

Ortho RTi Announces Initiation of Pivotal Study on Ortho-R for Rotator Cuff Repair

Formal meeting with FDA later this month to formalize path to initiate human trials on Ortho-R.

KIRKLAND, QC, Feb. 11, 2019 /CNW Telbec/ - Ortho Regenerative Technologies Inc. (CSE: ORTH) ("**Ortho RTi**" or the "**Company**"), an emerging Orthopaedic and Sports Medicine Technology company, today announced the initiation of a 6-month pivotal animal study on Ortho-R for rotator cuff repair. In addition, a pre-IND (Investigational New Drug) meeting is to be held later this month with the Food and Drug Administration ("FDA") to formalize the requirements for the filing of its application to commence human trials on Ortho-R.

"The pivotal study is designed and powered to show statistically significant healing for rotator cuff repair by way of MRI and Histopathology. The first series of MRI results will be available after 3 months and are expected to confirm our previous findings where we showed superior healing over standard of care. The study is also designed to assess whether the repair could be accelerated or further improved with a higher dose of Ortho-R", said Ortho RTi's Chief Scientific Officer, Dr. Michael Buschmann. "We had excellent results in our initial preclinical study, and it will be exciting to evaluate if more Ortho-R results in a further improved outcome".

Ortho RTi recently compiled and submitted documents for a formal pre-IND submission meeting with the FDA. The purpose of the meeting is to discuss moving Ortho-R into the clinic for human testing. The results of this pivotal study on Ortho-R are intended to augment the IND package with more information on the ideal dosage to take forward into patients.

"2019 is already shaping up to be a transformational year for Ortho RTi. With the initiation of our pivotal study on Ortho-R and the pre-IND meeting a few weeks away, we are rapidly progressing towards demonstrating the clinical merits of using our lead biologic Ortho-R for rotator cuff repair", said Dr. Brent Norton, Ortho RTi's Chief Executive Officer.

About Rotator Cuff Injury

The rotator cuff is the name given to the collection of four tendons that stabilize the shoulder joint. The tendons around the joint can suffer tears as a result of injury to the tendon or as a result of degeneration over time. Repetitive overhead activity is often associated with cuff tears. Symptoms include a dull, aching pain, and patients often suffer secondary symptoms including lack of sleep and weakness in the arms resulting from a lack of exercise. If conservative therapy is not successful, surgery will often be performed. The principal aim of surgical intervention is to reattach the torn tendon to the bone. The standard of care involves the use of suture anchors placed into the bone and the tendon then being held in place with sutures. There are 4 million Americans with rotator cuff injuries, and all are at risk for disability. It is estimated that 25% of U.S. adults over the age of 40 will develop a rotator cuff tear, with aging 'weekend warriors' escalating the problem.

About Ortho Regenerative Technologies Inc.

Ortho RTi is an emerging Orthopaedic and Sports Medicine biologics company dedicated to the development of novel therapeutic soft tissue repair technologies to dramatically improve the success rate of sports medicine surgeries. Our proprietary biopolymer has been specifically designed to increase the healing rates of sports related injuries to tendons, meniscus, ligaments and cartilage. The polymer can be directly placed into the site of injury by a surgeon during a routine operative procedure without significantly extending the time of the surgery and without further intervention. Considering the significant bioactivity and residency of our proprietary biopolymer, Ortho RTi continues to assess its potential for therapeutic uses outside of the soft tissue repair. Further information about Ortho RTi is available on the Company's website at www.orthorti.com and on SEDAR at www.sedar.com.

Forward-Looking Statements

This news release may contain certain forward-looking statements regarding the Corporation's expectations for future events. Such expectations are based on certain assumptions that are founded on currently available information. If these assumptions prove incorrect, actual results may differ materially from those contemplated by the forward-looking statements contained in this press release. Factors that could cause actual results to differ include, amongst others, uncertainty as to the final result and other risks. The Corporation disclaims any intention or obligation to publicly update or revise any forward- looking statements, whether as a result of new information, future events or otherwise, other than as required by security laws.

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