

Ortho Regenerative Technologies Receives Clinical Hold Letter From the U.S. FDA

- **Additional CMC related data and characterization requested by the FDA**
- **Company confident of providing requested information over the coming weeks**
- **Phase I/II clinical trial preparation activities to continue in preparation of anticipated IND approval.**

MONTREAL, June 4, 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 received a clinical hold letter from the U.S. Food and Drug Administration ("FDA") related to its Investigational New Drug (IND) application to begin a phase I/II clinical trial for ORTHO-R, its drug/biologic combination product candidate used as an adjunct to standard of care surgery in rotator cuff tear repair.

The FDA has requested additional Chemistry, Manufacturing, and Control ("CMC") related information. The Company is confident in its ability to address and provide the FDA with the required information and testing data over the coming four to six weeks.

"We appreciate the FDA's guidance and assistance to Ortho, in the development of a first-in-class 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. "We will work diligently to address the FDA's questions as quickly as possible and look forward to continuing to work closely with them to secure IND approval. In parallel, we will continue working on our Phase I/II clinical trial preparation activities to ensure we minimize the impact on our overall timelines."

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.

NEITHER THE CANADIAN SECURITIES EXCHANGE NOR ITS REGULATIONS SERVICES PROVIDER HAVE REVIEWED OR ACCEPT RESPONSIBILITY FOR THE ADEQUACY OR ACCURACY OF THIS RELEASE.

View original content to download multimedia:

<http://www.prnewswire.com/news-releases/ortho-regenerative-technologies-receives-clinical-hold-letter-from-the-us-fda-301305839.html>

SOURCE Ortho Regenerative Technologies Inc.

View original content to download multimedia: <http://www.newswire.ca/en/releases/archive/June2021/04/c5656.html>

%SEDAR: 00037950E

For further information: Claude LeDuc, President and Chief Executive Officer, (514) 693-8804, leduc@orthorti.com; or Frederic Dumais, Director Communications and Investor Relations, (514) 782-8803, dumais@orthorti.com

CO: Ortho Regenerative Technologies Inc.

CNW 07:00e 04-JUN-21