# FDA Advisory Panel Recommends Pre-Market Clinical Evidence Requirement in Proposed Reclassification of Bone Growth Stimulators

September 9, 2020

LEWISVILLE, Texas--(BUSINESS WIRE)--Sep. 9, 2020-- Orthofix Medical Inc. (NASDAQ:OFIX), a global medical device company focused on musculoskeletal healing products, today announced support for the U.S. Food and Drug Administration (FDA) Medical Devices Advisory Committee, Orthopaedic and Rehabilitative Devices Panel recommendation to require robust and complete clinical data for the proposed reclassification of bone growth stimulators from Class III to Class II with “special controls” to ensure patient safety and therapy efficacy.

"We are pleased the FDA Advisory Panel recognizes the importance of rigorous PMA-like clinical data for these devices,” said Orthofix President and Chief Executive Officer Jon Serbousek. “Because bone growth therapy devices encompass a range of distinct technologies, waveform parameters, functionalities, designs, dosimetries and intended uses, it is imperative that manufacturers are required to submit robust clinical data under the approval or clearance process to ensure the safety and efficacy of these devices for patients. We will be submitting comments in response to the FDA’s proposed rulemaking to underscore the Advisory Panel’s recommendation of the need for robust clinical data prior to approval or clearance of bone growth stimulator products, together with post market surveillance requirements.”

Bone growth stimulators are currently Class III devices. In 2015, the FDA listed bone growth stimulator devices along with 32 other product categories as candidates for possible reclassification. The purpose of the listing and review by the FDA of these product categories was to further one of the FDA’s general strategic priorities of reducing regulatory and administrative burdens. Today’s Advisory Panel recommendation, that the proposed reclassification to Class II include the condition that the devices be subject to rigorous clinical studies and post market surveillance for any new products, will ensure continued safety and efficacy of the device category. This would be in addition to other special controls and the Class II general requirement that any new products show “substantial equivalence” to already-cleared or approved devices.

**About Orthofix Bone Growth Stimulators**

Orthofix has the market-leading Bone Growth Stimulation platform with the only cervical spinal indication granted by the FDA and the only mobile device app accessory designed to help patients follow their prescriptions and provide remote visibility of adherence to physicians (STIM onTrack ™ 2.1). Orthofix is also investing in investigational device exemption (IDE) studies to expand indications for use in areas such as rotator cuff tears. To learn more about Orthofix Bone Growth Therapy devices, visit www.BoneGrowthTherapy.com.

**About Orthofix**

Orthofix Medical Inc. is a global medical device company focused on musculoskeletal products and therapies. The Company’s mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, Orthofix’s spine and orthopedic extremities products are distributed in more than 70 countries via the Company's sales representatives and distributors. For more information, please visit www.Orthofix.com.

**Forward Looking Statements**

This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the estimates, projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries, are based on Orthofix management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements.

The forward-looking statements in this release do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: practices of health insurance companies and other third-party payors with respect to reimbursement for our PEMF devices and other risks described in the "Risk Factors" section of our 2019 Annual Report on Form 10-K, as well as in other reports that we file in the future. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release.

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