

# Ortho Regenerative Technologies selects US based specialized CRO, MCRA LLC, for its upcoming phase I/II rotator cuff human trial

MONTREAL, Sept. 12, 2019 /CNW/ - [Ortho Regenerative Technologies Inc.](#) (CSE: ORTH) ("**Ortho RTI**" or the "**Company**"), an emerging Orthobiologics company, announced today that it has selected MCRA, LLC as its US based orthopedic specialty clinical research organization ("CRO"), to conduct its upcoming Phase I/II rotator cuff Ortho-R human trial.

Ortho-R utilizes Ortho RTI's proprietary RESTORE technology platform, which consists of a muco-adhesive CHITOSAN based biopolymer matrix mixed with patient conditioned plasma of a concentrate of proteins/growth factors to deliver biologics to increase the healing rates of occupational and sports related injuries.

The Ortho-R Phase I/II clinical trial plans to enroll 75 patients, randomized across 3 arms of 25 patients across multiple sites in the US.

MCRA is a leading advisory firm and CRO focused on the neuro-musculoskeletal industry. MCRA has key relationships with hundreds of US surgical sites and has provided assistance to more than 600 companies including the top 10 largest US Orthopaedic companies. MCRA will be integrating regulatory and reimbursement expertise in conjunction with its CRO services for the Ortho-R Phase I/II clinical program.

"The choice of a CRO for our upcoming Phase I/II clinical trial is a key component of our Ortho-R clinical program. It was especially important for us to select a CRO with extensive hands-on orthopaedic experience for biologics and combination products, easy access to top US orthopaedic surgeons, plus expertise in other key areas such as regulatory strategy and submissions", said Claude LeDuc, President and Chief Executive Officer of Ortho RTI. "We expect the coming months to be exciting for Ortho RTI. The disclosure of our pivotal pre-clinical results before the end of 2019, the filing of our IND and the start of a state of the art Rotator Cuff Tear repair clinical program in Q1 2020 should create significant value for our shareholders".

## 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](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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