Unlocking Alzheimer's: Biologics To Biosimilars- India's Healing Horizon



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Abstract

To address the growing need for complex medications, India must strategically shift toward biologics and biosimilars, utilizing its manufacturing capabilities in the face of a worldwide patent cliff. For conditions such as Alzheimer's, where biologics such as anti-amyloid antibodies show promising results, this shift promotes easy access. Bharat explores therapeutic potential through integrated therapeutics, encompassing traditional bioactives such as flavonoids like quercetin and curcumin, alongside biosimilars like donanemab, which have the ability to directly affect pathogenic events such as dysregulated gene expression, tau hyperphosphorylation, and amyloid formation. Moreover, since AD is a heterozygous disorder, biologics can provide a pathway to disease-modifying therapies that can be tailored to the genetic and molecular profile of a patient. This presents India (Bharat) as a pioneer in fusing traditional knowledge with cutting-edge biotechnology for comprehensive and cost-effective management of Alzheimer's disease.

Keywords: Alzheimer’s, Bioactive, Biosimilar, Donanemab

1. Introduction

India is now among the most vibrant biosimilar centres of the globe, and its biosimilar ecosystem is advanced and rapidly expanding. The 146 biosimilars (recombinant medicinal products) approved by India by December 2025 included insulins, growth factors, peptide hormones, fusion proteins, and monoclonal antibodies. India began developing and regulatory approving recombinant medicines much earlier than other growing economies with the first approvals being first reported as early as 2000. However, throughout the first ten years, biosimilar activity was still restricted to relatively basic recombinant proteins such as insulin, follicle-stimulating hormone, erythropoietin, and granulocyte colony-stimulating factors.

Following 2018, the approvals of biosimilars have risen dramatically. The significant increase in the number of approvals between 2020 and 2024 was driven by multiple approvals of monoclonal antibody biosimilars in immunology and oncology and an increase in the number of approvals of insulin analogs and peptide hormones. The peptide- and protein-based biosimilars constitute the basic layer of the ecosystem in India biosimilars and have been able to secure about 74 approvals within this time. The biggest and quickest growing segment since 2013 is antibody and fusion protein-based biosimilars, which have about 72 approvals as of December 2025.

The common type of dementia is Alzheimer disease (AD), a multifactorial neurodegenerative CNS disease prevalent in the elderly population. With over 300 million elderly people in a silver tsunami by 2026, India is projected to have over 5 million cases of Alzheimer's (third in the world) and 10 million cases in 2030 (1). On the molecular scale, AD is defined by oxidative stress that causes deposition of neurofibrillary tangles (2, 3). β-amyloid plaques and mitochondrial dysfunction (4), neuroinflammation (5), loss of synapses (6), and eventually, massive neuronal degeneration, especially in the hippocampus and cerebral cortex. Thus, it may be possible to prevent the appearance of these aggregates by using natural antioxidants or ROS scavengers (7). The recent advancements of fluid and imaging biomarkers in the prediction of AD even during preclinical stages have been significantly improved, including computerized cognitive tests and plasma phosphorylated tau (pTau217). The changes in the Apolipoprotein E (ApoE) gene, especially the ApoE4 allele, have been significantly linked to an increased likelihood of AD and a younger onset (8). Likewise, anti-aggregating/AB-degrading molecules might be useful in preventing AD. Otherwise, conventional anti-Alzheimer medications like AChEl and NMDA receptor antagonists (9) improve memory and attention deficits but only superficially help to prevent or reverse disease progression. Over the past years, biologic therapies, including monoclonal antibodies, vaccines, antisense oligonucleotides (ASOs), and gene therapies, have become a significant part of promising disease-modifying approaches.

2. Current situation of Alzheimer's disease in India

India is a country with a growing burden of Alzheimer's disease, with the highest number of patients in the world and a potential 80 lakh cases of dementia by 2030. Due to the rising aging population and unmet needs, the market size of the Alzheimer's therapeutics market will grow by a compound annual growth rate (CAGR) of 28% between the 2022 value of USD 41.3 million and USD 297.4 million by 2030. Most of the existing therapies consist of symptomatic small molecule drugs, but only a limited number of disease modification options exist, which are expensive (10).

2.1. New Biologics for Alzheimer's and Access in India

Disease-modifying biologics, such as lecanemab (Eisai/Biogen) and donanemab (Eli Lilly), which are monoclonal antibodies that target amyloid plaques, are a breakthrough. Donanemab was approved globally and in India in late 2025, with a scheduled launch in 2026. These reduce cognitive deterioration, but most Indians cannot afford them without affordability measures because they cost thousands of dollars per dose (11).

2.2. The Biologics and Biosimilars Ecosystem in India

The country is currently growing through BioPharma SHAKTI (a ₹10,000 crore project from the 2026 Union Budget) and 2025 draft guidelines that are in accordance with FDA/EMA for quicker approvals and non-animal testing. The biosimilars market is expected to increase at a 21% CAGR from USD 184 million in 2026 to USD 1.02 billion by 2035, driven by manufacturing strengths and patent expirations. By 2025, more than 200 novel biologics are expected to be developed (12).

2.3. Why India Needs This Alzheimer's Shift

Biosimilars could reduce costs by 30–40% through local manufacturing, legislative support (such as clinical trial waivers), and export agreements such as the 2026 India-US trade agreement. Originator biologics, such as donanemab, are expensive and unavailable on a large scale. This is consistent with the Indian pharmaceutical industry's shift from generics to high-value biologics and biosimilars, tackling Alzheimer's epidemics with precision treatments, biomarkers, and monoclonal antibody research and development. Regulations and hefty development expenses are obstacles, yet programs like SHAKTI establish India as a worldwide center (13).

2.4. Mechanistic approach of biologics and biosimilars in Alzheimer’s

Curcumin is a pharmacologically safe natural product, which suppresses the expression of Egr-1 protein and Egr-1 DNA-binding activity in THP-1 monocytic cells induced by Ab. Previous studies have shown that curcumin inhibits tissue factor gene expression in endothelial cells by affecting the transcription factors Egr-1, AP-1 and NF-kB. was effective in blocking amyloid peptide-induced cytochemokine expression, indicating that a low dose of curcumin may be effective in preventing amyloid peptide-induced neuroinflammation in Alzheimer’s disease (14, 15).

Previous studies have implied that long-term (12-month) oral preventive quercetin administration significantly reduces amyloidosis and tends to reduce tauopathy in the amygdala and hippocampal regions. These reductions had a positive impact on the 3xTg-AD mice's cognitive functional recovery without changing their emotional abilities (16). Quercetin crosses the blood-brain barrier, lowers ROS levels through Nrf2 activation, and modifies microglia (M1 to M2 shift).

Meta-analyses from 2024-2026 highlight promising cognitive benefits of natural compounds like curcumin and flavonoids in mild Alzheimer's disease (AD), while India-led nano-curcumin research addresses bioavailability hurdles for better progression control (Cognitive Improvement Meta-Analyses) (15–30%) (17). Curcumin inhibits BACE1 (Aβ synthesis) and AChE (cholinergic boost). Aβ/tau sites have binding affinities of -7 to -9 kcal/mol according to in silico docking.

Using measures such as the MMSE (Mini-Mental State Exam) and Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog), recent systematic reviews (2024–26) pooled RCTs on natural extracts/compounds (≥6 weeks), demonstrating 15–30% improvements in mild AD/MCI.

Conventional curcumin bioavailability is low (~1%, fast metabolism); however, brain transport is made possible by nanoformulations (liposomes, SLNs, and micelles) that increase it 12–20 times (or 700–2000% with piperine/nano adjuvants). AIIMS/NIMHANS research: ICMR-funded Indian studies from 2023 to 2026 examine nano-curcumin, which results in a 20% slower development of mild AD (Morris Water Maze/MMSE metrics); it also restores Akt/CaMKII-α signaling and reduces hippocampal apoptosis by 40–50% in STZ models (brain insulin resistance). One study found that simple curcumin reduced plaque by 20% compared to 20x plasma levels (15).

The top drug authority in India has approved donanemab, one of the two groundbreaking treatments praised worldwide for exhibiting encouraging outcomes in the treatment of Alzheimer's disease, and its manufacturer, Eli Lilly and Company, is getting ready to introduce it in a few months

For patients with mild cognitive impairment (MCI) and those in the mild dementia stage of early symptomatic Alzheimer's disease, the most prevalent type of dementia, medication is administered as monthly injections that target amyloid.

Given the poor results of previous pharmacological treatments for Alzheimer's disease, the introduction of lecanemab and donanemab has sparked global interest. However, researchers and medical professionals have cautioned that these medications have limitations. Monoclonal antibodies are produced in laboratories. They are used to treat a variety of illnesses, and they are created to bind to particular targets in the body. Donanemab is the second monoclonal antibody licensed in several nations to treat Alzheimer's, a neurodegenerative disease that frequently advances quickly, after lecanemab by Eisai and Biogen.

According to the findings of clinical trials, they may have adverse effects, such as bleeding and swelling of the brain, which can be fatal. Additionally, according to Lilly, donanemab may cause severe side effects, including infusion-related responses and amyloid-related imaging abnormalities (ARIA). There are currently no disease-modifying medications such as donanemab available in the market. To produce safety and efficacy data for India, a local Phase IV study or post-marketing surveillance would be carried out.

3. Conclusion

India can provide scalable disease-modifying medicines, reducing the AD epidemic while exporting innovation, turning burden into a healing horizon by creating donanemab biosimilars and producing nano-bioactives.

4. References

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