Ortho Regenerative Technologies Submits Formal Response to U.S. FDA Clinical Hold

- **All additional CMC-related data and characterization requested submitted**
- **Company is confident that additional data submitted makes for a robust and compelling IND package**
- **Phase I/II clinical trial preparation activities progressing well with seven (7) leading U.S. clinical sites already pre-qualified**

MONTREAL, July 20, 2021 /CNW/ - **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, today announced that it has provided and filed all requested CMC-related data and characterization information in a formal response to the U.S. Food and Drug Administration (FDA) aiming to address the clinical hold on its Investigational New Drug (IND) application for ORTHO-R. ORTHO-R is a drug/biologic combination product candidate used as an adjunct to improve the success rate of standard of care surgery in rotator cuff tear repair.

The FDA requested additional Chemistry, Manufacturing, and Control (CMC) related data and characterization in its June 2021 clinical hold letter. The Company is confident that the data submitted, complementary new information, and test results will address the FDA's requests. The Company will continue to interact with the FDA as needed, should the FDA have any further questions or need additional clarification during the upcoming 30-day review period.

"Once again, we appreciate the FDA's guidance and assistance to Ortho, in the development of a robust and first indication in a new class of orthobiologics combination product to improve outcomes of standard of care surgery in rotator cuff tear repair," said Claude LeDuc, President and Chief Executive Officer of Ortho. "In the interim, we have continued to work on finalizing clinical sites selection, qualification, and documentation in anticipation of our IND approval. We have already prequalified seven (7) high profile clinical sites across the U.S. and have several other sites currently undergoing the qualification process."

About Ortho Regenerative Technologies Inc.

Ortho Regenerative Technologies Inc., 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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