Christi Shaw, JPM19 (Credit: Jeff Rumans)

March 8, 2021 07:29 AM EST

Regulatory

Gilead's Kite keeps adding to CAR-T Yescarta's bag of tricks with FDA approval in follicular lymphoma — a first

Nicole DeFeudis
Associate Editor

Several months after creating the first commercial CAR-T portfolio with the FDA's nod for Tecartus, Gilead's Kite has racked up a sought-after new indication for its flagship cell therapy Yescarta.

The FDA on Friday granted Yescarta — also known as axicabtagene ciloleucel — an accelerated approval as a third-line therapy for adults with relapsed or refractory follicular lymphoma (FL).

The decision was based on the Phase II ZUMA-5 trial, an open-label study in which 146 indolent non-Hodgkin's lymphoma patients received a single infusion of Yescarta after two or more lines of treatment — including 124 with FL and 22 with marginal zone lymphoma.

The OK came right on time for Yescarta's PDUFA date, making it the first CAR-T approved for FL. Gilead's stock $GILD was up 2.2% early Monday morning, pricing at $64.62 a share.

Regulators did, however, slap a boxed warning on the label for cytokine release syndrome and neurologic toxicities. In a safety analysis of the 146 patients, Grade 3 or higher CRS and neurologic toxicities occurred in 8% and 21%, respectively.

At ASH20, Kite said adverse events of any grade occurred in 99% of patients, with Grade 3 or higher events occurring in 86%. The most common were neutropenia (33%), decreased neutrophil count (27%), and anemia (23%), the company said.

Last month, Kite tapped Takeda vet Frank Neumann to head global clinical development, replacing Ken Takeshita who's jumping to Daiichi Sankyo on April 1.

"Advancing CAR T therapies for patients across lymphomas remains a cornerstone of our cell therapy development program, and we are excited about the potential of Yescarta for patients with indolent follicular lymphoma," Kite CEO Christi Shaw said in a statement.

FL is the most common form of indolent lymphoma, with a five-year survival rate of only 20% for patients in the third line. Patients with FL have malignant tumors that grow slowly and can become more aggressive over time.

"Once a follicular lymphoma patient's disease relapses, the duration of response to care shortens with each round of therapy," said Caron Jacobson, medical director of the Dana-Farber Cancer Institute's Immune Effector Cell Therapy Program and assistant professor at Harvard Medical School.

Gilead became an overnight CAR-T leader when it bought Kite for $12 billion back in 2017, snatching up clinical-stage Yescarta in the process. It nabbed a quick OK in relapsed or refractory large B-cell lymphoma two weeks later — not long after Novartis' Kymriah became the world's first approved CAR-T therapy. This past July, Kite nabbed its second approval with Tecartus for treatment for relapsed or refractory mantle cell lymphoma.

Upon reading out the ZUMA-5 results at ASH, Kite's VP and head of medical affairs Ibrahim El-

March 22, 2021 04:45 PM EDT
R&D

Kyle Blankenship

March 22, 2021 09:54 AM EDT
Pharma, Regulatory

Pfizer has run 41 trials over 15 years for tanezumab. As adcomm nears, the FDA remains unimpressed — and more than a little worried

Zachary Brennan
Senior Editor

Ahead of an advisory committee meeting later this week, the FDA on Monday released its in-depth review of Pfizer and Eli Lilly's anti-NGF osteoarthritis drug tanezumab, concluding that it "provides substantial evidence of effectiveness" but also raising concerns that the proposed risk evaluation and mitigation strategy (REMS) may not be enough to lessen its significant safety risks.

Osteoarthritis] and would not ensure that the benefits of tanezumab outweigh the risks of RPOA."

March 21, 2021 01:00 PM EDT
Updated 19 hours ago
People

UPDATED: José Baselga, acclaimed drug hunter, physician and AstraZeneca's pioneering cancer R&D chief, has died

John Carroll
Editor & Founder

José Baselga, the brilliant oncology R&D chief at AstraZeneca and a towering figure in cancer drug development who had earlier been chief medical officer at Memorial Sloan Kettering, has died at the age of 61.

Baselga succumbed to Creutzfeldt-Jakob disease, a rapidly progressive and lethal neurodegenerative disease closely associated with mad cow disease that is triggered in about 1 in every million people.

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March 22, 2021 08:29 AM EDT
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Pharma, Regulatory

PhRMA attacks New Mexico's 'short on detail' plan for Canadian drug imports

Zachary Brennan
Senior Editor

Industry group PhRMA continues to fight a Trump-era final rule to allow drug imports from Canada as the lobbying group has now petitioned the FDA to reject New Mexico's import plan because of missing details that may make the imported drugs unsafe and not cost-effective.

Editor & Founder

Last summer, San Diego-based Odonate $ODT CEO Kevin Tang enthusiastically sought to bolster investors' enthusiasm for the company with what the biotech called "a potential important clinical advance for patients with metastatic breast cancer." Their late-stage study had hit the primary endpoint, the company noted, and they were laying the groundwork for an NDA in mid-2021.

That message didn't work so well, though, as investors trimmed the company's market cap considerably from its earlier, high-flying ways. But it was still in the game with a market cap north of $730 million — until this morning. The stock collapsed, eviscerating 75% of its value ahead of the bell in a slide down to cash.

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March 20, 2021 06:09 AM EDT
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Weekly

Amber Tong

marketing officer post at Merck for greener pastures. Reportedly in the running for the CEO job as Frazier retires, Nally ultimately lost out to CFO **Robert Davis**, who is now leading a fresh C-suite with **Dean Li** as R&D chief and **Frank Clyburn**, inaugural president of the global oncology business and most recently chief commercial officer, in Nally's previous position.

Eli Lilly stirs Alzheimer's controversy

Nothing drums up excitement and controversy quite as instantly and intensely as Alzheimer's — as **Eli Lilly** has once again demonstrated with the presentation of mixed results from its Phase II trial of **donanemab**. While the pharma giant heralded a statistically significant result for the unconventional primary endpoint it chose, even the optimists were cautious to jump to conclusions while critics homed in on the meh numbers on the secondary endpoints (which represented more traditional metrics used in previous studies) and side effects. Lilly, though, maintained the data were "tremendously important" and is upbeat about its upcoming pivotal before heading to regulators — by which time they may also have a precedent in Biogen's aducanumab.

FTC pledges pharma M&A crackdown

Rebecca Kelly Slaughter didn't mince words in calling out pharma megamergers. Now as FTC's acting chair, she's vowing to "rethink" the antitrust watchdog's review approach by setting up an international working group to scrutinize these deals and vowing to consider new proposed deals in light of conduct like price fixing, reverse payments and other regulatory abuses. The group will comprise state attorneys general, the Department of Justice, as well as UK, European and Canadian regulatory counterparts. At least one big buyout may be on the line.

FDA holds the line on Covid-19 antibodies

Emerging variants of the coronavirus are threatening to undermine the three antibody treatments from Eli Lilly and Regeneron that have been authorized for emergency use, and the FDA is vowing to stay on top of it. The US government is no longer distributing Lilly's bamlanivimab into California, Arizona and Nevada because of the prevalence of a viral variant, acting commissioner **Janet Woodcock** told a meeting of doctors. And after releasing a letter requiring the two companies to monitor the activities of their drugs, her agency spelled out the available data on the performance of bamlanivimab alone, bamlanivimab plus etesevimab, and the imdevimab/casirivimab cocktail.

Financing

Elisabet de los Pinos and her team fuel up for a late-stage quest to deliver a safe eye cancer drug

Nicole DeFeudis
Associate Editor

Since its founding in 2009, Aura Biosciences has been laser-focused on creating a safer alternative to currently available eye cancer therapies. And on Monday, the biotech pulled in $80 million to walk its lead candidate to Phase III.

The Series E round brings the Cambridge, MA-based company's total raise to over $200 million. The biotech will use the funds for its virus-like drug conjugates, including its lead candidate, AU-011, which is headed for a pivotal late-stage study in choroidal (ocular) cancer.

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