

# Ortho Regenerative Technologies Provides Business Update on its Ortho-R Rotator Cuff Program

- **On track to file Phase I/II clinical trial Investigational New Drug ("IND") application by fiscal year-end**
- **6-month pivotal preclinical study in-life portion completed**

MONTREAL, Aug. 14, 2019 /CNW/ - [Ortho Regenerative Technologies Inc.](#) (CSE: ORTH) ("Ortho RTi" or the "Company"), an emerging Orthobiologics company, provided today a business update on its Ortho-R rotator cuff program.

Following a successful pre-IND meeting with the Food and Drug Administration ("FDA") in February 2019, the Company is now completing its preparation in order to start its rotator cuff Phase I/II clinical trial. The IND filing is anticipated by fiscal year-end. Ortho RTi started a 6-month pivotal preclinical study in January 2019 to provide the required data and address remaining FDA requirements in order to finalize the Phase I/II protocol. The in-life portion of the 6-month preclinical study as well as data collection have now been successfully completed. Final reporting is expected in the fall of 2019, along with other final IND requirements regarding manufacturing and stability.

"We are pleased to have completed this milestone according to schedule and look forward to updating our shareholders with the study results before year-end." said Claude LeDuc, President and Chief Executive Officer of Ortho RTi. "It is an exciting time for ORTHO RTi, as in parallel to the study, we continue working hard at multiple important deliverables in order to meet our coming IND submission timeline".

"This upcoming Rotator cuff tears repair clinical trial is planned to be a state-of-the-art study in the industry. We are presently completing the CRO selection to lead the execution and management of our US/Canada multicenter human trial, a key step in our program", added Mr. LeDuc.

## 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 Orthobiologics company dedicated to the development of novel therapeutic soft tissue repair technologies to dramatically improve the success rate of sports medicine surgeries. Our proprietary RESTORE technology platform, is a muco-adhesive CHITOSAN based biopolymer matrix, which in the case of Ortho-R, is mixed with patient conditioned plasma of a

concentrate of proteins/growth factors (Platelet-Rich Plasma or "PRP") to deliver biologics to increase the healing rates of occupational and sports related injuries to tendons, meniscus, ligaments and cartilage. The polymer-biologics hybrid combination can be directly applied 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](http://www.orthorti.com) and on SEDAR at [www.sedar.com](http://www.sedar.com). Also follow us on LinkedIn and Twitter.

## **Forward-Looking Statements**

This news release may contain certain forward-looking statements regarding the Company'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 Company 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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