The Floodgates are Open: FDA Approves Second Cancer Gene Therapy

By Julianna LeMieux — October 23, 2017

This past summer, we covered the approval of the first gene therapy for cancer by the Food and Drug Administration (FDA). We ended the article with the following sentiment,

>This drug is not just a boon for the B-cell ALL community, but, for the cancer field as a whole. It is the first drug of its kind of that opens up the possibility of a very effective new cancer treatment - something that does not come frequently or easily. This is nothing short of a historic moment in cancer therapies that gives long overdue hope to not only the families suffering with pediatric cancer but everyone searching for an end to this horrific disease.

Now, just two months later, a second gene therapy (Yescarta) has received FDA approval. It will be used to treat adults with a type of non-Hodgkin lymphoma, large B-cell lymphoma, who have failed to respond to other treatments. Yescarta was developed by the company Kite Pharma - recently obtained by Gilead Science Inc.

The first approved therapy, made by Novartis, is called Kymriah and is used to treat certain pediatric and young adult patients with a form of B-cell acute lymphoblastic leukemia (ALL).

Both gene therapies work the same way. They are both T-cell immunotherapies and use the body's own T cells to fight the cancerous cells. The patient's T cells are collected, altered to carry
a chimeric antigen receptor (CAR) that allows the T cells to find and kill the cancer cells, and placed back into the patient.

The clinical trial that tested the effectiveness of Yescarta had 101 participants. The ZUMA-1 study, as it is called, showed that 72 percent of patients treated with a single infusion of Yescarta responded to the therapy. In addition, 51 percent of patients had no detectable cancer remaining.

Gilead's press release [3] states that the manufacturing company, Kite, achieved a 99 percent manufacturing success rate and produced the personalized drug in 17 days - an important factor when every day counts.

Like Kymriah, Yescarta carries dangerous side effects. In the ZUMA-1 study, 13 percent of patients experienced cytokine release syndrome (CRS) and 31 percent experienced neurologic toxicities. Fatal cases of CRS and neurologic toxicity occurred. This is one of the reasons that Yescarta will be rolled out in only sixteen medical centers, each of which will have undergone special training for monitoring side effects.

The list price for Yescarta, is set at $373,000 - a one time fee as it the drug is given in a single delivery. That is a steal compared to Novartis's Kymriah which costs $475,000. As the first and second approved drugs of their kind, they have set a high bar in the cost category. That said, if the second drug dropped in price by $100,000, perhaps the third and fourth will be even more affordable.

So, I'll end this article about the second CART drug with the same sentiment as the first CART drug. With the assurance that there will, most definitely, be many more CAR-T drugs to follow.

David Chang, MD, PhD, Chief Medical Officer at Kite shared a similar feeling in his statement regarding the future of CAR T therapies and cancer treatments, “Engineered cell therapies like Yescarta represent the potential for a changing treatment paradigm for cancer patients. Together, Gilead and Kite will accelerate studies of CAR T therapy in multiple blood cancers and advance other cell therapy approaches for solid tumors, with the goal of helping patients with diverse cancers benefit from this new era of personalized cancer therapy.”

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