Anika Investor Relations

Anika Announces FDA 510(k) Clearance for Its Injectable HA-Based Bone Repair Treatment

BEDFORD, Mass.--(BUSINESS WIRE)-- Anika Therapeutics, Inc. (NASDAQ: ANIK), a global, integrated orthopedic medicines company specializing in therapeutics based on its proprietary hyaluronic acid ("HA") technology, today announced that its HA-based bone void filler received 510(k) clearance from the U.S. Food and Drug Administration (FDA) and is indicated for filling bone voids or defects of the skeletal system (i.e. extremities and pelvis), which are not intrinsic to the stability of the bone, created during surgery or resulting from traumatic injury. The bone void filler, which is composed of a synthetic, biocompatible bone graft substitute material, is injected into a void, hardens at body temperature, and is then resorbed and replaced by the growth of new bone during the healing process.

Over one million musculoskeletal procedures performed in the U.S. involve bone void filling, also known as bone grafting,, and such procedures are most commonly required for spinal fusion, trauma, and revision total joint replacement procedures. We estimate the current market size for treating tibial plateau fractures, stress fractures around joints, and decompression of necrosed bone to be around $300 million.

"We're proud to announce the U.S. regulatory clearance of our innovative injectable HA-based bone void filler, which represents the U.S. commercial debut of our robust regenerative medicine portfolio," said Charles H. Sherwood, Ph.D., Chief Executive Officer of Anika Therapeutics. "The rapid 510(k) clearance is a testament to Anika's operational and strategic expertise. In addition, this new treatment represents a promising revenue growth opportunity, and advances our mission to provide innovative treatments to patients that address the full continuum of orthopedic care."

While the use of autologous bone or autograft has been the gold standard of treatment for bone grafting, the increased risk of procedural complications has prompted a shift towards alternate treatments1, such as synthetic, resorbable bone graft substitute materials. According to Dr. John Tierney, D.O., an orthopedic surgeon affiliated with New England Baptist Hospital, who has worked with our bone repair treatment: "Anika's 510(k) clearance allows for the marketing of one of only a handful of bone graft substitutes that can be administered in a minimally invasive manner. It offers physicians an additional option for treating bone defects or injuries, without the need for expensive and high risk surgeries, while also reducing the operating room time spent on each case." This positive physician feedback enhances our excitement about bringing this much-needed treatment to patients in the U.S.

About Bone Repair Treatment

Anika's bone repair treatment is an injectable, HA-based, settable osteoconductive calcium phosphate bone graft substitute material, and is indicated for filling bone voids or defects of the skeletal system (i.e., extremities and pelvis) that are not intrinsic to the stability of bone structure. It is provided in a kit with two components (an aqueous solution in a pre-loaded syringe and a dry powder) that must be mixed, intra-operatively using the supplied mixing system, to form a cohesive paste, prior to administration. Anika's bone void filler is provided sterile for single use in volumes ranging from 1.5cc to 4cc.

About Anika Therapeutics, Inc.

Anika Therapeutics, Inc. (NASDAQ: ANIK) is a global, integrated orthopedic medicines company based in Bedford, Massachusetts. Anika is committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions with clinically meaningful therapies along the continuum of care, from palliative pain management to regenerative cartilage repair. The Company has over two decades of global expertise developing, manufacturing, and commercializing more than 20 products based on its proprietary hyaluronic acid (HA) technology. Anika's orthopedic medicine portfolio includes ORTHOVISC®, MONOVISC®, and CINGAL®, which alleviate pain and restore joint function by replenishing depleted HA, and HYALOFAST®, a solid HA-based scaffold to aid cartilage repair and regeneration. For more information about Anika, please visit www.anikatherapeutics.com.

Forward-Looking Statements

The statements made in the last sentence of the second paragraph and the last sentence of the third paragraph of this press release, which are not statements of historical fact, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, those relating to the potential market for, and revenue growth opportunity for the Company associated with, this product. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks, uncertainties, and other factors. The Company's actual results could differ materially from any anticipated future results, performance, or achievements described in the forward-looking statements as a result of a number of factors including, but not limited to, (i) the Company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all; (ii) the Company's ability to obtain pre-clinical or clinical data to support domestic and international pre-market approval applications, 510(k) applications, or new drug applications, or to timely file and receive FDA or other regulatory approvals or clearances of its products; (iii) that such approvals will not be obtained in a timely manner or without the need for additional clinical trials, other testing or regulatory submissions, as applicable; (iv) the Company's research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (v) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations, and production planning; (vi) the strength of the economies in which the Company operates or will be operating, as well as the political stability of any of those geographic areas; (vii) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (viii) the Company's ability to successfully commercialize its products, in the U.S. and abroad; (ix) the Company's ability to provide an adequate and timely supply of its products to its customers; and (x) the Company's ability to achieve its growth targets. Additional factors and risks are described in the Company's periodic reports filed with the Securities and Exchange Commission, and they are available on the SEC's website at www.sec.gov. Forward-looking statements are made based on information available to the Company on the date of this press release, and the Company assumes no obligation to update the information contained in this press release.

1Marc Bohner, Resorbable biomaterials as bone graft substitutes, In Materials Today, Volume 13, Issues 1-2, 2010, Pages 24-30, ISSN 1369-7021, https://doi.org/10.1016/S1369-7021(10)70014-6. (http://www.sciencedirect.com/science/article/pii/S1369702110700146)

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