Globus Medical Announces FDA Approval for its Non-Fusion Scoliosis Correction System, the Latest Advancement for Young Patients with Idiopathic Scoliosis

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REFLECT™ is approved through the FDA's Humanitarian Device Exemption pathway

AUDUBON, Pa., May 15, 2023 (GLOBE NEWSWIRE) -- Globus Medical, Inc. (NYSE: GMED), a leading musculoskeletal solutions company, today announced the REFLECT ™ Scoliosis Correction System has been granted approval from the US Food and Drug Administration, as the company's first humanitarian device. REFLECT ™ is designed to correct progressive scoliosis in young patients while preserving motion, maintaining stability, and allowing for future modulated growth.

Unlike rigid metal rods for fusion, REFLECT ™ uses a flexible, durable cord to harness the power of innate patient growth for correction. The flexible cord is tensioned on the convex side to control the curve, while allowing growth on the concave side. The implants may be inserted using a minimally invasive approach through a few small incisions between the ribs.

"Treating scoliosis in the growing spine presents challenges related to reduced spinal mobility," says Dr. Juan C. Rodriguez-Olaverri, board-certified orthopedic surgeon and Director of Pediatric Spinal Deformity Surgery and Early Onset Scoliosis at NYU Langone. "REFLECT ™ is an exciting development for curve correction that preserves freedom of motion in these young patients, and employs their own remaining growth to help repair the spinal curvature without the need for fusion."

Kelly Baker, Senior Vice President, Regulatory and Clinical Affairs at Globus Medical, commented, "REFLECT ™ has been available internationally for several years, and Globus Medical is very excited to make this system available to patients in the United States. This innovative solution highlights our commitment to addressing the clinical needs of the growing spine and improving the quality of life in these children. It is the latest advancement in scoliosis treatment that provides a non-fusion option for patients and their parents, as they consider the best treatment plan for their lifestyle and goals."

To learn more, visit GlobusMedical.com/products/REFLECT.

Indications

The REFLECT ™ Scoliosis Correction System is indicated for skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, who have a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or are intolerant to brace wear.

About Globus Medical, Inc.

Globus Medical, Inc. is a leading musculoskeletal solutions company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders. Additional information can be accessed at http://www.globusmedical.com.

Safe Harbor Statements

All statements included in this press release other than statements of historical fact are forward-looking statements and may be identified by their use of words such as "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan" and other similar terms. These forward-looking statements are based on our current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect our businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, health epidemics, pandemics and similar outbreaks, including the COVID-19 pandemic, factors affecting our quarterly results, our ability to manage our growth, our ability to sustain our profitability, demand for our products, our ability to compete successfully (including without limitation our ability to convince surgeons to use our products and our ability to attract and retain sales and other personnel), our ability to rapidly develop and introduce new products, our ability to develop and execute on successful business strategies, our ability to comply with laws and regulations that are or may become applicable to our businesses, our ability to safeguard our intellectual property, our success in defending legal proceedings brought against us, trends in the medical device industry, general economic conditions, and other risks. For a discussion of these and other risks, uncertainties and other factors that could affect our results, you should refer to the disclosure contained in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission, including the sections labeled "Risk Factors" and "Cautionary Note Concerning Forward-Looking Statements," and in our Forms 10-Q, Forms 8-K and other filings with the Securities and Exchange Commission. These documents are available at www.sec.gov. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof.

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