Ortho Regenerative Technologies Announces Successful Type A Meeting With U.S. FDA on CMC Elements For Which More Information Was Required to Clear IND Clinical Hold

- **Agreement reached with FDA on Elemental impurity testing using selected standard reference material.**
- **IND clearance expected in November.**
- **Patient enrolment still expected to start by year end.**

MONTREAL, Oct. 6, 2021 /CNW/ - Ortho Regenerative Technologies Inc. (CSE: ORTH) (OTC: ORTIF) ("Ortho" or the "Company"), a clinical stage orthobiologics company focused on the development of novel soft tissue repair regenerative technologies, today announced a successful Type A meeting with the U.S. Food and Drug Administration ("FDA").

In a letter received on October 1, 2021, related to two pending CMC elements for which more information was required, the FDA cleared the small-molecule impurity testing issue, with Ortho committing to using a GC-LC-MS testing method. Regarding the last pending topic, which is related to elemental impurity testing, the FDA request the use of standard reference material and provided a list of certified standards to consider.

"Today we achieved a mutual agreement with the FDA during a collaborative Type-A meeting" said Claude LeDuc, President and CEO of Ortho. "Ortho Regenerative Technologies is committing to performing the requested recovery study using one of the suggested standard reference material. We are appreciative of the guidance received from the FDA during our IND application regulatory process. Ortho Regenerative Technologies will provide the protocol and testing results during the coming weeks, and the FDA has confirmed the clinical hold will then be cleared within 30 days of the submission concluded Mr. LeDuc".

Immediately after IND clearance and IRB sites approval, the company will start patient enrolment, in a Phase I/II prospective, randomized, controlled, and blinded clinical trial, to evaluate the safety and efficacy of ORTHO-R as an adjunct to 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 ten clinical sites throughout the U.S.

About Ortho Regenerative Technologies Inc.

Ortho 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 continues to assess new therapeutic target uses outside of the soft tissue repair field. Further information about Ortho 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: Company, 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

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