European Medicines Agency
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The Netherlands

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Background

Dementia disorders are a tremendous burden for patients, relatives and the health-care system and a leading cause of disability and morbidity. Alzheimer's disease (AD) is the most common type of dementia and 1 in 10 people aged 65 and older has AD dementia. The prevalence of dementia is estimated to triple by 2050 to 115 million and the worldwide costs of dementia today already exceeds that of cancer, heart disease and stroke collectively. The annual cost in Sweden for dementia disorders is 81 mSEK estimated to reach 250 mSEK in 15-20 years.

We meet AD patients every day who intensively are searching for a cure, many of them in their middle age, between 50-65 years old. Their whole life turns upside down with an extreme burden on the whole family. The deadly diagnose is tough, and in addition the life situation will be a huge burden for the whole family.

We meet affected patients and families every day, so the trend is unfortunately increasing.

Research has long faced major challenges in developing effective drugs against AD, and patients have had to settle for treatments that only temporarily alleviates the symptoms. But, over the past decade, science has made important discoveries that form the foundation for a new era of treatments that impact the cause of the disease.

Of importance for therapeutics today is the FDA-approved immunotherapy Lecanemab. Finally, a light in the tunnel!

As the first disease-modifying treatment for early AD, Lecanemab received full approval in US and Japan, and shortly after the turn of the year also in China and now there are high expectations that the treatment also will be approved in Europe during 2024.

Given the success from the Swedish Biotech company Bioarctic, who developed Lecanemab, it would be a huge failure if Europe will not have the approval during 2024.

Early diagnosis methods in combination with Lecanemab

Around 50% of patients undergoing dementia assessment in primary care in Sweden are diagnosed incorrectly, which delays or hinders correct treatment and care. This is a huge problem that now can be solved.

Swedish Alzheimer scientists have been very successful in improving the diagnostic accuracy of AD and other cognitive disorders in primary care by developing diagnostic and prognostic algorithms that include AD blood tests, novel cognitive tests, and imaging.

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Preliminary results show promising avenues for implementing an AD blood test in primary care and providing decision support to PCPs through diagnostic and prognostic algorithms. This is of great importance, especially considering the emergence of disease-modifying AD treatments.

The combination of early diagnosis and a therapeutic treatment such as Lecanemab will therefore be a huge breakthrough in the field.

In order not to lose important time, the approval of Lecanemab in Europe during 2024 is therefore of utmost importance.

The business case for the patients and for the whole society is substantial if Lecanemab will be approved in Europe.

The Swedish Alzheimer's foundation and The Swedish Dementia Association now express our utmost concern regarding the information that has come to our attention. The delay of the approval process for Lecanemab in Europe is devastating for all Swedish and other European patients suffering from AD. They are eagerly awaiting the possibility to receive one of the novel drugs in the world that in clinical trials has shown clear data - that the drug effectively enables a delay in the progression of the disease in Alzheimer patients. Lecanemab is a trailblazer achievement for the scientific society, who are working around the clock to begin the path towards an effective treatment that the world has not seen in over 20 years. We are overwhelmed by calls from worried and anxious AD patients asking for the possibility to become eligible for Lecanemab. It is their last hope and lifeline.

We understand that Lecanemab is not a cure, but as in all other areas long term treatment, success has been achieved by stepwise improvements over time. Disease modifying treatments such as Lecanemab offers a first step on the journey towards a cure and European patients should not be left out.

Below, a patient story from Susanne Åsander, who is currently undergoing treatment with Lecanemab with good results.

We urge EMA to accelerate the hearing process and shortly announce the approval for Lecanemab in Europe.

Yours sincerely,

Liselotte Jansson
Secretary General

The Swedish Alzheimer's foundation

Liselotte Björk
Chairman of the Board

The Swedish Dementia Association

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A patient's story from Sweden

"My name is Susanne Åsander. I'm 65 years old. More than 5 years ago; I was diagnosed with AD. It was a shock, and I thought my life wasn't worth living anymore. I had seen several of my relatives struggle and died with this disease, so unfortunately, I did know how the future would be for me.

Fortunately, I got information about clinical trials, and I was lucky to be approved to participate in Sweden for Lecanemab. I have been so well treated and suddenly my life was worth living again! I stopped being depressed as I realized that this could mean several more good years for me. My prescription for life is to make 'everyday count'. Today it is more than 5 years since I got my diagnose and I have a slow progress and I'm sure that it is due to the medication. I have been open with my diagnose and tries to help others with AD as I know how hard it was to accept the diagnose.

Every time I tell people with AD about Lecancemab, it gives them hope and all of them ask me 'how and when they can get the medicine'. So, it is very urgent to get an approval so that other patients within EU/Sweden will have the opportunity to be treated with Lecanemab to prolong and enhance their lives. Time is their biggest enemy - They can't wait as AD is progressive disease".

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