

Aduhelm's accelerated approval for the treatment of Alzheimer's diseaseAayat Ellahi Buksh,¹ Fahd Niaz Shaikh,² Muhammad Hasnain Mankani³

Madam, despite the life-threatening manifestations that Alzheimer's disease (AD) possesses, to date, only five medical treatments have been approved for AD, which involve two classes of drugs that merely control the symptoms rather than altering the course of the disease. Moreover, in the last decade, relatively few clinical trials have been undertaken in AD, which have had a 99.6% failure rate.¹ However, the United States Food and Drug Administration recently approved a drug, Aduhelm, a monoclonal antibody that directly targets the fundamental pathophysiology of the disease.²

With the advancing health care system, life expectancy in Pakistan has increased from 65.41 to 67.48 years in the past ten years, consequently raising diseases in the elderly population, such as AD.³ In efforts to find a treatment for AD, researchers carried out three trials that enrolled approximately three thousand patients who were given Aduhelm in a randomized, placebo-controlled study of different dosages. The patients who received Aduhelm showed reduced prevalence and impact of the manifestations of AD.²

The "amyloid cascade hypothesis" suggests that the accumulation of the beta-amyloid plaques results from an imbalance between the plaque accumulation and clearance in the brain, which is the main cause of AD pathogenesis. Designed specifically in keeping with the above fact, Aduhelm selectively targets and clears aggregated forms of beta-amyloid plaques, including soluble oligomers and insoluble fibrils, thus promoting

healthy brain aging.⁴

We want to draw the attention of the readers towards the alarming number of patients being diagnosed with AD and the importance of the role of this drug in managing the manifestations of this disease. This drug has been approved for everyone with AD but it is not yet available.⁵ Pakistan is a developing country and unfortunately, due to economic constraints, an expensive drug like Aduhelm is an unlikely choice, a situation that leaves very few viable options. However, to reduce the inequity in the accessibility of this drug, the government could make a review in policies to subsidize the price of the drug and make it more affordable and accessible to the masses.

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References

1. Briggs R, Kennelly SP, O'Neill D. Drug treatments in Alzheimer's disease. *Clin Med (Lond)* 2016; 16: 247-53.
2. FDA Grants Accelerated Approval for Alzheimer's Drug. [Online] 2021 [Cited 2021 Jun 15]. Available from: URL: <https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug>
3. Pakistan Life Expectancy 1950-2021. [Online] 2021 [Cited 2021 Jun 15]. Available from: URL: <https://www.macrotrends.net/countries/PAK/pakistan/life-expectancy>.
4. Ferrero J, Williams L, Stella H, Leitermann K, Mikulskis A, O'Gorman J, et al. First-in-human, double-blind, placebo-controlled, single-dose escalation study of aducanumab (BIB037) in mild-to-moderate Alzheimer's disease. *Alzheimers Dement (N Y)* 2016; 2: 169-76.
5. 5 Things to Know About the New Alzheimer's Drug, Aducanumab. [Online] 2021 [Cited 2021 Jun 15]. Available from: URL: <https://www.aarp.org/health/dementia/info-2021/aducanumab-questions.html>.

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