Choosing Kisunla: Hope for Alzheimer's Patients

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Abstract

Alzheimer's Disease challenges the world as one of the most devastating diseases known to humanity. Stealing the mind, Alzheimer's destroys a victim's independence, financially ruins families, and tears communities apart. However, extensive study results promise hope for many victims through a treatment Eli Lilly trademarked as Kisunla. Kisunla is not a cure, and it is far from perfect, though it does work for most victims who begin treatment during early diagnosis. Though many researchers disagree that Kisunla is the right choice for therapy, Kisunla offers the best available potential to thwart an almost certain patient death without treatment. Choosing to pursue therapy with Kisunla poses great yet surmountable challenges to victims and their caregivers. Based on quality studies by a leading drug company backed by the FDA, patients and their caregivers must quickly negotiate decision challenges to extend both the duration and quality of life of Alzheimer's victims.

Alzheimer's Disease is a brain disorder that gets worse over time, causing a gradual decline in mental skills that leaves its victims unable to care for themselves. At least 6.5 million Americans live with Alzheimer's, crippling a large part of a primarily elderly population. Globally, of the 55 million people worldwide who have dementia, roughly 70% of those also have Alzheimer's. Tragically, no cure exists for Alzheimer's, which damages brain function and contributes to complications that can result in death. As a significant health challenge for our society and the families of victims, Alzheimer's imposes detrimental impacts upon everyday life, such as debilitating dementia and loss of memory, critically impaired thinking, and drastic behavioral changes. (Alzheimer's disease, 2024)

Though no cure for Alzheimer's is currently available, promising drug treatments are being researched, with at least one effective treatment option already available. In June 2024, the Food and Drug Administration (FDA) approved Kisunla, made by the American drug manufacturer Eli Lilly, for treating early symptomatic Alzheimer's Disease. (FDA approves treatment for adults with Alzheimer's disease. *FDA.gov,* 2024)

To arrive at a treatment option, Eli Lilly conducted extensive research studies for up to 72 weeks of over 1700 patients who received Kisunla to mitigate the effects of Alzheimer's. The Lilly patients performed better on Kisunla than other limited, comparatively ineffective treatment options. Results suggested that patients treated with Kisunla showed a significantly reduced decline on the Integrated Alzheimer's Disease Rating Scale (iADRS), which assesses cognition and the ability to perform activities of daily living, compared to the placebo. The FDA was so confident in Kisunla that they awarded Lilly a rarely granted status for Fast Track, Priority Review, and Breakthrough Therapy, accelerating the processes necessary to take Kisunla to market. (FDA approves treatment for adults with Alzheimer's disease, 2024) Based on Lilly's

success in bringing a viable therapy to market and the FDA's solid backing, victims and their families must expediently choose Kisunla treatment to provide the best chance to extend patient life.

The rationale for choosing Kisunla quickly rather than delaying the decision was demonstrated through Lilly's testing that continued for up to 72 weeks and covered over 1700 patients. Studies showed that treatment shortly after early diagnosis was most effective, as the longer a patient waits, the less effective treatment becomes. The best results–therapy within 90 days of an Alzheimer's diagnosis–showed a significantly higher decline in Alzheimer's progression than the results of patients who suffered a more advanced form of the disease. These findings underscore the urgency needed by victims and families weighing Kisluna as an option. (FDA approves treatment for adults with Alzheimer's disease, 2024)

Kisunla researchers traveled a rigorous journey to achieve drug approval. The FDA closely monitored and reviewed the lengthy and tedious studies, initially rejecting Kisunla for approval despite initially positive results because an insufficient number of patients used the drug for at least one year during trials. However, when Lilly returned with more comprehensive phase 3 trial data showing that the drug slowed cognitive and functional decline by 35%, and demonstrated testing in groups where at least half of participants completed treatment for at least one year, the FDA optimistically fast-tracked approval. At the review disclosure, the president of the Alzheimer's Association, Joanne Pike, called the FDA approval of Kisunla "real progress towards ensuring multiple treatment options" exist to benefit Alzheimer's patients. (Wanneh, 2024)

Unsurprisingly, not all researchers agree that Kisunla should be FDA-approved. Some Kisunla opponents point out apparent discrepancies in the trial study that lacked genetic and

ethnic diversity since over 91% of the participants are of Caucasian descent. Other trial weaknesses include skewed results that depend heavily on one specific type of patient—one with a low "tau" value. Tau, a brain protein, causes tangling or clumping inside the brain. Kisunla targets Tau to break down clumping, which causes brain tissue damage due to reduced blood circulation. Since Kisunla was most effective on patients with low tau levels, researchers suggest that tau screening should be required to approve Kisunla treatment, as patients with higher tau levels would likely not experience benefits. Unfortunately, tau screening is not readily available today, exposing another weakness in treatment strategy decisions. Patients who choose Kisunla without knowing their Tau level could cause more harm than good. (Couzin-Frankel, 2023)

Other objecting researchers reported in Science magazine that the often severe side effects of treatment, such as brain swelling, headaches, confusion, and even death, warrant further drug testing. At least three patients died from brain swelling or bleeding attributed to Kisunla. (Couzin-Frankel, 2023) Even though Alzheimer's itself is ultimately mostly fatal, patients must weigh the real possibility of dying even earlier, or unnecessarily, due to toxic side effects from Kisunla.

Public health advocacy groups voiced concerns about study timing, dampening Eli Lilly's victory celebration. Public Citizen, a public advocacy and harm reduction group, marginalized the potential benefits of Kisunla by claiming that the drug "…should not have been approved" as serious risks far outweigh any possible benefits and that longer-term studies should be conducted before approval. (Steinbrook, R., 2024)

Despite widespread contrarian views about Kisunla approval in such a short timeframe, many victims and their families see study timing as an obstacle in a life-or-death choice, one that

must be made without the years-long wait for additional study results. Victims simply do not have time for more testing and must choose between a hazardous Kisunla treatment or an almost certain death sentence of untreated Alzheimer's. Once an Alzheimer's diagnosis occurs, an unstoppable clock begins ticking that only accelerates as the disease progresses. The longer the wait, the less chance there is for a victim to survive. Burdened with decisions about timing, families often overlook potentially disqualifying factors like drug costs.

Adding to the challenges of efficacy, safety, and timing, patients must also decide on funding. Estimated costs for a single year of treatment are $32,000. However, one year of therapy may not be enough to halt Alzheimer's progression, forcing families to produce even higher funds in consecutive years of therapy. Further, many insurance companies are reluctant to cover the treatment, and many families do not have the necessary savings to fund treatment. (Anderson, L.A., 2024)

In light of these challenges, deciding on Kisunla treatment is inarguably difficult. Efficacy, safety, timing, and funding factors immensely weigh upon those deciding whether to pursue treatment. Efficacy limitations cannot be ignored. Yet, victims can accept the possibility of reduced efficacy, given the alternative grim path forward of no treatment. And the safety issues that scare everyone–from patients to doctors to researchers–are outweighed by the potential hope of saving a life. Timing urgencies that demand rapid decisions create a window of opportunity for those diagnosed in the early stages. Finally, patients who can afford the treatment clear the final major hurdle. Although any one of these obstacles can prevent a patient from choosing Kisunla, a clear path forward exists for those able to accept the drawbacks and fund treatment.

Every friend or family member caring for an Alzheimer's victim knows the agony of watching a loved one slip away. Caregivers weigh seemingly impossible decisions regarding patient care and weigh a host of difficult choices in deciding the best path forward. Fortunately, both patient and caregiver can navigate these choices quickly and confidently, knowing that Kisunla treatments offer hope to keep patients alive longer and improve their quality of life. Developed by the leading drug maker Eli Lilly, Kisunla is approved by the FDA for treating Alzheimer's. Faced with frighteningly grim alternative options, caregivers must quickly overcome tough decisions to choose Kisunla as the best available option for extending, indeed saving, the life of an Alzheimer's Disease victim.

References

Alzheimer's disease. (2024, July 10). Retrieved from Mayo Clinic: https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/symptoms-causes/syc-20350447

What is Alzheimer's Disease? *Alzheimer's Association.* (2024) https://www.alz.org/alzheimers-dementia/what-is-alzheimers

FDA approves treatment for adults with Alzheimer's disease. *FDA.gov* (2024). News & Events for Human Drugs

Wanneh, G. (2024). Donanemab Secures Full FDA Approval, CMS Firm On Coverage Limits. *InsideHealthPolicy.com* (2024). Vol. 16, Iss. 27 ProQuest document ID 3075203942 https://www.proquest.com/central/trade-journals/donanemab-secures-full-fda-approval-cms-firm-on/docview/3075203943/sem-2?accountid=212688

News Release: Lilly's Donanemab Significantly Slowed Cognitive and functional Decline in Phase 3 Study of Early Alzheimer's Disease. *Eli Lilly and Company.* (2023). https://investor.lilly.com/news-releases/news-release-details/lillys-donanemab-significantly-slowed-cognitive-and-functional

Couzin-Frankel, J. (2023). Alzheimer's trial shows clear benefits and significant risks of Eli Lilly antibody. *Science* (2022). Science.org https://doi.org/10.1126/science.adj8110

Kisunla (Donanemab): A Promising New Option in Alzheimer's Treatment. *National Council on Aging.* https://www.ncoa.org/article/kisunla-donanemab-alzheimers-treatment/ (2024).

Steinbrook, R. (2024, July 2). *FDA Fails Patients By Approving Flawed Alzheimer's Disease Drug Donanemab (Kisunla)*. Public Citizen. Retrieved September 15, 2024, from https://www.citizen.org/news/fda-fails-patients-by-approving-flawed-alzheimers-disease-drug-donanemab-kisunla/

Anderson, L. A. (2024, September 21). *Will insurance cover Kisunla treatment?* Drugs.com. Retrieved September 10, 2024, from https://www.drugs.com/medical-answers/insurance-cover-kisunla-treatment-3577955/#:~:text=How%20much%20does%20Kisunla%20cost,18%2Dmonth%20course%20of%20therapy