BAUSCH Health

FDA Approves Bausch + Lomb ClearVisc™ Dispersive Ophthalmic Viscosurgical Device

April 07, 2021

New OVD Offers Exceptional Corneal Protection, Visibility During Ophthalmic Surgery

LAVAL, QC, April 7, 2021 /PRNewswire/ -- Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), today announced that the U.S. Food and Drug Administration (FDA) has approved ClearVisc™ dispersive ophthalmic viscosurgical device (OVD) for use in ophthalmic surgery.

"The ClearVisc™ dispersive OVD is the latest advancement in Bausch + Lomb's rich pipeline of ophthalmic surgical devices and is representative of our company's ongoing commitment to delivering innovations that fulfill the unmet needs of our customers," said Joe Gordon, U.S. president, Bausch + Lomb. "OVDs play a critical role in cataract surgery as well as many other ophthalmic surgeries. ClearVisc™ offers significant advantages that can help surgeons deliver the best possible outcomes for their patients."

OVDs aid in cataract extraction and intraocular lens (IOL) implantation by creating and maintaining space, aiding in tissue manipulation, enhancing visualization, and protecting the corneal endothelium and other intraocular tissues. OVDs may also be used to coat IOLs and instruments during cataract surgery.

ClearVisc™ contains Sorbitol, which is a unique chemical agent that has been shown in a laboratory study to deliver superior free radical protection compared to other dispersive OVDs.[1,2] Free radicals form as a result of chemical reactions caused during phacoemulsification, irrigation/aspiration and as part of the insertion and removal of instruments and implants. Free radicals can contribute to corneal damage and possible decompensation, which can lead to post-surgical complications such as a cloudy cornea. ClearVisc™ helps provide physical protection of the cornea from thermal and mechanical damage as well as chemical protection from damaging free radicals.

In a multicenter, randomized, clinical study of 372 subjects, ClearVisc™ met its primary safety and efficacy endpoints and was demonstrated to be non-inferior to VISCOAT®. No serious adverse events were seen with ClearVisc™ eye surgeries. Clear corneas were seen in 91% of eyes for ClearVisc™ and 92% of eyes for VISCOAT® at 1-day post-operative and in 100% of eyes for ClearVisc™ and 98% of eyes for VISCOAT® at 1-week post-operative.[1]

"The dual protection provided by ClearVisc™ helps to ensure protection of the cornea as well as outstanding surgical outcomes," said John Berdahl, M.D., clinician and researcher, Vance Thompson Vision, Sioux Falls, S.D. and ClearVisc™ clinical trial investigator. "In my experience as an investigator, I was pleased with the level of control and safety that ClearVisc™ delivered throughout the procedure."

ClearVisc™ helps to ensure excellent tissue visualization, maintains anterior chamber space throughout all phases of lens removal and IOL insertion and is easily removed during

irrigation/aspiration.[1] ClearVisc™ is also supplied in a 1.0 ml syringe, which reduces the need to open a second pack mid-procedure.[1]

About Cataracts and Cataract Surgery

A clouding of the normally clear lens of the eye most commonly caused by aging,[3] cataracts are a leading cause of vision loss in the United States and the leading cause of blindness worldwide.[4] In the U.S., more than 20 million people aged 40 years and older have a cataract, and more than 6 million of these Americans undergo surgery to have the lens removed.[4] An ophthalmic surgeon removes the cloudy lens and replaces it with a clear, artificial implant called an intraocular lens (IOL).[5] According to the U.S. National Eye Institute, cataract surgery is one of the safest, most common and effective surgical procedures performed in the United States.[6] In most cases, people experience improved vision after the procedure.[6]

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR CLEARVISC™ OVD

INDICATIONS FOR USE

ClearVisc™ is indicated for use as a surgical aid in ophthalmic anterior segment procedures including: Extraction of a cataract; Implantation of an intraocular lens (IOL)

CONTRAINDICATIONS

There are no contraindications to the use of ClearVisc™ when used as a surgical aid in ophthalmic anterior segment procedures.

PRECAUTIONS

Precautions normally considered during anterior segment procedures are recommended. Pre-existing glaucoma may place patients at risk for increases in intraocular pressure from the OVD during the early postoperative period.

WARNINGS

- Do not use if the sterile barrier has been breached. Sterility cannot be guaranteed, and the patient will be at increased risk for infection.
- An excess quantity of ClearVisc™ should not be used. Excess OVD can cause increased intraocular pressure.
- ClearVisc™ should be removed from the anterior chamber at the end of surgery to prevent or minimize postoperative intraocular pressure increases (spikes). OVD remaining in the eye can cause increased intraocular pressure.
- If the postoperative intraocular pressure increases above expected values, corrective therapy should be administered. Increased intraocular pressure may lead to inflammation or vision loss.
- Do not re-use the cannula. Even after cleaning and rinsing, resterilized cannula could release particulate matter as ClearVisc™ is injected. It is recommended that a single-use disposable cannula be used when administering ClearVisc™. Reuse may cause eye inflammation.
- If any particulate matter is observed, it should be removed by irrigation and/or aspiration. Particulate matter left in the eye may cause increased IOP or Light scattering /obstruction.
- Store at 2° to 8°C (36° to 46°F). Protect from freezing. The shelf life of ClearVisc™ is not guaranteed if it is not properly stored.

ADVERSE REACTIONS

Sodium hyaluronate is a natural component of tissues within the body and is generally well tolerated in human eyes. Transient postoperative inflammatory reactions and increases in intraocular pressure have been reported. Inflammation may result from increased intraocular pressure caused by use of the OVD. Intraocular inflammation, i.e., toxic anterior segment syndrome (TASS), has been attributed to OVDs. Furthermore, vision loss may be possible as a result of increased intraocular pressure and inflammation.

ATTENTION
Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION
Federal (USA) law restricts this device to the sale by or on the order of a physician.

About Bausch + Lomb
Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., is solely focused on helping people see better to live better. Its core businesses include over-the-counter products, dietary supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in approximately 100 countries. For more information, visit www.bausch.com
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About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at www.bauschhealth.com
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Forward-looking Statements
This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in Bausch Health's most recent annual report on Form 10-K and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, and costs (which may increase). Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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