**Narrator:** *The BioWorld Insider* podcast.

**Lynn Yoffee:** This is *The BioWorld Insider* podcast, and I'm Lynn Yoffee. In a year of big news with a huge amount of breakthrough science underway, few stories outside of COVID-19 vaccines have been more closely followed than that of Biogen's Alzheimer's disease therapy Aducanumab. On Monday, it won accelerated approval from the FDA and will now be marketed in the US as Aduhelm. In today's episode, news editor Michael Fitzhugh is talking with Ivana Rubino, Biogen's Vice President of Global and US Medical Affairs for Alzheimer's Disease. Thanks for joining us today, Ivana. Michael, take it away.

**Michael Fitzhugh:** Thanks, Lynn. Hi, Ivana. Thank you so much for making time to talk to us today.

**Ivana Rubino:** Thank you, Michael and Lynn. It's my pleasure.

**Michael:** Congratulations on the approval. It's clearly a momentous day for Biogen, your work, and potentially for millions of people with Alzheimer's disease.

**Ivana:** Yes. Thank you, Michael. It is.

**Michael:** When the FDA approved Aduhelm on June 7th, it called it a first of its kind treatment for Alzheimer's. What's special about this medicine?

**Ivana:** Aduhelm is a monoclonal antibody that targets one of the pathological features of Alzheimer's disease, the amyloid beta. In the past 18 years, there were no new approved drugs for the treatment of Alzheimer's disease. However, in this period, many attempts, and many trials were done in order to address this disease, which is one of the highest unmet medical needs for humanity.

Our clinical trial program had the opportunity to learn and implement a lot of this critical elements that we realized were so important with regard to the disease and how to address the underlying pathologies. The results and the news on Monday is really belonging to the entire community because it was really a community effort that enable us to design study that gave us an answer on how we can address one of the pathologies that characterize Alzheimer's disease, the presence of this amyloid pathology.

**Michael:** The community really in receiving this medicine, they're getting it with a broad label, one that states really simply that is just for the treatment of Alzheimer's disease. I imagine that must have been good to see and also could prove a challenge to a certain degree since doctors have to decide how to use it on their own and for how long. Can you tell me a little bit about that?

**Ivana:** Alzheimer's disease is really a complex pathology. You may have seen that the underlying changes occurs decades before the symptoms. Therefore, the idea that one therapy may address the disease for all the patients is quite far from reality. Aduhelm represents the first of hopefully a long series of options for the patients. What we know about Aduhelm, the data that was shared with the FDA during the review, are related to patients with very specific characteristics, the patient that we studied in our phase III program.

Specifically, the patients were in the early stages of the disease, either MCI, or mild dementia clinical stages, and they were all positive for the presence of the amyloid pathology. Based on this data, we do believe that the most appropriate patients that should receive Aduhelm are the patients with similar characteristics. Overall, we will learn more and more about this medicine, and in the future, we will be able to address in a more robust fashion questions such as the durability of the fact or whether the medicine can be used in a broader population.

**Michael:** Like all important work, some of the work surrounding and supporting the approval of Aduhelm generated some controversy even among experts in the field of Alzheimer's disease, like CDER director, Patrizia Cavazzoni even said Monday that some of the support left residual uncertainties regarding clinical benefit. How is Biogen approaching that landscape as it moves toward launch?

**Ivana:** June 7 is the first day and the beginning of a new chapter for us to further understand Aduhelm and how to best use it. As you have seen, we will conduct another randomized study, but we will also work on expanding our knowledge of Aduhelm in the real world through data generation. A lot of these questions will have an answer. June 7 approval really speaks about the fact that our patients have no time to wait, and we can start finally offering them an option.

**Michael:** Can you tell me a little bit about that clinical work that lies ahead? With an accelerated approval, it's a confirmatory study, as I understand it. What will that look like?

**Ivana:** Well, as you can imagine, we have been very busy with the preparation of the work for June 7. Now the work begins with regard to this study, and we will soon be able to share more details about the study design.

**Michael:** Great. Are there particular questions, apart from the study design itself, are there particular questions that you'll be looking to answer as you continue to explore the therapy's potential?

**Ivana:** It will be premature from my end to give an answer to this question. We will certainly look at designing a study that address the key questions but also takes into account the progresses that the scientific community in this field has made in the past years.

**Michael:** Got it. Cool. Well, I look forward to hearing about that as it unfolds. The initial list price for Aduhelm has been set, as I understand it, at $56,000 per year, which was higher than many industry observers had anticipated. Biogen CEO, Michel Vounatsos said that it's in line with the overall value that this treatment brings to patients. How is Biogen measuring and thinking about that value?

**Ivana:** When we think about the value of a therapy, we think about the impact that that therapy can have on patient's family and society at all. In an area like Alzheimer's disease, where for so many years we've been waiting for an option, all these elements were taken into account. We also consider sustainability, innovation, and access. As you may have seen from our press release, we have a lot of programs in place to enable our patients to have access to this therapy.

**Michael:** Great. As the future of Aduhelm unfolds, any parting thoughts about what it will mean to Biogen's broader future as a company?

**Ivana:** Biogen has had an history of tackling some of the most complex disease. Usually, as you will see from our pipeline, we don't just rest up to one. We tend to tackle the disease for the longest. June 7, to me, means the beginning of the era of Biogen involvement in Alzheimer's disease more and more. Of course, it's super humbling to be part of the company who was part of this challenge and was able to cross these milestones, along with our patients, families, and all the physicians and care team that were part of this journey.

**Michael:** Excellent. How does your role and your responsibilities change? What are some of your top priorities just near term? What's most on your mind now as you enter this next chapter for the program?

**Ivana:** The medical organization, specifically in the US, has been working toward this potential launch for over one year. Our key areas are related to medical education and data generation. What our goal is, is to be there for our community of treating physicians, making sure that we can support them and we can keep them in order to provide the best care to our Alzheimer's patients.

**Michael:** Thank you so much for taking time out of your busy schedule to join us and to talk about this new approval of Aduhelm.

**Ivana:** Thank you, Michael. The pleasure was mine.

**Lynn:** Thank you, Ivana and Michael. That's our show for today. If you need to track the development of drugs, turn to bioworld.com. Follow us on Twitter or email us at newsdesk@bioworld.com.

**Narrator:** *The BioWorld Insider* podcast. BioWorld is a subscription-based new service, but all of our COVID-19 content, almost 5,000 articles and data entries since the start of the pandemic, are freely accessible.