Leqembi

BioArctic has developed Leqembi, the world's first fully approved disease-modifying treatment for Alzheimer's disease. The drug has now been approved in more than 50 countries, and the development of new treatment forms and indications is continuing. The next paradigm shift in the treatment of Alzheimer's disease is a subcutaneous autoinjector that patients can administer themselves at home, similar to today's drugs for diabetes. Moreover, studies are ongoing in people with asymptomatic Alzheimer's disease, i.e. people with elevated levels of amyloid-beta, but who are not yet showing any symptoms. The hope is that the disease can be treated before symptoms appear.

The world's first disease-modifying drug against Alzheimer's disease

The success of Leqembi is built on solid research and a robust clinical development program. Clarity AD, the global Phase 3 study, demonstrated efficacy that resulted in a meaningful slowing of disease progression in early Alzheimer's disease, as measured by slower cognitive and functional decline. Follow-up data after four years of treatment show that the improvement is sustained over time and early initiation of treatment appears to yield the best efficacy.

Leqembi has been approved for the treatment of adult patients with early Alzheimer's disease. This approval is based on the Clarity AD Phase 3 study, a global, randomized, double-blind, placebo-controlled study involving 1,795 patients with early Alzheimer's disease (mild cognitive impairment or mild dementia caused by Alzheimer's disease). In the study, lecanemab 10 mg/kg was administered every two weeks for 18 months, and the study showed statistically significant improvements in both the primary endpoint and all secondary endpoints. Leqembi is the first treatment that has been shown to slow the progression of the disease as well as cognitive and functional decline.

Modeled data presented at the 2025 CTAD congress show that the time when patients, with mild cognitive impairment and low levels of amyloid, reach the moderate stage in the progression of the disease, can be delayed with an an estimated

8 years or more

if they receive continous long-term treatment with Leqembi.

Endpoints in the clinical lecanemab program

- **Primary endpoint: CDR-SB**
  Measures global cognitive and functional decline in Alzheimer's disease. Summarizes assessments in memory, orientation, judgment, social activities, home and hobbies, and personal hygiene.
- **Secondary endpoint:**
  Amyloid PET: Measures amyloid deposits (plaques) in the brain. Reduction of amyloid aggregates in the brain correlates with clinical effect.

  ADCS MCI-ADL: Measures capacity for performing everyday activities.

  ADAS-Cog14: Cognitive test for memory and attention.

  ADCOMS: A composite measure for more sensitive assessment of changes in early stages of the disease, combining elements of CDR-SB, ADAS-Cog and ADCS-ADL.

These scales provide an overall picture of the efficacy of treatment on both cognition and function in the lecanemab clinical trials.

Positive efficacy on primary and secondary endpoints

The primary endpoint was to reduce clinical deterioration on the Clinical Dementia Rating-Sum of Boxes (CDR-SB) global cognitive and functional scale compared with placebo after 18 months of treatment. The results showed an average change from baseline of 1.21 points for the lecanemab group and 1.66 for the placebo group. This meant that treatment with lecanemab significantly reduced clinical deterioration by 0.45 points compared with placebo after 18 months (p=0.00005), representing a reduction of 27 percent.

As early as six months, and at all measurement points thereafter, treatment with lecanemab showed a highly statistically significant difference compared with the placebo group regarding changes in the CDR-SB.

All secondary endpoints also showed highly significant results compared with placebo. Secondary effects were measured by change from baseline at 18 months of treatment compared to placebo and evaluated brain amyloid levels measured with positron emission tomography (PET) scans, and changes according to the three clinical efficacy scales: ADAS-Cog 14 (Alzheimer's Disease Assessment Scale-cognitive subscale 14), ADCOMS (Alzheimer's Disease Composite Score) and ADCS MCI-ADL (Alzheimer's Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment).

The PET scans showed a statistically significant reduction in amyloid plaques after treatment with lecanemab at all points in time, starting at three months. The average change measured in centiloids after 18 months was -55.5 for lecanemab and 3.6 for the placebo group.

The progression of the disease, measured on the ADAS-Cog after 18 months, showed a decrease of 26 percent. Measured on the ADCS MCI-ADL scale, which assesses ability of individuals with mild cognitive impairment relating to activities in daily life (ADL), deterioration had slowed by 37 percent.

On the ADCOMS scale, lecanemab slowed the progression of the disease by 24 percent after 18 months. Lecanemab slowed the deterioration in daily living activities, as measured by the ADCS MCI-ADL scale, by 37 percent after 18 months.

Side effects

In the lecanemab group, 17.3 percent of the patients developed ARIA-H (micro- and macrobleeds as well as superficial siderosis). The corresponding level in the placebo group was 9.0 percent.

12.6 percent of patients in the lecanemab group developed ARIA-E (swelling/edema) compared with 1.7 percent in the placebo group. 2.8 percent of patients developed symptomatic ARIA-E.

Strong results as early as Phase 2b

Positive data from the clinical Phase 2b study formed the basis for lecanemab's accelerated approval in the United States in January 2023. Following the presentation of the Phase 3 results, BioArctic's collaboration partner Eisai submitted a supplementary application for full approval, which was obtained in July 2023. The results of the study showed that lecanemab significantly reduced amyloid plaque in the brain and yielded slower clinical deterioration compared with placebo. The treatment reduced the rate of deterioration by between 26.5 and 55.9 percent, depending on the clinical measure and statistical method used. Moreover, positive effects were seen on biomarkers that reflect the underlying pathophysiology of the disease. Lecanemab was generally well tolerated, although amyloid-related imaging abnormalities (ARIA-E) were observed in fewer than 10 percent of participants – in most cases, asymptomatic.

Long-term monitoring shows sustained improvement after four years

Of the 1,795 patients who completed the Clarity AD Phase 3 study, 95 percent chose to continue their participation in an open-label extension study. During the summer of 2025, follow-up data was presented for the 478 patients who had then been treated with lecanemab for four years, and the results show that the medicine continued to slow cognitive decline over time. The reduced deterioration compared with the natural progression of the disease was 1.01 points after three years and 1.75 points after four years, based on comparative data from the Alzheimer's Disease Neuroimaging Initiative (ADNI), which predicts progression of the disease in patients with mild Alzheimer's disease. Similarly, a difference of 1.40 points over three years and 2.17 points at four years was shown when comparing the performance of the lecanemab group with patients from BioFINDER, which models disease progression in patients with milder degrees of Alzheimer's disease. Taken together, this data indicates that lecanemab treatment slows the progression of the disease by around one year compared with no treatment during a four-year period.

At the same time, the treatment had an expected stable safety profile throughout the four-year period. The amyloid-related imaging abnormalities (ARIA) were most common in the first six months but decreased and remained stable thereafter. Overall, long-term data from four years of monitoring suggest that Leqembi has a lasting positive effect on disease progression in many patients, with effects including preserved cognitive function and reduced amyloid burden.

New Leqembi data presented at the CTAD congress in December 2025 showed that continuous treatment with Leqembi can potentially delay progression of the disease by up to 8.3 years. Furthermore, each additional year of Leqembi may extend the delay in the progression of the disease, compared with discontinuing treatment, even long after the plaque is expected to have been removed.

Leqembi has been approved in more than 50 countries, on the basis of the results from the clinical development program.

Sustainability facts

Patient safety and health are essential elements of the company's sustainability agenda. The company's research has led to the development of the world's first disease-modifying drug for Alzheimer's disease, but without understanding and knowledge there is no way to establish structures for diagnosis and treatment in groundbreaking areas. The company's work with healthcare representatives and policymakers is therefore crucial for ensuring that treatments benefit patients. Patient safety is a guidepost in all aspects of the operation, and during the year it received particular focus as part of the preparations for a commercial launch in the Nordic region.

Read more about BioArctic's sustainability agenda in Patient safety and health on page 167.

Next goal: Easy to use home treatment

Based on Leqembi's clear disease-modifying effects in clinical studies, development has continued with the aim of further improving the accessibility and administration of the treatment. An autoinjector – similar to an insulin pen – allows patients to administer the treatment at home.

Leqembi was originally developed as an intravenous treatment (inserted into the bloodstream), but as the treatment began obtaining approval around the world, the development of a subcutaneous formulation (administered under the skin) has increasingly come into focus. This forms the basis for three important future breakthroughs in the treatment of Alzheimer's disease.

Easily accessible treatment at home

Extension studies from the clinical development program behind Leqembi have shown that continuing maintenance treatment with the medicine is important, even after the initial 18-month course in order to maintain the slowing of disease progression. Discontinuing treatment can lead to a rate of decline similar to that seen with placebo. Maintenance treatment can continue as a monthly intravenous treatment, but the new subcutaneous formulation – which has been developed and already been approved in several markets – may further

BioArctic's collaboration partner Eisai is conducting the Phase 3 study,

AHEAD 3–45

in which lecanemab is being evaluated as a treatment for people who are cognatively unimpaired with elevated brain amyloid. The purpose is to evaluate whether early treatment can slow changes to biomarkers and cognitive decline in these patients.

improve accessibility. For subcutaneous administration, Leqembi is injected weekly using a home autoinjector. The US brand name for the subcutaneous autoinjector is Leqembi Iqlik (pronounced "I click") and the treatment takes an estimated 15 seconds. Leqembi Iqlik was approved as a maintenance treatment in the US in August 2025.

The autoinjector has been developed for ease of use, thereby reducing the need for hospital visits and nursing care compared with intravenous administration. This form of administration may facilitate continued maintenance dosing and further simplify the treatment of Alzheimer's disease.

Regulatory processes are underway in the US, Japan and China to offer subcutaneous treatment with the autoinjector as early as the initial phase of treatment.

Treatment before symptoms emerge

Since 2020, BioArctic's collaboration partner Eisai has been running the AHEAD 3-45 Phase 3 study, in which lecanemab is being evaluated as a treatment for people with asymptomatic Alzheimer's disease. Participants in the study are not showing any symptoms yet, but have moderately elevated or high levels of amyloid-beta in their brains. The purpose is to evaluate whether early treatment with lecanemab can slow changes to biomarkers and cognitive decline in these patients.

The final participant was recruited to the study in October 2024 and the treatment period runs for over four years. The results of the study are expected in late 2028.

Estimated time gained with 10 years of treatment

There is no defined time limit for how long patients are to be treated, but there are ongoing studies on the effects of treatment over several years. The initial phase of 18 months is the introductory treatment period, after which maintenance treatment can continue at the discretion of the physician. According to the drug's label, treatment should be stopped when the patient reaches moderate levels of the disease.

Maintenance treatment allows patients to slow the progression of their disease and maintain the efficacy of the treatment, which means that patients get help to maintain their cognitive and functional abilities for longer.

At the Clinical Trials on Alzheimer's Disease (CTAD) scientific conference, which was held in San Diego, US, in December 2025, data was presented from Leqembi treatments in the US, Japan and China showing that the efficacy and safety profile of the treatment continues to be on a par with or better than the Phase 3 data. Furthermore, a simulation was presented of estimated time gained for patients who are identified early in disease progression and begin early treatment with Leqembi. It is estimated that long-term treatment with Leqembi in this early group could delay the time before patients reach the moderate stage of the disease by more than eight years. The data presented continues to show that the earlier treatment is started, the more time is given to patients in a healthier stage of the disease.

Introduction in Nordic region initiated

Following approval by the EU Commission in April 2025, Leqembi has been launched in stages in several European countries. In October 2025, Finland became the first Nordic country to treat a patient with Leqembi.

BioArctic is marketing Leqembi in the Nordic countries in collaboration with Eisai. The launch in the region marks an important strategic step for BioArctic in the company's ambition to establish itself as Sweden's next big pharmaceutical company.

In recent years, BioArctic has built up a commercial organization with more than 20 employees divided among its head office in Sweden and its subsidiaries in Finland, Norway and Denmark. The organization consists of a team with extensive experience in launching new treatments, and intensive efforts in preparing for the launch of the drug are now underway. With a long history of partnering with academic and healthcare institutions in the Nordic region, the conditions for a successful launch are good.

Health economics and pricing

Following approval from the European Commission, BioArctic and Eisai have collaborated with both European and national regulatory authorities to fulfill all necessary requirements for the launch. The process for health economics assessments, pricing and subsidies is underway.

First patient in the Nordic region treated in Finland

Finland became the first country to treat patients with Leqembi after a controlled introduction program was implemented. This program allows private clinics like Terveystalo Ruoholahti – where the first patients were treated – to offer treatment for people with early Alzheimer's disease. A controlled introduction program involves a structured and supervised introduction of a drug into clinical practice with a focus on safety, monitoring and risk management. The program involves patients undergoing MRI scans before treatment and several times during the initial treatment to monitor potential side effects such as ARIA-E (edema) and ARIA-H (bleed).

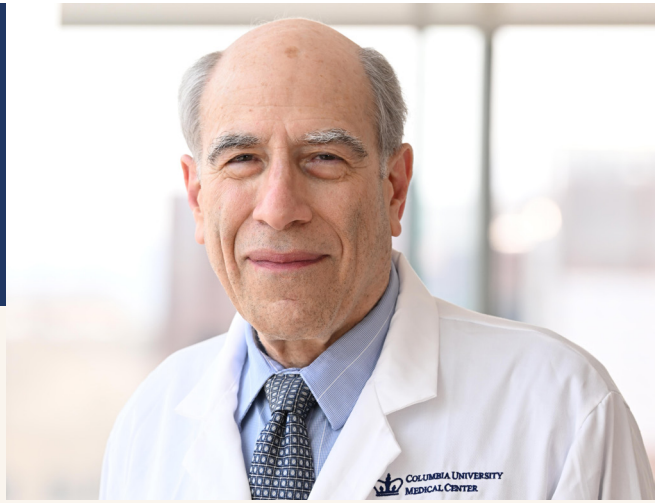
The first treatments were administered before a decision on subsidies was made in Finland and were paid for by the patients themselves or their health insurance, if they had any. In parallel, an assessment for including Leqembi in the publicly funded health system, in line with the other Nordic countries, is in progress.

Sharp focus on the patient journey

The working group responsible for the launch is in dialogue with many clinics in the Nordic region to discuss the patient journey and what resources may be required. Some clinics are well informed and experienced in innovative biologics, while others are less prepared. To educate healthcare professionals, BioArctic has established a new online education platform and initiated a recurring Alzheimer's symposium – Campus Alzheimer – which was held for the first time in September 2025.

Experiences from New York – Leqembi in clinical practice

Interview with Lawrence S Honig, Professor of Neurology at Columbia University, NY



Since the 2023 FDA approval of Leqembi, patients with early Alzheimer's Disease have been treated at the Columbia University Irving Medical Center Neurological Institute in the heart of New York. During the first two years, more than 200 patients received over 4,000 infusions both at the medical center and at infusion centers closer to their homes.

The Columbia University Irving Medical Center is situated along the Hudson River in Upper Manhattan. Patients who are diagnosed with early Alzheimer's disease can be offered lecanemab-irmb (Leqembi), the first disease-modifying treatment approved in the US, which slows the progression of Alzheimer's disease. The treatment is prescribed by around ten specialists and is administered both in the university hospital's own infusion centers and at a number of independent infusion centers in the greater New York Metropolitan area.

"It works a bit like a pharmacy system, but for infusion drugs. Patients receive their treatment at one of the infusion centers that are distributed across the New York region", says Lawrence S. Honig, Professor in Neurology at Columbia University, NY.

Via the clinic, over 200 patients were prescribed Leqembi during the first two years after USA FDA approval, and more than 4,000 infusions were given. While this was a new procedure, neurological providers were able to quickly institute procedures for a broad outreach of the new treatment, says Lawrence S. Honig.

The FDA approved a broader patient population than the European Medicines Agency, EMA. In Europe, the treatment is not approved for use in patients with two copies of the APOE4 gene, which is associated with an increased risk of side effects. To properly select eligible patients in Europe, genetic counseling and testing are required before treatment can be prescribed. In the USA, genetic testing for the APOE4 gene is recommended by the FDA, but not mandatory.

"We have discussions with the patients about eligibility, and risks of treatment, but apart from that providers follow the package insert without adding any special requirements. The procedures are straightforward, and no extensive infrastructure is needed. To monitor patients for brain side effects, we conduct the mandated MRI scans, and in each case wait for the results of the MRI, before prescribing additional treatment", says Lawrence S. Honig.

Before starting treatment with Leqembi, the patient must have undergone an MRI-scan, and there are four follow up scans over 7 months to monitor and identify any Amyloid-Related Imaging Abnormalities, known as ARIA. There are two broad types of ARIA, brain edema and hemorrhage, called ARIA-E and ARIA-H. In the clinical trials laying the ground for the Leqembi approval, most patients did not experience ARIA-E or ARIA-H, and most identified ARIA were asymptomatic. Likewise, in clinical practice the risk of side effects such as edema and hemorrhage was relatively small, not greater than in the trials, and serious side effects were extremely rare, according to Lawrence S. Honig.

"The most serious side effects, such as macro bleeds, are fortunately very unusual and occur in less than one percent of patients."

The initial treatment with Leqembi is 18 months, following which patients may continue with maintenance therapy at the same dose or treatment at less frequent intervals of every four weeks, or by subcutaneous weekly administration, which is now available in the USA, but not yet in the EU. Patients have a high compliance with therapy, and strong interest in continuing treatment to slow their Alzheimer's disease, says Lawrence S. Honig.