



Anika Announces Publication of Data Demonstrating the Efficacy and Safety of HYALOFAST® in Combination with Stem Cells for the Treatment of Cartilage Lesions on the Knee

BEDFORD, Mass.--(BUSINESS WIRE)-- **Anika Therapeutics, Inc.** (NASDAQ: ANIK), a global, integrated orthopedics medicines company specializing in therapeutics based on its proprietary **hyaluronic acid ("HA") technology**, today announced the publication of data demonstrating that **HYALOFAST®**, a biodegradable HA-based scaffold, used in combination with autologous adult mesenchymal stem cells (MSCs), regardless of a patients' age, is a viable and effective option for the treatment of cartilage lesions of the knee joint. The data, published in the Knee Surgery Sports Traumatology Arthroscopy - Volume 25 - Number 8 edition of August 2017, demonstrated that treatment outcomes were equally effective among patients under the age of 45 as they were with patients over the age of 45, who are difficult to treat with traditional approaches such as microfracture.

"Cartilage lesions are reported in almost 2 out of 3 patients aged 40 to 50 years who are undergoing knee arthroscopy, and current interventions for cartilage repair have limited utility, in part due to the age-related decrease in regenerative potential of articular chondrocytes observed in vitro," said Charles H. Sherwood, Ph.D., Chief Executive Officer of Anika Therapeutics. "This study shows that we may be able to fill a significant treatment gap in the management of cartilage defects among older patients, and offer a more convenient and cost-effective alternative or adjunct to traditional, invasive approaches such as microfracture with HYALOFAST."

The study evaluated 40 patients with full thickness cartilage lesions of the knee joint, 20 of whom were over the age of 45 and the remaining, who were under the age of 45. All patients were implanted with HYALOFAST soaked in bone marrow aspirate concentrate (BMAC) containing MSCs, and were prospectively evaluated for 4 years. Functional outcomes were assessed using a variety of validated scales¹ preoperatively, at 2-years and at the final follow-up at 4 years. At final follow-up, all functional outcomes' scores significantly improved (P < 0.001) in both groups of patients, and researchers concluded that the outcomes were not impacted by age or concomitant surgical procedures, but by the size and quantity of lesions.

"We're encouraged by the results of this long-term study that shows the potential clinical utility of combining stem cells with the HYALOFAST biodegradable hyaluronic acid-based scaffold to treat cartilage defects in a simple one-step procedure," said Alberto Gobbi, President of the OASI Bioresearch Foundation Gobbi NPO, visiting professor at the UC San Diego, the next President of the International Cartilage Repair Society (ICRS), and the study's lead author. "One of the key learnings from our four-year follow-up was that cartilage lesion size and quantity might be a better indicator for surgery than advanced age, which we concluded did not impact outcomes associated with the use of stem cells and HYALOFAST."

HYALOFAST is a non-woven biodegradable hyaluronic acid-based scaffold for hyaline-like cartilage regeneration to treat cartilage injuries and defects. HYALOFAST is commercially available in over 15 countries and has been used in more than 11,000 patients to date. HYALOFAST is pending regulatory submission in the United States and its 'FastTRACK' Phase III trial is currently enrolling patients across the U.S. and Europe.

The full manuscript is available here: <https://link.springer.com/article/10.1007/s00167-016-3984-6>

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 [GINGAL®](#), 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.

1 Visual Analog Scale (VAS) for pain, International Knee Documentation Committee (IKDC), Knee Injury & Osteoarthritis Outcome Score (KOOS), and Tegner.

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