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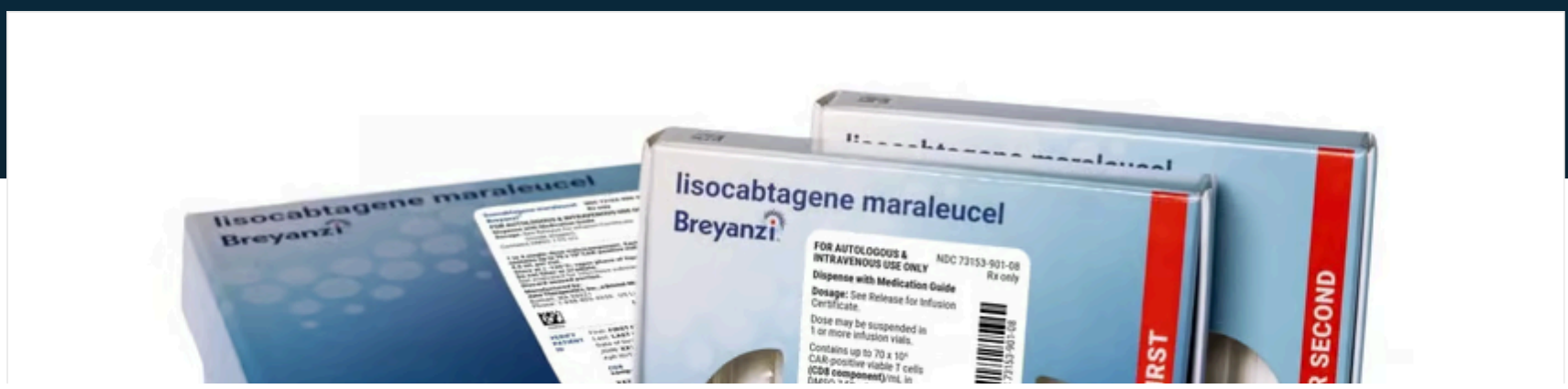
Breyanzi | Bristol Myers Squibb | FDA



The recent Breyanzi approval follows two other recent regulatory wins for the Bristol Myers Squibb cell therapy. (Bristol Myers Squibb)

In the years since gaining an initial FDA approval for Breyanzi, Bristol Myers Squibb has worked hard to expand the reach of its cell therapy. For the third time in as many months, those efforts have yielded a label expansion at the FDA.

Thursday, the company said Breyanzi secured FDA approval to treat certain patients with mantle cell lymphoma (MCL). The agency specifically endorsed the CAR-T therapy to treat adult patients with relapsed or refractory MCL who've received at least two other therapies, including one BTK inhibitor.

With the nod, Breyanzi becomes the first CAR-T cell therapy to gain FDA approval in four subtypes of non-Hodgkin lymphoma, BMS said in a press release (https://news.bms.com/news/corporate-financial/2024/U.S.-Food-and-Drug-Administration-Approves-Bristol-Myers-Squibbs-Breyanzi-as-a-New-CAR-T-Cell-Therapy-for-Relapsed-or-Refractory-Mantle-Cell-Lymphoma/default.aspx).

The drug gained its original FDA nod in 2021 to treat certain patients with relapsed or refractory large B-cell lymphoma and expanded its reach (https://www.drugs.com/newdrugs/u-s-fda-approves-bristol-myers-squibb-s-car-t-cell-therapy-breyanzi-relapsed-refractory-large-b-5855.html) in that disease the following year.

But in recent months, Bristol has accelerated its pace of regulatory expansion for the medicine.

In March, the drug scored an accelerated FDA nod (https://www.fiercepharma.com/pharma/bristol-myers-nabs-new-fda-nod-breyanzi-brings-car-t-class-chronic-lymphocytic-leukemia) in previously treated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). In doing so, the drug became the first cell therapy to enter the CLL/SLL field, where BTK inhibitors such as BeiGene's Brukinsa are typically used as first-line treatments.

And two weeks ago, Breyanzi gained an FDA approval (https://www.fiercepharma.com/pharma/bristol-myers-breyanzi-bags-fda-nod-follow-car-t-rivals-gilead-novartis-follicular-lymphoma) to treat patients with relapsed or refractory follicular lymphoma (FL) after at least two prior lines of therapy. In that disease area, the drug followed rival cell therapies from Gilead Sciences and Novartis into the market.

The FDA's latest approval for Breyanzi is based on results from the MCL cohort of TRANSCEND NHL 001, which enrolled patients who had tried at least two lines of therapy, including a BTK inhibitor. The drug triggered a response in 85% of patients, with nearly 68% of recipients achieving a complete response, according to Bristol's release. More than half of responders remained in response one year after receiving the one-time therapy.

Breyanzi is given as a single infusion consisting of genetically reengineered T cells from individual patients.

Aside from Bristol's regulatory efforts to support the launch, the company has placed an emphasis on boosting its manufacturing capacity. Part of that effort includes the establishment of a Massachusetts production facility, which scored its own FDA go-ahead last year.

In its latest press release, Bristol said it "has made continuous investments to increase manufacturing capacity and is prepared to meet demand for Breyanzi."

Alongside these launch efforts, the med's sales have steadily ticked up over the years, hitting $87 million in 2021, $182 million in 2022 and $303 million in 2023.

Meanwhile, the drug's recent label expansions should "roughly double" the drug's addressable patient population, BMS chief commercial officer Adam Lenkowsky said on a recent conference call.

Besides Breyanzi, Bristol also markets another blood cancer cell therapy called Abecma. That drug generated $358 million last year.

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PHARMA

US government appeals Gilead's trial win in Truvada, Descovy patent fight

By **Fraiser Kansteiner**
Jul 9, 2024 11:00am

Gilead Sciences | Truvada | Descovy | HIV

Last year's win for the company in Delaware let Gilead off the hook for more than $1 billion the government was seeking in its PrEP patent infringement case. (Photo by Justin Sullivan/Getty Images)

As Gilead Sciences tussles with a web of HIV drug litigation, a high-stakes case tied to patents for prevention medicines is coming back to test the drugmaker.

On Friday, the U.S. Department of Justice appealed Gilead's May 2023 victory in a Delaware court, which found that use of Gilead's pre-exposure prophylaxis (PrEP) regimens did not infringe three key patents the U.S. has credited to the CDC.

The federal jury further ruled that the patents were invalid due to obviousness, letting Gilead avoid paying the $1 billion the government was seeking in its infringement case.

The latest challenge to Gilead's PrEP patents comes after the Delaware federal court in March granted (https://storage.courtlistener.com/recap/gov.uscourts.ded.70560/gov.uscourts.ded.70560.496.0.pdf) the government's motion to dispute the jury's findings.

Gilead did not immediately reply to Fierce Pharma's request for comment on the Justice Department's appeal.

It's unusual for the U.S. government to challenge a company over alleged patent infringement, much less take the case to trial. Gilead's PrEP imbroglio dates back to the mid-2000s, when Gilead and the CDC teamed up on research to determine whether HIV treatments could help prevent virus transmission.

The U.S. ultimately locked down several patents stemming from the CDC work and offered Gilead licenses to the patents in exchange for a royalty. But when the drugmaker refused that offer, a 2019 lawsuit from the government ensued (https://www.fiercepharma.com/pharma/unsuccessful-licensing-talks-hhs-sues-gilead-for-prep-patent-infringement).

Separately, Gilead is awaiting a decision this month in similar yet separate state litigation in the California Supreme Court, which also centers around claims Gilead delayed the rollout of newer HIV treatments to maintain profits on older drugs.

For all of 2023, Truvada—which the FDA approved for HIV prevention in 2012—generated (https://www.gilead.com/news-and-press/press-room/press-releases/2024/2/gilead-sciences-announces-fourth-quarter-and-full-year-2023-financial-results) $114 million. Newer drug Descovy, which scored its U.S. PrEP greenlight in 2019, brought home nearly $2 billion.

Pharma | HIV prevention | PrEP | patent litigation | U.S. Department of Justice | Centers for Disease Control and Prevention