



# ORTHO REGENERATIVE TECHNOLOGIES ANNOUNCES U.S. IND CLINICAL HOLD LIFTED BY THE FDA & CLEARANCE TO PROCEED WITH U.S. CLINICAL TRIAL.

MONTREAL, Dec. 13, 2021 /CNW Telbec/ - [Ortho Regenerative Technologies Inc.](#) (CSE: ORTH) (OTCQB: ORTIF) ("Ortho" or the "Company"), a clinical-stage orthobiologics company focused on the development of novel soft tissue repair regenerative technologies, announced today that **the clinical hold on its U.S. Investigational New Drug ("IND") application has been lifted by the U.S. Food and Drug Administration ("FDA") and that the Company is cleared to proceed with its Phase I/II U.S. clinical trial** to evaluate the safety and efficacy of ORTHO-R as an adjunct treatment to standard of care surgery in rotator cuff tear repair. By lifting the clinical hold, the FDA confirms that Ortho has **satisfactorily addressed all issues related to the August 16, 2021, clinical hold letter.**

"We are delighted to have reached this critical regulatory milestone, and we are grateful for the FDA's productive guidance and collaboration" said Claude LeDuc, President and CEO of Ortho. "Achieving this green-light to begin our clinical study is the result of committed efforts from the ORTHO team, which includes Polytechnique Montreal's Biomaterial and Cartilage Laboratory scientific team, MCRA's regulatory and clinical team, and our manufacturing and analytical partners."

"We can now proceed with our Phase I/II U.S. clinical trial", said Claude LeDuc. "There is a clear and significant unmet medical need to improve the success rate of orthopedic and sports medicine soft-tissue surgeries. ORTHO-R is a unique FDA-designated Drug/Biologic Combination Product, offered as a tissue-regeneration novel solution for soft tissue repair. The physicochemical configuration of the drug interacts with Platelet-Rich Plasma's (PRP) biological elements, including expressed growth factors. In preclinical studies, it results in enhanced and sustained biological activity that has shown faster and better tissue repair."

The Phase I/II clinical trial will enroll 78 patients at ten clinical sites throughout the U.S. Ortho will now advance to Institutional Review Board (IRB) filings for each selected clinical site to enable patient enrollment. The ORTHO-R Phase I/II study is a prospective, randomized, controlled, and blinded clinical trial.

## 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](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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