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New Classification System Developed for Regenerative Cell-Based Therapies

For Immediate Release on February 20, 2020

FARMINGTON – Doctors at UConn Health have developed the first classification system for regenerative cell-based therapies designed to stratify therapies based on scientific evidence and potential for harm. Today, there are concerns regarding the clinical safety and efficacy of cell-based therapies throughout the scientific community and within public discourse. The unregulated U.S. stem cell market has been widely reported as it offers potentially harmful therapies to patients without FDA approval. Currently, there are no regenerative cell-based therapies approved by the FDA, although high demand for such treatments is ongoing.

In light of these concerns, the current climate has generated demand for a systematic method to assess potential therapies. Dr. Cato T. Laurencin, CEO of The Connecticut Convergence Institute for Translation in Regenerative Engineering at UConn Health, has created a new classification system for cell-based therapies. The objective was to create a strategy that will benefit patients, encourage regulatory efforts, and further inform the scientific community.

"The rapidly expanding direct-to-consumer marketplace allows for public consumption of unregulated treatments, so we identified an opportunity to enhance regulation and ensure greater public health," says Laurencin.

The new system will aid in categorizing proposed interventions to determine suitability for immediate clinical use or therapies that require further investigational studies prior to clinical use. Utilization of this system will result in increased regulation and widespread standardization, which in turn decreases patient health and financial risks associated with unregulated treatments.

To learn more about the new classification system, view the newly published article here.