

## How KU Cancer Center landed trial for Novartis' cancer gene therapy



Dr. Roy Jensen, director of the University of Kansas Cancer Center, explains how the hospital's ability to attract immunotherapy trials traced back to a decision 11 years ago.

By [Elise Reuter](#) – Reporter, Kansas City Business Journal  
May 8, 2018

The University of Kansas Cancer Center will offer Novartis' cancer immunotherapy treatment, Kymriah, after it was approved by the Food and Drug Administration to treat adults with a subset of non-Hodgkin's lymphoma on May 1.

The treatment would be the third-ever approved gene therapy in the U.S. In 2017, Kymriah was first approved to treat young patients with treatment-resistant acute lymphoblastic leukemia (ALL), one of the most common childhood cancers. Now, it is approved for one of the most common adult lymphomas.

Kymriah is manufactured using a patient's T-cells, a type of immune cell. Those are genetically modified to include a protein that directs them to target cancer cells before

they are reintroduced to the patient. The cost for the non-Hodgkin's lymphoma treatment is steep, at \$373,000, but less than when the treatment was initially approved for ALL, at \$475,000.

Leading up to the therapy's approval, KU Cancer Center ran a phase two clinical trial of Kymriah to test its safety and effectiveness.

KU Cancer Center Director Roy Jensen said the hospital's ability to attract immunotherapy trials traced back to a decision 11 years ago to combine KU Cancer Center's and Kansas City Cancer Center's bone marrow transplant teams, forming the largest in the area.

"We said we could take this to the next level by combining our efforts," Jensen told the *Kansas City Business Journal*. "In retrospect, that was one of the smartest decisions that we ever made."

Over time, Jensen said the patient volumes and outcomes from that program garnered the attention of drugmakers. Although bone marrow transplantation trials are different than cellular therapy trials, they require similar skillsets and resources.

"These companies started coming to us and saying, 'we think you have the ability to pull this off,'" Jensen said.

Funding from the Johnson County Education and Research Triangle also helped KU Cancer Center seal the deal, by building out its clinical trial infrastructure.

### **More trials ahead**

Now, with Kymriah's success, more pharmaceutical companies are knocking at KU Cancer Center's door. Dr. Joseph McGuirk, medical director of KU's blood and marrow transplant program, said they planned to open seven chimeric antigen receptor T-cell (CAR-T) trials in the next six months.

The team also is preparing for a future where these treatments could be expanded into solid tumors, not just blood cancers. They also plan to test a combination of CAR-T with checkpoint inhibitors, which prevent cancer cells from "switching off" T-cells.

"What is now getting really complicated is how do we get to the best place as fast as we can because we have a huge number of variables and we're trying to be as efficient as possible," Jensen said. "We just don't have unlimited resources to try every single thing."

We have to be thoughtful in how we're combining these therapies and what we think the best approach is."

The current CAR-T treatments aren't the end-all be-all of cancer immunotherapy. Kymriah has a 50 percent response rate, and patients undergoing treatments must be monitored for cytokine release syndrome, an immune response with flulike symptoms, or neurologic toxicity.

In the future, McGuirk said to expect more effective, more targeted treatments with less toxic side effects. Those models are already in the lab, but still have a distance to go.

"It's early — many of these studies, including at our own center, will be moving into phase one studies," McGuirk said. "The field is expanding logarithmically."

From a research perspective, the pace is picking up. But from a patient perspective, fast isn't fast enough.

"It's a jaw-dropping future that we're looking at," McGuirk said. "The pace is absolutely intense. It's unbelievably fast. But I have to see a patient tomorrow that I need a better therapy for, and a less toxic therapy."