



Cytonics Announces FDA Approval of an Investigational New Drug Application for the APIC Cell-Free System

Jupiter, FL: Cytonics Corporation has announced that an Investigational New Drug (IND) application for a phase I/II clinical trial of the company's APIC Cell-Free System has been approved by the FDA. The system is indicated for the rapid preparation of concentrated protease inhibitors in plasma, specifically Alpha-2-Macroglobulin (A2M), for the treatment of mild to moderate osteoarthritis (OA) in the knee.

This novel system concentrates A2M from a patient's own blood for direct injection into a joint that shows early signs of OA. The system is expected to be the first treatment for OA that can inhibit well known causes of cartilage breakdown and thereby prevent cartilage loss, reduce pain, and stop the progression of OA, as demonstrated by the company's research.

Cytonics' team of scientists and PhD's have been conducting research into OA and musculoskeletal diseases for almost 10 years at their research lab located in Jupiter, FL. The company developed the APIC Cell-Free System to inhibit MMP's, ADAMTS's and other proteases that cause cartilage degeneration and lead to OA. The company has successfully demonstrated that their system prevents cartilage degradation using an animal model. These findings were independently confirmed by a recent study published by Wang et al in *Arthritis and Rheumatology*, a journal of the American College of Rheumatology (Vol 66 No. 7, July 2014). The study's findings confirm that the plasma protease inhibitor A2M has been proven to provide chondral protection in post-traumatic OA.

"This approval by the FDA, 30 days after our initial submission and with no iterative rounds of review, is a testament to the comprehensive and high quality work that our team has executed," said Gaetano Scuderi, MD, President and Founder of Cytonics Corporation. "Cytonics' accomplishments in the scientific, intellectual property, regulatory, and now clinical aspects of A2M have positioned Cytonics to bring this important new molecular treatment for degenerative cartilage to the clinic and the market."

About Cytonics Corporation

Cytonics is a private research and development company developing molecular diagnostic and therapeutic products for chronic musculoskeletal and other diseases. The company developed the FACT diagnostic test to identify the source of back and joint pain and assist physicians in determining the most appropriate treatment. In addition, Cytonics developed the Autologous Platelet-Integrated Concentrate (APIC) System which was cleared in January of 2014 as a platelet-rich-plasma (PRP). The company also developed autologous cell-free A2M concentrate and other forms of A2M therapeutics, including optimized recombinant forms. Cytonics was founded in 2006 and is based in Jupiter, FL. For more information, visit www.Cytonics.com.

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