ENDPOINTS NEWS

Kodiak's Eylea contender falls flat in PhIII, wiping out nearly $2B in value

by **Jason Mast** on February 23rd, 2022

Last July, Kodiak Sciences turned down a $125 million payment from the investment firm Baker Bros. The second and final installment from a $225 million deal signed in 2019, it would have seen Kodiak accept cash now in exchange for a chunk of the royalties from its experimental eye disease drug KSI-301.

If KSI-301 proved effective, it would be shrewd: By pulling out, Kodiak shrunk the total royalty Baker Bros. could receive from $1 billion to $450 million.

The firm's partners, though, may now consider themselves lucky. On Wednesday, Kodiak announced that its eye drug had failed its first major test.

In a 559-patient study, KSI-301 wasn't as effective at treating wet-AMD — among the world's leading causes of blindness — as Regeneron's blockbuster Eylea, the current standard of care. Although Kodiak did not release full results, it said patients who received KSI-301 did not improve on a standard vision scale to the same degree as patients who received Eylea.

The safety data were also not completely clean: 3.2% of KSI-301 patients had eye inflammation, compared to 0% of the Eylea patients, although Kodiak noted that all cases resolved.

Kodiak shares $KOD were down 67% before the bell Wednesday, from $50.35 to $16.70, wiping out a little under $2 billion in value.

On the heels of $225M royalty deal, Kodiak shoots for $250M raise to fund pivotal programs of its Eylea slayer

The failure is not a death knell for Kodiak or its lead drug. Kodiak has four other Phase III trials underway, testing different dose regimens in a couple different diseases, including diabetic macular edema and retinal vein occlusion.

It does, however, bode poorly for Kodiak's ambitions of challenging Eylea on the market. The Regeneron drug is highly effective at treating wet AMD and diabetic macular edema, but has to be dosed between every eight weeks and every 12 weeks, depending on the patients.

Investors and pharma companies have spent billions chasing approaches, such as gene therapy or longer-acting antibodies, that might offer a more durable effect and less frequent dosing.

KSI-301, an antibody anchored down by a polymer, fell into the latter camp. Kodiak hoped to show it could be just as effective as Eylea while being dosed as little as once every fifth month.

But the new data suggest that was simply not often enough, the company said. Patients' eyes deteriorated and the dosing regimen "turned out to be insufficient," CEO Victor Perlroth said in a statement.

Carl Regillo, chief of the retina service at Wills Eye Hospital in Philadelphia and the study's lead investigator, estimated that about 30% of patients needed more than the once-every-three-month dosing of KSI-301 the study allowed.

"These patients' visual acuity deteriorated," he said.

Still, Regillo argued that KSI-301 nevertheless showed "clear and unprecedented durability." He pointed to a stat Kodiak released that more than half of patients on once-every-five-months dosing achieved 20/40 vision necessary to drive a car.

But that claim is difficult to evaluate without actual data. Notably, the company allowed patients with vision as good as 20/25 into the study — meaning a number of them already had good enough vision to drive a car before receiving any treatment.

Kodiak expects to announce results early next year on similar long-term regimens in diabetic macular edema and on a shorter regimen for wet AMD.

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