Bausch + Lomb Receives FDA Approval of the enVistaT Intraocular Lens

The Associated Press

Bausch + Lomb, the global eye health company, today announced the U.S. Food and Drug Administration (FDA) has approved the enVistaT hydrophobic acrylic intraocular lens (IOL). Bausch + Lomb's enVista lens represents a significant step forward in IOL technology as it is the first and only FDA-approved IOL in the U.S. with labeling that states: "No glistenings of any grade were reported for any subject at any visit in the clinical study".(1-2) "Based on my experience, the new enVista hydrophobic acrylic IOL is an exciting addition to our IOL choices, as it has been clinically-proven to be free of glistenings, a common issue observed in some other hydrophobic IOLs," saidLouis D. "Skip" Nichamin, M.D., medical director of the Laurel Eye Clinic and the Laurel Laser & Surgery Center and one of the principal investigators in the FDA IDE trial for enVista.

Glistenings are fluid-filled microvacuoles that can form within an IOL and are common in some hydrophobic acrylic IOLs. Literature reports indicate that glistenings may not only present an aesthetic issue post-surgery for surgeons, but they can impact visual function, including visual acuity and contrast sensitivity in patients, due to a portion of light coming into the eye being scattered.(3-4) "The enVista IOL is yet another example of how Bausch + Lomb is advancing eye health innovation to meet the needs of our customers and the patients they serve," said Cal Roberts, M.D., executive vice president and chief medical officer, Bausch + Lomb. "We've listened to our customers tell us how frustrating glistenings can be when conducting post-surgical examinations of their patients. We are proud to offer them an attractive, viable and technologically-advanced option to address this concern." "As our first entry into the hydrophobic acrylic market, which makes up a significant segment of the overall IOL market in the U.S., the approval of enVista represents a key milestone for Bausch + Lomb's Surgical business," said John Barr, executive vice president and global president, Bausch + Lomb Surgical. "We're happy to be the only company with the distinction of offering an IOL proven to be glistening-free." Also setting enVista apart from currently available IOLs is the unique combination of aspheric, aberration-free Advanced Optics (AO) technology.(5) Additionally, the enVista lens is designed to minimize Posterior Capsular Opacification (PCO), a common post-surgical complication with IOLs that cause vision to become clouded post-surgery. These features combined into one platform with the enVista lens, provide surgeons the opportunity to optimize short- and long-term outcomes for their patients.(6-7) The enVista lens received CE Mark approval in the European Union in September 2011 and is currently pending approvals worldwide. Full commercial release of the enVista IOL in the U.S. is planned upon FDA clearance of its supporting insertion system.

About Bausch + Lomb Surgical Bausch + Lomb Surgical offers a full suite of ophthalmic surgical products, intraocular lenses (IOLs) and delivery systems. The

intraocular lens portfolio features the Crystalens@ AO, Akreos@ MICS and the newest addition, enVista.

Surgical systems include the Stellaris@ and Stellaris@ PC line of phacoemulsification and vitrectomy equipment and a new introduction in Europe, the VICTUST femtosecond laser platform, which is being co-promoted with Technolas Perfect Vision GmbH (TPV), a leading ophthalmic laser company. The division also offers a full range of surgical instruments and devices, including the signature StorzT line of instruments and viscosurgical devices, Amvisc@ and Amvisc@ Plus.

About Bausch + Lomb Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Its core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, the company is headquartered in Rochester, NY, and employs more than 11,000 people worldwide. Its products are available in more than 100 countries. More information is available at www.bausch.com.

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