

Ortho Regenerative Technologies Announces Positive Results from Pivotal Preclinical Study in Rotator Cuff Tear Repair

- Safety profile of ORTHO-R confirmed.
- Statistical significance over standard of care demonstrated.
- ORTHO-R program advancing towards clinical phase.

MONTREAL, March 12, 2020 /CNW/ - [Ortho Regenerative Technologies Inc.](#) (CSE: ORTH) ("Ortho RTI" or the "Company"), an emerging orthobiologics company, today announced positive results following completion of its pivotal preclinical study in Rotator Cuff Tear repair. The results confirmed the safety profile of ORTHO-R as well as statistical significance over standard-of-care.

Ortho RTI has now completed its preclinical program in rotator cuff tear repair with the accomplishment of two studies in large animals. First a pilot study with 18 sheep with Magnetic Resonance Imaging ("MRI") data collected at 6 weeks and 3 months and histopathology at 3 months. Then, a pivotal GLP study with 48 sheep collecting MRI data at 3 and 6 months and histopathology at 6 months. Standard of care surgery (anchors + sutures) was compared to standard of care surgery plus ORTHO-R, the Company's proprietary muco-adhesive orthobiologics hybrid implant.

Both the pilot and pivotal studies, demonstrated a decrease in tendon gap at 3 months in the ORTHO-R treated groups compared to the standard of care control groups. A decreased tendon gap is indicative of faster restoration of tissue structure, observed by a more normal MRI signature.

In the pivotal study, the MRI showed a higher signal intensity ("SI") ratio at the humeral head at 6 months with standard of care compared to ORTHO-R treatment. Higher SI ratio is indicative of less trabecula (bone structural tissue), more fluid, or combination thereof. Severe heterotopic ossification ("HO") was less frequent with ORTHO-R treatment as scored by MRI. HO is a condition of abnormal formation of bone in tissue. *The formation of HO around the shoulder is a rare but potentially debilitating condition (Hallock 2019).*

In both the pilot and pivotal studies, histopathology at 3 months and 6 months showed equivalent safety.

In the pilot study, histopathology scores for tendon structural organization and enthesis structural appearance were improved by ORTHO-R treatment at 3 months. Structural organization and appearance scores are indicative of faster restoration of structure having more normal histological appearance.

"These positive preclinical results are the crowning of almost two years of hard work from ORTHO RTI's team and CRO collaborators, with the financial support from our investors and shareholders", said Mr. Claude LeDuc, CEO of Ortho RTI. *"We are now transitioning from preclinical to clinical stage, an important company milestone in our quest to build value for all our stakeholders. All our efforts are now focused on completing the ongoing regulatory process to start enrolling patients in our planned US Rotator Cuff Tear repair clinical trial. We look forward to continue delivering additional value creation milestones during 2020",* added Mr. Leduc.

About the ORTHO-R Biopolymer

Ortho RTI's proprietary technology platform is a muco-adhesive CHITOSAN based biopolymer matrix that acts as a biodegradable scaffold with great residency properties to help retain any type of bioactive material, prolong their therapeutic effect and significantly improve benefits to patients. In the case of Ortho-R, it is mixed with the patient's 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.

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 orthopedic and sports medicine surgeries. Our proprietary RESTORE technology platform is a muco-adhesive CHITOSAN based biopolymer matrix, specifically designed to deliver biologics such as Platelet-Rich Plasma (PRP) or Bone Marrow Aspirate Concentrate (BMAC), to augment and guide the regeneration of new tissue in various musculoskeletal conditions. Ortho-R, our lead Chitosan-PRP hybrid biologic implant product, is formulated and designed to increase the healing rates of occupational and sports related injuries to tendons, meniscus and ligaments. Other formulations are being developed for cartilage repair, bone void filling and osteoarthritis treatment. 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. An Ortho-R Rotator Cuff Tear Repair Phase I/II clinical trial is planned with an FDA IND submission in Q1 2020. Considering the significant bioactivity and residency properties of our proprietary biopolymer, Ortho RTI continues to assess its potential for therapeutic uses outside of the soft tissue repair field. Further information about Ortho RTI is available on the Company's website at www.orthorti.com and on SEDAR at 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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