Ortho Regenerative Technologies Releases New Positive Histology Results From Pivotal Preclinical GLP Rotator Cuff Tear Repair Efficacy Study in Large-Animal Model

- **New evidence confirms improved tendon, tendon insertion site and overall repair in Rotator Cuff Tear ("RCT")**
- **Ortho-R treated groups show statistically significant superiority to standard of care surgery control**

MONTREAL, July 23, 2020 /CNW Telbec/ - **Ortho Regenerative Technologies Inc**. (CSE: ORTH) ("**Ortho RTI**" or the "**Company**"), an emerging orthobiologics company, today announced new positive results following completion of its pivotal preclinical study report in Rotator Cuff Tear (RCT) repair under Good Laboratory Practices (GLP) conditions. The study compares Standard of Care (SOC) surgery augmented with Ortho-R 2ml or Ortho-R 3ml (Chitosan-PRP) treatment groups, versus SOC alone as a control.

The new results from the completion of the statistical analysis of the histological data performed respectively by independent biostatisticians and licensed veterinarian pathologists blinded to treatment groups, confirms evidence of better tendon and insertion site histology and overall repair in RCT treated with Ortho-R.

The statistical results report details analyses of histological scoring at 6 months post-intervention performed by Biomedical Statistical Consulting in support of the Ortho Regenerative Technologies sponsored study of 6-month rotator cuff repair in a mature female sheep model. Analyses include between-group comparisons and dose response analyses of histological scores for infraspinatus tendon (ISP tendon), infraspinatus enthesis (ISP tendon insertion site) and overall repair (ISP pan-enthesis).

For ISP tendon measurements, data are consistent with less severe cellularity in Ortho-R treated groups, indicative of a more normal tissue ($p = 0.031$, c-stat = 0.625). Moreover, all Ortho-R treated samples had no inflammatory cells observed in tendon tissue, compared to 42% of controls having minimal to moderate inflammatory cell scores, indicating there was no inflammation in Ortho-R treated groups ($p = 0.002$, c-stat = 0.708).

For ISP tendon insertion site measurements, the Ortho-R treated groups were associated with an increase in the proportion with no change or normal glycosaminoglycan (GAG) staining compared to the controls ($p = 0.071$, c-stat = 0.688).

For ISP pan-enthesis measurements (overall repair), evidence is consistent with more complete remodeling/healing within the Ortho-R treated groups compared to controls, as well as a dose-response association favoring improved remodeling/healing. In combined analyses, one-third (n=8/24) of Ortho-R treated samples had complete healing with a smaller degree of remodeling, whereas none of the control samples fell within this category or better ($p = 0.019$, c-stat = 0.726). There was also some evidence of more normal GAG staining compared to controls, particularly within the Ortho-R 3 mL group; 100% of the Ortho-RT 3 mL group had normal GAG staining ($p = 0.016$, c-stat = 0.774), whereas 75% were normal and 25% mild in the Ortho-R 2 mL group ($p = 0.118$, c-stat = 0.677) and 67% normal and 33.3% mild within controls.

NOTE: The c-statistic provides an estimation of the effect size (in this study, c-stat from 0.6 – 0.7 and > 0.7 were considered as moderate and strong evidence of a relationship).

A low p value combined with a c-stat value > 0.6 indicates that statistical significance observed is due to moderate to large effect sizes.

The veterinarian pathologist histology report conclusion highlights *"The microscopic appearance of comprehensive ISP tendon enthesis healing (i.e. based on the overall quality of healing across the entire anatomic site), Ortho-R tended to have more complete healing of the enthesis site. This corresponded microscopically to an overall better structured, well-organized enthesis site, with distinct, regular well-organized tendon bundles, and fibrocartilage, generally combined with a lower score or magnitude of the bone remodeling."*, indicating that Ortho-R treated groups had structural organization closer to normal overall.

On March 12, 2020, Ortho RTI announced initial safety and efficacy results from initial data generated in the same pivotal study covered by this press release. The March press release confirmed the safety profile of Ortho-R as well as statistically significant superiority of Ortho-R treated groups over standard-of-care from the 3-month MRI analysis portion of the preclinical pivotal study. Today's press release is based on newly obtained histology results from the pivotal study.

"*We are delighted with the results as we have successfully completed a state-of-the-art GLP preclinical study, which will be part of the expansive documentation basis for our FDA regulatory submission to start our Ortho-R Rotator Cuff Tear repair US clinical trial*" stated Claude LeDuc, CEO of Ortho RTI. "*The orthopedic medical community values these regulated preclinical studies, to validate the efficacy of new orthobiologics regenerative technologies before human use. Our clinical study will also compare Ortho-R treatment with standard of care surgery."*

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 their 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 based on an engineered 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. An Ortho-R Rotator Cuff Tear Repair US pilot clinical trial is being prepared and coordinated. In parallel, an IDE/IND FDA submission is planned for Q3 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.

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