

Several medical centers remain undecided on Aduhelm

In quiet debut, Alz's drug finds questions, skepticism

NEW YORK, Oct 18, (AP): The first new Alzheimer's treatment in more than 20 years was hailed as a breakthrough when regulators approved it more than four months ago, but its rollout has been slowed by questions about its price and how well it works.

Several major medical centers remain undecided on whether to use Biogen's Aduhelm, which is recommended for early stages of the disease. Big names like the Cleveland Clinic and Mass General Brigham in Boston say they'll pass on it for now.

One neurology practice has even banned the company's sales reps from its offices, citing concerns about the drug and its price, which can climb past \$50,000 annually.

Many doctors say they need to learn more about how Aduhelm works and what will be covered before they decide whether to offer it. That might take several months to sort out. Even then, questions may linger.

"The drug won't be for everybody, even with access," said Salim Syed, an analyst who covers Biogen for Mizuho Securities USA.

Syed estimates that only around one-tenth of the people diagnosed with early-stage Alzheimer's may wind up taking Aduhelm chronically, especially if regulators approve similar treatments from Biogen's competitors.

Biogen, which reports third-quarter financial results Wednesday, is not saying how many people have received the drug since it was approved on June 7. A company executive said last month that Biogen was aware of about 50 sites infusing Aduhelm, far fewer than the 900 the company had said it expected to be ready shortly after regulators approved the drug.

Aduhelm is the first in a line of new drugs that promise to do what no other Alzheimer's treatment has managed: slow the progress of the fatal brain-degenerating disease instead of just managing its symptoms.

"It's like a breath of fresh air," said Dr. Stephen Salloway, a Rhode Island neurologist and Biogen consultant who is prescribing the drug. People with Alzheimer's "know what's coming, and they want to do whatever they can to stay in the milder stage."

The US Food and Drug Administra-



This image provided by Biogen on Monday, June 7, 2021 shows a vial and packaging for the drug Aduhelm. The first new Alzheimer's treatment in more than 20 years was hailed as a breakthrough when regulators approved it in June 2021, but its rollout has been slowed by questions about its price and how well it works. (AP)

tion approved Aduhelm despite objections from its own independent advisers, several of whom resigned. The agency later said the drug was appropriate for patients with mild symptoms or early-stage Alzheimer's.

Aduhelm clears brain plaque thought to play a role in Alzheimer's disease, and regulators made the call based on study results showing the drug seemed likely to benefit patients.

Biogen, which developed Aduhelm with Japan's Eisai Co., had halted two studies on the drug due to disappointing results. It later said further analysis showed the treatment was effective at

higher doses.

The FDA is requiring Biogen to conduct a follow-up study.

The research Biogen submitted so far doesn't give doctors as much insight as they would normally have into a drug, said Dr. Brendan Kelley, a neurologist at UT Southwestern Medical Center in Dallas. Its experts are still reviewing Aduhelm.

Research

"Biogen went to the FDA with preliminary data, so it makes it really challenging to know how to navigate," he said. More complete research would

give doctors a better idea for how the drug will work in a broader patient population, Kelley said.

Cost is another concern.

Biogen's pricing for Aduhelm is "irresponsible and unconscionable," according to signs posted on office doors for The Neurology Center, a Washington, DC-area practice. The signs also refer to Aduhelm as a medication "of dubious effectiveness" and tell Biogen sales reps they are no longer welcomed in the center's offices.

"As physicians we feel compelled to speak out and protest BIOGEN's actions," one of the signs reads.

Neurology Center CEO Wendy Van Fossen said the signs went up in July, but she declined to elaborate on why they were posted.

A Biogen spokeswoman said in an email that it was disappointing that some centers are denying access to the drug.

As for Aduhelm's effectiveness, company data shows that plaque removal "is reasonably likely to predict a clinical benefit," said Biogen Chief Medical Officer Dr. Maha Radhakrishnan. She said regulators reviewed data from more than 3,000 patients, counting two late-stage studies and earlier research.

Doctors also are worried about wheth-

er patients taking Aduhelm will be able to get the regular brain scans needed to monitor their progress on the drug.

Issues with care access weren't explored in the clinical research, which also involved patients who were generally younger and healthier than those in the broader population, noted Dr. Zaldy Tan, director of the Cedars-Sinai memory and aging program.

The Los Angeles health system is still evaluating Aduhelm. Its committee of experts is considering things like which doctors will prescribe the drug and how to ensure patients are monitored for problems like dizziness or headaches develop. Bleeding in the brain is another potential side effect.

"Safety and access are real issues that need to be prioritized," Tan said.

Aduhelm also requires a deeper level of coordination among doctors than other Alzheimer's treatments, noted Radhakrishnan.

Prescribing doctors have to work with neurologists, radiologists and nurse practitioners to diagnose patients, confirm the presence of plaque in the brain, get them started on the treatment and then monitor them. "All of this is work in progress," Radhakrishnan said.

Uncertainty about insurance coverage is another holdup.

Some insurers have decided not to cover the drug. Others, including the major Medicare Advantage insurer Humana, haven't made a decision yet but are reviewing claims case by case in the meantime.

The federal Medicare program is expected to make a national coverage determination by next spring that will lay out how it handles the drug.

Biogen executives said recently they think most sites that will offer the drug are waiting for clarity on reimbursement, including that Medicare decision.

Medicare's determination looms large for the Cedars-Sinai experts. Tan said they know they should reach a decision before the Medicare decision prompts more patient inquiries.

He said doctors also realize they aren't just evaluating Aduhelm: They're also thinking about how to handle similar treatments that could get FDA approval.

"We want to make sure we get it right," Tan said.

A Reaffirming Statement of its Customer-Centricity

URC Developments "Hessah Towers", "Byout Hessah" and "Assoufid" wins Four 5-Star Prestigious Awards



United Real Estate Company (URC), a leading real estate developer in Kuwait and the MENA region, received four 5-star accolades for its Hessah Towers and Assoufid Development at the Africa & Arabia Property Awards 2021 in an online virtual ceremony on 7th October in Essex, UK.

Hessah Towers received "Best Residential High-Rise Architecture" and "Best Residential High-Rise

Development". In addition, the Assoufid Development in Marrakech, Morocco, won "Best Residential Development" and "Best Hotel Architecture" for The St. Regis Marrakech Resort.

Africa & Arabia Property Awards 2021 awarded "Best Architecture Multiple Resident" for Byout Hessah, a URC development conceptualized by SSH, one of the leading master planning and design firms in the Middle East.

Highlighted as a standard of



excellence in the regional real estate landscape, the Africa & Arabia Property Awards recognized all three projects by an independent judge panel of over 80 industry experts. The judging criteria are based on design, quality, service, innovation, originality, commitment to sustainability, and marketing.

URC Vice-Chairman & Group Chief Executive Officer Mr. Mazen Issam Hawwa, stated, "Winning these prestigious awards further resonates URC's position as a trusted real estate developer in delivering premium world-class developments, regionally and internationally. This achievement reaffirms our customer-focus approach to sustain our clients trust and needs by bringing the latest elements of innovation and creativity to craft our products in the MENA region, which includes residential, commercial, leisure, and hospitality, to introduce a new dimension of a unique community living for residents and commuters to live-work-play experience."

Chief Development Officer, Architect Mishary S. Al Muhailan, said, "The accolades won at the African & Arabian Property Awards 2021 reaffirms our position as a customer-centric developer that focuses on an aspirational and design-

led approach while embracing innovation, sustainability, and technology within the architecture and interiors of our developments. Additionally, these recognitions further reinforce our dedication to creating compelling luxury properties that consistently transcend fashions and trends."

Construction progress is underway for Hessah Towers and Byout Hessah, URC's latest developments within Hessah AlMubarak District. Soaring at 40-floors high, Hessah Towers is a modern take on high-end residential living that offers an upscale collection of apartments and duplexes, allowing owners to enjoy breath-taking views of the Arabian Gulf and Kuwait City.

Byout Hessah comprises 40 luxury four-bedroom townhouses and two 12-floor residential building with 104 upscale two-bedroom apartments, which include 7 penthouses, set amidst landscaped surroundings and conveniently located close to the Arabian Gulf and the heart of Kuwait City's commercial district.

The modern-living residential developments feature an array of premium services and exclusive amenities, setting new standards of luxury lifestyle, privacy, comfort, and smart living. URC achieved 57% sale of the available units in Hessah Towers and 24% in Byout Hessah.



Spanning across a total area of 2.5 million square meters, the Assoufid Development is a luxurious mixed-use integrated tourism and residential resort situated in the vibrant city of Marrakech, strategically located approximately 8 kilometers away from Marrakech International Airport in Morocco.

The first phase consists of a multiple award-winning 18-hole high-end golf club and several luxury residential villas.

The second phase of the Assoufid development will introduce the iconic five-star hotel brand, The St. Regis Marrakech Resort, operated by Marriott International, Inc. The hotel will consist of rooms and villas equipped with world-class amenities.

The second phase also includes branded residences, real estate residences of tourist promotion (RIPT), residential villas, apartments, and a retail area.

