Zimmer Biomet's Innovative Treatment for Young Patients with Scoliosis Receives FDA Approval

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The Tether™ represents the first approval order for a humanitarian use device in spinal pediatrics within the last 15 years

WARSAW, Ind., Aug. 16, 2019 /PRNewswire/ -- Zimmer Biomet Holdings, Inc. (NYSE and SIX: ZBH), a global leader in musculoskeletal healthcare, today announced U.S. Food and Drug Administration approval for The Tether™ for treatment of scoliosis, providing a fusion-less alternative for young patients requiring surgery.

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The current surgical treatment for scoliosis is an invasive operation involving large incisions, extensive soft tissue disruption and restriction of spinal motion with metal rods inserted along both sides of the spine to secure and align the vertebrae. Surgeons have tirelessly searched for alternative non-fusion surgical approaches to address scoliosis without limiting the skeletal development of these patients who are active and still growing.

Zimmer Biomet's anterior vertebral body tethering (AVBT) solution, The Tether, uses a strong, flexible cord, rather than metal rods, to pull on the outside of a scoliosis curve to initially straighten the spine, while the inside of the curve is left free to grow. This growth modulation approach now offers select, well-indicated patients an option to achieve a straighter spine, without the limitations of spinal fusion. Additionally, unlike fusion metallic rods, The Tether is positioned utilizing an endoscopic minimally invasive approach through a few small openings between the ribs.

"Often growth in children with scoliosis results in curve progression. With AVBT, that growth can be harnessed to gradually further correct the tethered portion of the spine," notes Dr. Amer Samdani, board-certified neurosurgeon and Chief of Surgery for Shriners Hospitals for Children in Philadelphia.

"The Tether provides clinicians who take care of children with spinal curves another option for treatment. When utilized in the appropriately selected patient, the results are dramatic with respect to curve control and maintenance of a mobile spine."

As an emerging treatment for a select patient population, The Tether is available through the FDA's humanitarian device exemption (HDE) pathway. This approval marks the culmination of more than five years of cooperation between the FDA and Zimmer Biomet to bring innovative pediatric solutions to market and represents the first approval order for a humanitarian use device in spinal pediatrics within the last 15 years. Considering the recent removal (per FDA final rule) of many semi-rigid stabilization systems that were historically used for AVBT, this solution arrives at a critical time for continuation of care.

"The Tether embodies Zimmer Biomet's mission to improve the quality of life for people around the world. This collaboration demonstrates how a focused, shared purpose can fundamentally change the way we approach treatment of diseases like scoliosis," said Jim Cloar, President of Zimmer Biomet Spine. "Working together, clinicians, the FDA and Zimmer Biomet have given surgeons an important fusion-less scoliosis treatment option for their pediatric patients. This procedure gives kids the best option for maintaining spine mobility and reaching their full potential."

Collaboration will continue as Zimmer Biomet and the FDA finalize a new clinical study for The Tether to optimally monitor patient outcomes. For the new study, Zimmer Biomet is excited to partner with the Harms Study Group, a worldwide cohort of surgeons with over 20 years of productivity who perform comprehensive, multi-center, prospective research studies focused on pediatric spinal deformity.

About The Tether - Vertebral Body Tethering System

The Tether is a non-fusion spinal device intended for use as a spinal tether. An anchor and bone screw are placed from a lateral approach into the spine on the convex side of a spinal deformity. A cord is secured to the bone screws with set screws to connect the levels of the construct, providing a lateral tension band to the spine that can arrest or correct the deformity. The Tether - Vertebral Body Tethering System is designed to treat skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. To be selected for this treatment, patients should have failed bracing and/or be intolerant to brace wear.

About the Company

Founded in 1927 and headquartered in Warsaw, Indiana, Zimmer Biomet is a global leader in musculoskeletal healthcare. We design, manufacture and market orthopedic reconstructive products;

sports medicine, biologics, extremities and trauma products; office-based technologies; spine, craniomaxillofacial and thoracic products; dental implants; and related surgical products.

We collaborate with healthcare professionals around the globe to advance the pace of innovation. Our products and solutions help treat patients suffering from disorders of, or injuries to, bones, joints or supporting soft tissues. Together with healthcare professionals, we help millions of people live better lives.

We have operations in more than 25 countries around the world and sell products in more than 100 countries. For more information, visit www.zimmerbiomet.com, or follow Zimmer Biomet on Twitter at www.twitter.com/zimmerbiomet.

Cautionary Statement Regarding Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning Zimmer Biomet's expectations, plans, prospects, and product and service offerings, including new product launches and potential clinical successes. Such statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties that could cause actual outcomes and results to differ materially. For a list and description of some of such risks and uncertainties, see our periodic reports filed with the SEC. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in Zimmer Biomet's filings with the SEC. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be set forth in our periodic reports. Accordingly, such forward-looking statements speak only as of the date made. Readers of this news release are cautioned not to place undue reliance on these forward-looking statements, since, while management believes the assumptions on which the forward-looking statements are based are reasonable, there can be no assurance that these forward-looking statements will prove to be accurate. This cautionary statement is applicable to all forward-looking statements contained in this news release.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit http://www.zimmerbiomet.com for additional product information.

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