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BAXTER ANNOUNCES U.S. FDA CLEARANCE OF NEW BONE GRAFT SUBSTITUTE, ACTIFUSE FLOW

- *Ready-to-use synthetic bone graft substitute designed for ease of use and fast application*
- *Enhances growing osteobiologics portfolio in Baxter's Advanced Surgery business*

DEERFIELD, Ill., SEPT. 06, 2018 – Baxter International Inc. (NYSE:BAX), a global leader in advancing surgical innovation, today announced U.S. Food and Drug Administration (FDA) clearance of **Actifuse Flow Bone Graft Substitute** for use in a variety of orthopedic surgical procedures. As the newest addition to Baxter's growing osteobiologics surgery portfolio, **Actifuse Flow** offers accelerated bone growth in a new, easy-to-use, prepackaged delivery syringe for precise placement into small bony voids or gaps in the skeletal system.

Actifuse Flow utilizes the proprietary silicate-substituted technology of Baxter's **Actifuse Bone Graft Substitute**, which enhances silicon levels to accelerate bone formation[1]. **Actifuse Flow** comes ready to use with no mixing or preparation involved and maintains its flowable consistency throughout surgery. The bone graft substitute is delivered directly from a pre-loaded syringe with the ability to start and stop delivery, making it compatible with open and less invasive surgical techniques and well-suited for filling small bone defects and complex geometries. As the graft substitute resorbs, it is replaced by the patient's own bone during the body's healing process. Baxter expects **Actifuse Flow** to be used in a variety of orthopedic surgeries in the pelvis, extremities, and posterolateral spine.

"Baxter's **Actifuse Bone Graft Substitute** has been demonstrated in preclinical models to show greater new normalized bone volumes over other available bone graft substitutes. As the graft

resorbs into the body, it is replaced by natural bone during the healing process. **Actifuse Flow** offers that same reliability in an easy-to-use delivery device. I am pleased to count on the science behind **Actifuse Flow** to accelerate bone formation in my patients," said Robert Norton, MD, an orthopedic spine surgeon serving patients in Boca Raton, Florida.

"As part of our growing product portfolio, **Actifuse Flow** builds on the extensive clinical experience of our **Actifuse Bone Graft Substitute**," said Wil Boren, president of Baxter's Advanced Surgery business. "We strive to pioneer products that provide surgeons innovative and dependable tools to help enhance healing, improve outcomes and reduce the total cost of care."

Actifuse Flow is the latest addition to Baxter's osteobiologics surgery portfolio, which also includes **Actifuse ABX**, **Actifuse Shape**, **Actifuse MIS** and **Altapore**. These products are based on a proprietary silicate-substituted technology designed to accelerate bone growth and come in varying configurations to accommodate different surgical needs. Baxter expects **Actifuse Flow** to be available to U.S. customers by year-end. It will be sold in three convenient sizes: 5 mL, 3 mL and 1.5 mL.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

Actifuse Flow Bone Graft Substitute Indication

Actifuse Flow is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bone structure. **Actifuse Flow** is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Important Risk Information for Actifuse Flow Bone Graft Substitute

Actifuse Flow is contraindicated where the device is intended as structural/load-bearing support in the skeleton system. **Actifuse Flow** bone graft substitute has not been cleared for vertebroplasty.

Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration.

The effect of mixing **Actifuse Flow** with substances other than sterile saline/water, autologous blood or bone marrow aspirate is unknown.

Rx Only. For safe and proper use of this device, refer to the full Instructions for Use.

*This release includes forward-looking statements concerning **Actifuse Flow**, including potential benefits associated with its use [and anticipated launch dates]. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

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[1] Hing KA, et al. Comparative performance of three ceramic bone graft substitutes. Spine J. 2007; 7(4):475-490.