PRESS RELEASE

FOR IMMEDIATE DISCLOSURE

ORTHO REGENERATIVE TECHNOLOGIES ANNOUNCES EXTENSION OF FDA CLINICAL HOLD OF ORTHO-R INVESTIGATIONAL NEW DRUG APPLICATION

- **Most complex, and majority of additional information on characterization at point of care and CMC related data submitted accepted by the FDA**
- **Supplemental clarifications on methods of characterization assessing impurities, including additional proposed testing method from the FDA to be addressed in coming weeks**
- **Clinical aspects are all good and still targeting patient enrolment this Fall**

Montreal, QC, August 20, 2021 – **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 that the U.S. Food and Drug Administration ("FDA") has extended the clinical hold on the Company's Investigational New Drug ("IND") application to proceed with the initiation of a U.S. Phase I/II clinical trial of ORTHO-R in rotator cuff tear repair.

The FDA has accepted the three most complex requested additional information submitted in response to the initial clinical hold letter received in early June 2021. The FDA has however requested supplemental clarifications on two advanced methods of characterization of impurities.

"We are pleased to see that the FDA has accepted the recently submitted sterility and endotoxin level testing on the autologous PRP/ORTHO-R preparation workflow, as well as the identification of the drug substance following reconstitution in water, rather than in PRP", said Claude LeDuc, President and CEO of Ortho. "We are already working with our CMC experts, on the new CMC clarifications requested by the FDA. They relate to advanced methods of characterization used in the CMC processes, to assess impurities. We will continue interacting with the Agency as required and are confident that we can address the last few remaining deficiencies, to the full and final satisfaction of the FDA over the coming weeks".

Our planned 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 ten clinical sites throughout the U.S., starting during Fall 2021.

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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Contacts

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