PRESS RELEASE

FOR IMMEDIATE DISCLOSURE

Ortho Regenerative Technologies Announces FDA Regulatory Designation and Jurisdictional Assignment for Ortho-R

- **Ortho-R orthobiologics implant designated as Drug/Biologic combination product**
- **Jurisdictional Assignment to the Center for Biologics Evaluation and Research (CBER)**
- **Now focused on IND submission and Rotator Cuff Tear repair US clinical trial**

Montreal, (Quebec), August 6, 2020 – Ortho Regenerative Technologies Inc. (CSE: ORTH) an emerging orthobiologics company focused on the development of novel soft tissue repair regenerative technologies, today announced that Ortho-R is designated as a Drug/Biologic combination product, by the FDA Office for Combination Products. The jurisdictional assignment for Ortho-R will be the Center for Biologics Evaluation and Research (CBER).

On March 26th, 2020, a pre-Request for Designation application was submitted to the FDA's Office for Combination Products to seek for guidance on designation status for Ortho-R product, a Chitosan-based matrix biopolymer mixed with Platelet Rich Plasma (PRP) to form an in-situ deliverable biologic implant to augment the repair of Rotator Cuff Tears after standard of care surgery. During the evaluation period, technical, scientific and preclinical information was exchanged with the FDA, and multiple rounds of questions and clarifications were addressed. This substantial information demonstrated that Ortho-R has various physicochemical interacting actions on various cell types and other PRP components, therefore supporting a combination product with the Ortho-R reconstituted in PRP considered a Drug/Biologics that is delivered through accessory Devices.

"We are delighted with the FDA's Office for Combination Products decision, which is based on scientific facts and will position the company to address a unique leadership opportunity in the orthobiologics market" stated Claude LeDuc, CEO of Ortho RTI. *"The orthopedic community is seeking new technologies to improve patients' outcomes following standard of care surgery procedures in various musculoskeletal soft tissue*

conditions. With this first regulatory milestone completed, we look forward to working with the CBER jurisdiction of the FDA, focusing on the IND submission during the coming months and completing the preparation work for our planned Rotator Cuff Tear repair US clinical trial."

About the ORTHO-R Biopolymer

Ortho RTi's proprietary technology platform is a muco-adhesive CHITOSAN based biopolymer matrix that acts as a biodegradable scaffold with great residency properties to help retain any type of bioactive material, prolong its therapeutic effect and significantly improve benefits to patients. In the case of Ortho-R, it is mixed with the patient's conditioned plasma of a concentrate of proteins/growth factors (Platelet-Rich Plasma or "PRP") to deliver biologics to increase the healing rates of occupational and sports-related injuries to tendons, meniscus, ligaments and cartilage. The polymer-biologics hybrid combination 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.

About Rotator Cuff Injury

The rotator cuff is the name given to the collection of four tendons that stabilize the shoulder joint. The tendons around the joint can suffer tears as a result of injury to the tendon or as a result of degeneration over time. Repetitive overhead activity is often associated with cuff tears. Symptoms include a dull, aching pain, and patients often suffer secondary symptoms including lack of sleep and weakness in the arms resulting from a lack of exercise. If conservative therapy is not successful, surgery will often be performed. The principal aim of surgical intervention is to reattach the torn tendon to the bone. The standard of care involves the use of suture anchors placed into the bone and the tendon then being held in place with sutures. There are 4 million Americans with rotator cuff injuries, and all are at risk for disability. It is estimated that 25% of U.S. adults over the age of 40 will develop a rotator cuff tear, with aging 'weekend warriors' escalating the problem.

About Ortho Regenerative Technologies Inc.

Ortho RTI is an emerging 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 biologic implant 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 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. A multi-site US Ortho-R Rotator Cuff Tear Repair Pilot Phase I/II clinical trial is being planned and organized. In parallel, an FDA submission is planned for the fall of 2020. Considering the significant potential of our technology platform, Ortho RTI continues to assess new therapeutic target uses outside of the soft tissue repair field. Further information about Ortho RTI 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.

For further Information, please contact:

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