



Ortho Regenerative Technologies Announces Submission of Investigational New Drug Application for ORTHO-R

- Phase I/II clinical trial initiation for rotator cuff tear repair in the U.S. anticipated in Q2 2021

MONTRÉAL, April 6, 2021 /CNW/ - [Ortho Regenerative Technologies Inc.](#) (CSE: ORTH) (OTC: ORTIF) ("Ortho RTI" or the "Company"), a clinical stage orthobiologics company focused on the development of novel soft tissue repair regenerative technologies, today announced that it has submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for the initiation of a Phase I/II clinical trial of ORTHO-R in rotator cuff tear repair.

"The IND submission for our first ORTHO-R human trial is a key milestone for the Company. It brings us one step closer to the enrollment of our first patient, a recognized value creation event in our industry", said Claude LeDuc, President and CEO of Ortho RTI. "There is a clear need for improved rotator cuff tear repair treatments, as estimates have put the re-tear (or non healing) rate at an average of 50%. With more than 600,000 patients undergoing rotator cuff surgery every year in the U.S., this represents an enormous commercial opportunity, and as demonstrated in 2020 by our GLP preclinical program results, we strongly believe that ORTHO-R can help address these significant unmet needs and meaningfully improve the success rate of these surgeries."

The Phase I/II clinical trial is a prospective, randomized, controlled and blinded study to evaluate the safety and efficacy of ORTHO-R + standard of care surgery vs standard of care surgery alone in rotator cuff tear repair. The clinical trial will enroll a total of 78 patients at 6 to 10 clinical sites throughout the U.S. Enrollment is expected to begin in Q2 of 2021.

About ORTHO-R

ORTHO-R, a Chitosan-Platelet-Rich Plasma (PRP) hybrid implant, has been designated by the US FDA as a drug/biologic combination product. It is formulated and designed to augment the healing rate of occupational and sports related injuries to tendons, meniscus and ligaments. The physicochemical configuration of our proprietary Chitosan-based biopolymer matrix acts as a biodegradable mucoadhesive scaffold which chemically interacts with the PRP biologic components. Some of the benefits of this interaction between the drug/biologic combination are the significant increase in the residency time of the PRP bioactive material delivered at the surgically repaired site, and prolongation of the release of growth factors from PRP, enhancing the therapeutic effect with potential to significantly improve benefits to patients. ORTHO-R is 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 a clinical stage 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 proprietary 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 drug/biologic implant combination 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 proprietary Chitosan-PRP combination ORTHO-R implant 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 potential of our technology platform, Ortho RTI continues to assess new therapeutic target 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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For further information: Claude LeDuc, President and Chief Executive Officer, (514) 651-1282, leduc@orthorti.com; Investors: Frederic Dumais, Director Communications and Investor Relations, (514) 782-8803, dumais@orthorti.com; Mike Cavanaugh, Westwicke ICR, (617) 877-9641, mike.cavanaugh@westwicke.com

CO: Ortho Regenerative Technologies Inc.

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