

## Novartis inks a deal with CDMO to make CAR T-cell Therapy

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In anticipation of Kymriah's regulatory approval in Europe, Novartis has signed a deal with CELLforCURE.

The bio production laboratories at French contract manufacturer CELLforCURE could soon be crafting Novartis' cancer cell therapies for clinical and potential commercial use, pending a technology transfer that's planned for 2019.

Manufacturing at CELLforCURE 's site in Les Ulis, a city southwest of Paris, would mimic the processes Novartis has in place at its Morris Plains, New Jersey hub, which currently produces Kymriah for sale in the U.S. Currently, manufacturing of the bespoke cell treatment is handled in Morris Plains and at the Leipzig, Germany-based Fraunhofer Institut, which is dedicated to supporting clinical trials.

Adding in CELLforCURE would give Novartis additional capacity and help it manage the supply challenges involved with shipping live patient cells from hospitals to production hubs and back again, a journey that can span hundreds or even thousands of miles depending on where a patient is treated. CELLforCURE will be responsible for producing CAR-T therapies which are considered the embodiment of personalized medicine. Unlike traditional treatments each dose is tailored individually to, and manufactured for, each patient using their own blood cells.

In the near term, however, manufacturing support will be largely run from the Morris Plains site, as production won't be set up at CELLforCURE's site until 2019 at the earliest.

The pharma already has experience supplying Kymriah across international borders through its pivotal clinical studies ELIANA and JULIET, which involved sites in the U.S., Europe, Canada, Australia and Japan.