1 Article：
EDITORIAL | Like the U.S., Japan Must Quickly Approve Drug for Alzheimer's

Directions: Read the following article aloud.

On June 7, the United States Food and Drug Administration (FDA) approved aducanumab, a treatment for Alzheimer's disease produced by Japanese pharmaceutical giant Eisai and American biopharmaceutical giant Biogen.

It is the first medicine that aims to prevent the progression of the disease by targeting the mechanism of the disease. In the United States, it is the first treatment for Alzheimer's approved since 2003.

Until now, the only medicines available were to treat symptoms, and patients and their families were eagerly awaiting a drug that would cure the disease. This is the first step towards that goal. We, along with the patients, are pleased with this news.

In Japan as well, an application for approval was submitted to the Ministry of Health, Labor, and Welfare in December 2020. Chief Cabinet Secretary Katsunobu Kato expressed his expectations and said that, if used in Japan, the treatment will contribute to the goals outlined in the Framework for Promoting Dementia Care, which include preventing the disease and supporting those with Alzheimer's.

Approval could be announced as soon as within 2021. We hope for a swift judgment.

This treatment works for people in the early stages of Alzheimer's and for people with mild cognitive impairment, a precursor to the disease. Dementia that is not Alzheimer's and those in advanced stages are not eligible. The treatment is administered once a month via intravenous drip.

Alzheimer's disease occurs when a protein called amyloid beta accumulates in the brain and destroys nerve cells and causes cognitive decline.

In a clinical trial conducted during the approval process, it was found that the amount of this protein decreased after the treatment was used for a year and a half. However, improvements in cognitive function were limited.

This was a problem in the approval process as well, and the FDA, while approving the drug in consideration of the seriousness of the disease, also requested the implementation of additional studies to prove its clinical usefulness. Depending on the results, they may withdraw their approval. We are observing this process with hope.

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https://japan-forward.com/editorial-like-the-u-s-japan-must-quickly-approve-drug-for-alzheimers/

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EDITORIAL | Like the U.S., Japan Must Quickly Approve Drug for Alzheimer's

Directions: Read the following article aloud.

The development of treatments for dementia has been difficult worldwide. As pharmaceutical companies continue to withdraw from the effort, those manufacturers who have maintained their intentions to develop a treatment are highly valued.

The cost of this treatment will be roughly ￥6.1 million JPY ($55,400 USD) per patient per year. Unlike in the U.S., if the treatment is approved in Japan, it can be used under the National Health Insurance system.

However, in 2020, the number of dementia patients in Japan was about 6 million, of which just under 70% were Alzheimer's patients. Even a small percentage of those patients using the treatment would cost on the scale of hundreds of billions of JPY (billions of USD). Determining who will be eligible for the treatment and reducing the price are important considerations.

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2 Key phrases and vocabulary

Directions: First repeat after your tutor and then read aloud by yourself.

1. **aim to ～ ～を目標とする、～に狙いを定めている**
These treatments aim to reduce the frequency and severity of asthma attacks .

2. symptom (病気などの)症状、兆候
Common symptoms of COVID-19 to watch out for are as follows.

3. cognitive impairment 認識機能障害

Is it true that heading the ball in soccer may result in chronic cognitive impairment?

4. eligible (法的に) 適格な、資格がある、(選ばれる人として)望ましい・ふさわしい、～に値する、妙齢の
They will be eligible to permanent residence after living five years in the country.

5. maintain (動作などを)持続する、(良い状態に)維持する
We need to maintain high standards of security.

3 Questions

Directions: Read the questions aloud and answer them.

1. How is this new treatment different form all other medicines available now?

2. When could it be approved in Japan?

3. What seems to be a problem in the approval process?

4. There are clinical trials performed in human volunteers. Would you ever take part in drug trials? Why/Why not?

4 日本語関連記事：アルツハイマー病　新治療薬の審査を迅速に

米食品医薬品局（FDA）が、日本の製薬大手エーザイと米バイオ医薬品大手バイオジェンが開発したアルツハイマー病の治療薬「アデュカヌマブ」を迅速承認した。

病気が進む疾患の仕組みに働きかけて、進行の阻害を狙った初めての薬である。米国では2003年以来のアルツハイマー病治療薬の承認だ。

これまでは対症療法的な薬しかなく、患者や家族は疾患を「治す」薬を待ちわびていた。その最初の一歩である。患者とともに登場を喜びたい。

日本でも昨年12月に厚生労働省に承認申請が出された。加藤勝信官房長官は「日本でも実用化されれば、認知症施策推進大綱が掲げる共生と予防の推進にも資する」と期待感を示した。

早ければ年内にも承認の可否が示される。迅速に審査をしてもらいたい。

この薬が効くのは、アルツハイマー病の初期の人や、この病気の前段階に当たる軽度認知障害の人だ。アルツハイマー病でない認知症や、進行した人は対象外となる。月1回点滴で投与される。

アルツハイマー病は、脳内に蓄積された「アミロイドベータ」と呼ばれるタンパク質が神経細胞を壊し、認知機能の低下を引き起こすとされる。

承認のために行われた治験では、1年半の使用でこの有害なタンパク質を減らすことが確認された。ただ、患者に表れる認知機能の改善効果は限定的だった。

承認でもこの点が課題になり、FDAは疾患の深刻さなどに配慮して承認すると同時に、臨床上の有用性を証明する追加試験の実施を求めた。結果次第で承認の撤回もあり得るとする。希望をもって見守りたい。

認知症の治療薬開発は世界的に難航してきた。製薬各社の撤退が続く中で開発の意志を貫いたメーカーの取り組みは評価される。

今回の治療薬の費用は患者1人当たり年間約610万円と試算される。米国の制度と異なり、日本では薬剤が承認されれば国民皆保険下で使うことができる。

ただ、日本における認知症患者の数は令和2年で約600万人と推定され、うち7割弱がアルツハイマー病だ。その数%でも数千億円規模となる。対象者の設定や、価格引き下げの努力なども課題となる。

出典：アルツハイマー病　新治療薬の審査を迅速に
https://www.sankei.com/article/20210613-DQ5SBYEMUVICVGEPSCSB2NM3PM/