Toric 1-Piece IOL for astigmatism correction. Each lens in the Tecnis Family of IOLs features a sophisticated proprietary design based on validated science and optical principles designed to offer patients multiple options for post-surgical vision that best meet their specific visual demands.

About Abbott:

At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world – in nutrition, diagnostics, medical devices and branded generic pharmaceuticals – that create more possibilities for more people at all stages of life. Today, 74,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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1. 2016 Comprehensive Report on the Global IOL Market, Market Scope(r), LLC.

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