



University of Colorado **Anschutz Medical Campus**

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## **Gates Biomanufacturing Facility readies first shipment of clinical trial cancer treatments**

*Groundbreaking moment represents years of planning, training and biomedical expertise*

**AURORA**, Colo. (May 3, 2018) - The Gates Biomanufacturing Facility at the University of Colorado Anschutz Medical Campus has passed an important landmark in manufacturing its first clinical trial-grade product for direct infusion into patients.

The groundbreaking effort by the facility represents the culmination of several years of planning and work installing the requisite quality systems and trained team to deliver its first cell therapies for patient use.

The materials for a clinical trial in multiple myeloma treatment by a private research firm will soon be followed by clinical trial processing for pioneering teams at the Gates Center for Regenerative Medicine at the University of Colorado Anschutz Medical Campus.

“It’s the first product we’ve produced to infuse into a patient,” said Ryan Crisman, interim facility director at the Gates Biomanufacturing Facility.

The treatment, based on the production of CAR-T cells to attack cancer, is shipped to the locations of clinical trials around the nation.

“It’s a big benchmark for our facility, for the Gates Center and for the university,” Crisman said.

CU Chancellor Donald M. Elliman Jr. agreed.

"The Gates Biomanufacturing Facility has reached another important milestone in collaborative efforts at the CU Anschutz Medical Campus to be a leading bench-to-bedside research and treatment center," he said. "This first material delivery should be a harbinger of opportunity and promise for our talented investigators and clinicians, for our campus and for patients. It's exciting to be part of the safe and expedited translation of scientific discovery into new human therapies and cures."

Gates Center Director Dennis Roop, Ph.D., who also conducts team research on inherited skin diseases with treatments headed for clinical trials, lauded the manufacturing success.

"Since we established the Gates Center of Regenerative Medicine in 2007, my dream has been to build a facility that would allow the translation of basic research into therapies that would benefit patients. This achievement by The Gates Biomanufacturing Facility has now brought this dream to fruition," Roop said. "My new dream is that this is only the beginning."

The Gates Biomanufacturing Facility also expects soon to assist recently recruited researcher Terry J. Fry, M.D., in producing materials for additional clinical trials.

Terry J. Fry, M.D., one of the nation's leading cancer researchers, was named Co-Director of the Human Immunology and Immunotherapy Initiative on the CU Anschutz Medical Campus in February.

Dr. Fry was among the first scientists to investigate the potential to insert modified genes into a child's own T-cells to combat lymphoblastic leukemia. Approved by the FDA for pediatric use in August 2017, the therapy achieved an astonishing 80 percent remission rate in kids with otherwise unresponsive cases of the leukemia. Dr. Fry is now working to develop targeted treatments to decrease resistance and increase durability of remission. He's also working to apply CAR-T technology to other types of cancer.

The Gates Biomanufacturing Facility is one of six combined cell therapy and protein manufacturing facilities in the United States and the only one of its kind within an 800-mile radius: <http://gatesbiomanufacturing.com/> The facility has been a key element in the recruitment and retention of some of the nation's top regenerative medicine researchers for the CU Anschutz Medical Campus.

"It's a very highly regulated field," Crisman said. "Any time you are doing cutting edge research and clinical trials, you want to make sure the process is not in

question. “We are proud of our efforts to eliminate the process as a variable, so we can focus on the clinical efficacy for the patient.”

### **About the Gates Center for Regenerative Medicine**

The Gates Center for Regenerative Medicine was established in 2006 with a gift in memory of Denver industrialist and philanthropist, Charles C. Gates, who was captivated by the hope and benefit stem cell research promised for so many people in the world. The Gates Center aspires to honor what he envisioned—by conducting leading-edge research in stem cell biology and regenerative medicine to accelerate discoveries from the lab through clinical trials leading to effective cures and therapies for patients.

Led by Founding Director Dennis Roop, Ph.D., the Gates Center is located at the University of Colorado’s Anschutz Medical Campus, the only comprehensive academic health sciences center in Colorado, the largest academic health center in the Rocky Mountain region and one of the newest education, research and patient care facilities in the world.

The Gates Center shares its services and resources, with a growing membership of researchers and clinicians at the Anschutz Medical Campus, which includes University of Colorado Hospital, Children’s Hospital Colorado and the future Veterans Administration Medical Center, as well as the Denver and Boulder campuses, National Jewish Health, Colorado State University, the Colorado School of Mines, and business startups. This collaboration is designed to draw on the widest possible array of scientific exploration relevant to stem cell technology focused on the delivery of innovative therapies in Colorado and beyond.