

# Ortho RTi Confirms Timeline to Initiate Human Clinical Program After Meeting with the FDA

- IND can be submitted in parallel with completion of pivotal study on Ortho-R for Rotator Cuff repair
- Product characterization, safety and toxicology in order, representing significant savings.

KIRKLAND, QC, Feb. 27, 2019 /CNW/ - Ortho Regenerative Technologies Inc. (CSE: ORTH) ("Ortho RTi" or the "Company"), an emerging Orthopaedic and Sports Medicine Technology company, today announced that following a formal meeting with the FDA, its development program to date has exceeded expectations. As a result, the Company is in the position to submit its IND (Investigational New Drug) while completing its pivotal study and confirms the timeline to initiate human clinical program by year end.

"The review of our scientific and preclinical package and the meeting with the FDA went very well. Consequently, we are in a position to address whether we can adjust our timelines favourably as we progress towards the clinic. Furthermore, a streamlined testing of our product around safety, toxicology, and characterization "CMC" (Chemistry Manufacturing and Controls) was deemed to be acceptable for our IND and eventual final submissions "BLA" (Biologics License Applications), saving Ortho RTi millions of dollars in additional expenses", said Dr. Michael Buschmann, Ortho RTi's Chief Scientific Officer. "As we reported recently, we can confirm that the results of the recently initiated pivotal study on Ortho-R will be used to augment the IND package with more information on the ideal dosage to take forward into patients".

"2019 is shaping up to be a transformational year for Ortho RTi. With the confirmation of our development program and the recent completion of the surgeries in our pivotal study on Ortho-R, 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](http://www.orthorti.com) and on SEDAR at [www.sedar.com](http://www.sedar.com).

## 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.*

NEITHER THE CANADIAN SECURITIES EXCHANGE NOR ITS REGULATIONS SERVICES PROVIDER HAVE REVIEWED OR ACCEPT RESPONSIBILITY FOR THE ADEQUACY OR ACCURACY OF THIS RELEASE.

View original content:

<http://www.prnewswire.com/news-releases/ortho-rti-confirms-timeline-to-initiate-human-clinical-program-after-meeting-with-the-fda-300803101.html>

SOURCE Ortho Regenerative Technologies Inc.

View original content: <http://www.newswire.ca/en/releases/archive/February2019/27/c3454.html>

%SEDAR: 00037950E

**For further information:** Brent Norton MD, MBA, ICD.D, Chief Executive Officer, 514.782.0951, [norton@orthorti.com](mailto:norton@orthorti.com)

CO: Ortho Regenerative Technologies Inc.

CNW 08:00e 27-FEB-19