**Biogen Inc to Discuss the Approval of ADUHELM Call - Final**

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Presentation

OPERATOR: Good morning. My name is Jennifer, and I will be your conference operator today. At this time, I would like to welcome everyone to the **Biogen** ADUHELM webcast. (Operator Instructions)

Thank you. I would now like to turn the conference over to Mr. Mike Hencke, Director, Investor Relations. Mr. Hencke, you may begin your conference.

MICHAEL HENCKE, DIRECTOR OF IR, **BIOGEN** INC.: Good morning, and welcome to today's conference call to discuss the approval of aducanumab-avwa or ADUHELM. I encourage everyone to go to the Investors section of **biogen**.com to find slides that will accompany the discussion related to this call.

ADUHELM is indicated for the treatment of Alzheimer's disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial or trials. ADUHELM can cause serious side effects, including amyloid-related imaging abnormalities or ARIA. ARIA is a common side effect that does not usually cause any symptoms, but can be serious. It is most commonly seen as temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain with the swelling.

Although most people with swelling in the areas of the brain do not have symptoms, some people may have symptoms such as headache, confusion, dizziness, vision changes and nausea. The patient's health care provider will do magnetic resonance imaging or MRI scans before and during treatment with ADUHELM to check for ARIA. Patients should call their health care provider or go to the nearest hospital emergency room right away if they have any of these symptoms.

Before receiving ADUHELM, patients should tell their health care provider about all of their medical conditions including if they are pregnant or plan to become pregnant or breastfeeding or plan to breastfeed. It is not known if ADUHELM will harm their unborn baby or if aducanumab, the active ingredient in ADUHELM, passes into breast milk. ADUHELM can cause serious side effects, including ARIA, which I previously described, and serious allergic reactions. Swelling of the face, lips, mouth or tongue and hives have happened during ADUHELM infusion. Patients should tell their health care provider if they have any of the symptoms of a serious allergic reaction during or after an ADUHELM infusion.

The most common side effects of ADUHELM include swelling in areas of the brain, with or without small spots of bleeding in or on the surface of the brain or ARIA, headache and fall. Patients should call their health care provider for medical advice about side effects. Patients may report side effects to FDA at 1-800-FDA-1088. Please see the full prescribing information, including the medication guide on aduhelm.com.

Today's call will include discussion of certain forward-looking non-GAAP financial measures. We believe non-GAAP financial measures better represent the ongoing economics of our business and reflect how we manage the business internally. I would like to point out that we will be making forward-looking statements, which are based on our current expectations and beliefs. These statements are subject to certain risks and uncertainties, and our actual results may differ materially. I encourage you to consult the risk factors discussed in our SEC filings for additional detail.

On today's call, I am joined by our Chief Executive Officer, Michel Vounatsos; Dr. Al Sandrock, Head of Research and Development; Nicole Murphy, Head of Global Manufacturing and Technical Operations; and our CFO, Mike McDonnell. We are also joined by Chirfi Guindo, Head of Global Product Strategy and Commercialization; Alisha Alaimo, President of our U.S. Organization; and Dr. Samantha Budd Haeberlein, Head of Neurodegeneration Development. (Operator Instructions)

I will now turn the call over to Michel.

MICHEL VOUNATSOS, CEO & DIRECTOR, **BIOGEN** INC.: Good morning, everyone. Today is a truly exciting day for the Alzheimer's patients, for science and for **Biogen**. Before I continue, I would like to thank everyone who has touched the ADUHELM development program over the years, including the patients, physicians, caregivers involved in our clinical studies, the wide range of advisers who have guided us along the way, our collaborators at both Eisai and Neurimmune, and our current and former employees here at **Biogen**.

This has been a long and challenging journey as we continuously follow the science, and we at **Biogen** are grateful for the incredible contributions of everyone involved. We are truly humbled by the opportunity to start the journey ahead to support patients with Alzheimer's disease, particularly those in the early stage of the disease where ADUHELM was studied.

Alzheimer's disease is not only a global health crisis, but also a devastating disease with an enormous impact on daily life for patients and their loved ones. It is estimated that over 30 million people worldwide are suffering from Alzheimer's disease, which is expected to triple over the next 30 years. This disease is the sixth leading cause of death in the U.S. With the immense burden that Alzheimer's disease imparts on patients, their caregivers and society, academia and the industry have been desperately searching for decades for the potential approval of new therapeutic interventions.

Allow me to now summarize why we at **Biogen**, we are so excited to be here with you today. First, ADUHELM is the first and only FDA-approved therapy to address a defining pathology of Alzheimer's disease. We believe that this accelerated approval will usher in a new era of Alzheimer's drug development, one that is characterized by continued innovation with a fundamental science now starting to break in this complex disease area. Second, **Biogen** has experienced building new market for serious neurological diseases, and we are leveraging our core capabilities to build a new market focused on early-stage Alzheimer's patients. Establishing the infrastructure for ADUHELM treatment will require interdisciplinary partnership within the community with specialist at the center. We, at **Biogen**, stand ready to work with all stakeholders to support patients in need.

Third, **Biogen** has been working for months in preparation of the U.S. PDUFA date. And I am proud to say that we stand ready to launch with a goal of maximizing access for early-stage patients, including underserved populations. Our field teams are in place, and we expect to begin shipping products in about 2 weeks. Fourth, our long-term commitment to Alzheimer's disease is today becoming a reality. And we are executing a comprehensive strategy aimed at long-term leadership in this space. This includes both working to expand access to ADUHELM with broader patient populations over time while also continuing to advance a pipeline of potential novel treatments, such as BAN2401 or lecanemab with Eisai and programs targeting tau, another pathological hallmark of Alzheimer's disease.

Finally, ADUHELM represents a significant step forward in our goal of transforming **Biogen** from what was once an MS company to one that is built upon a multi-franchise portfolio across a broad spectrum of neuroscience therapeutic areas. This is a pivotal moment in **Biogen** story, making 2021 a transformative year for our company.

Let me now provide more details about our launch readiness in the U.S. First, we have engaged with key medical experts to discuss the importance of early diagnosis and mild cognitive impairment as a stage of Alzheimer's, as well as the latest scientific understanding of biomarkers in this disease. Second, the desire to confirm amyloid beta pathology by physician could be a major bottleneck. With this in mind, we have established a program with Labcorp and Mayo Clinic Laboratories to help physicians and patients access CSF diagnostic laboratory testing to aid in the diagnosis of Alzheimer's disease. And we continue to advocate for PET reimbursement from CMS joining a coalition of health care organization who supports a revised coverage policy.

Third, our plan addresses site readiness and focuses on multiple phases of the patient journey from formulary approval to infusion center capacity and reimbursement. Based on our work to date, we estimate there are over 900 sites ready to implement treatment with ADUHELM shortly after approval. These sites include clinical trial centers with currently confirmed amyloid beta positive patients, as well as other sites with the necessary infrastructure to diagnose and treat patients.

 

When considering ADUHELM's value proposition, it is important to note that this therapy was studied in early-stage patients. There are several aspects of treatment with ADUHELM that we believe will likely make it a treatment handled mainly by specialists in collaboration with primary care physicians. In determining the price, we engaged with stakeholders, including clinical experts, health economics, policymakers and payers on ADUHELM, and we remain true to **Biogen**'s pricing principles.

With this consideration in mind, we have priced ADUHELM at WAC of approximately $56,000 per year for an average patient of 74-kilogram at the full maintenance dose. We expect the cost during the first year to be lower due to the dose titration resulting in an average WAC of approximately $41,000 for an average patient. Importantly, we have committed to not increasing the price of ADUHELM for the next 4 years.

One critical near-term priority for the launch will be securing payer coverage. The vast majority of Alzheimer's patients in the U.S. are 65 or older. And as a result, most of our patients are expected to be covered by Medicare, either through fee-for-service or Medicare Advantage. For Medicare fee-for-service, coverage is automatically presumed with FDA approval. We expect most Medical Advantage plans to define their medical policies within the first several months after launch. **Biogen** is committed to an equitable launch with a goal of maximizing access for all patients with early-stage Alzheimer's disease, including the underserved population which can be disproportionately impacted.

We are pursuing value-based contracts with payers such as Cigna to help streamline patient access to treatment. We are working with providers groups such as CVS as well as the National Association of Free and Charitable Clinics, which have neighborhood level reach with the goal of engaging underserved people in their local communities to provide them with education about mild cognitive impairment and to enable access to cognitive screening. And we are working to finalize a multiyear agreement with the Veteran Health Administration in order to support access for veterans.

In summary, we are incredibly humbled to bring ADUHELM to the Alzheimer's community. **Biogen** is ready for this launch, and we look forward to making this therapy available to patients.

I am pleased to now pass the call to Al, who has dedicated much of his career to the pursuit of therapeutic advancements for patients suffering from neurological diseases. Together with Samantha and our talented teams within **Biogen** R&D, they are all instrumental in making this moment a reality.

ALFRED W. SANDROCK, EVP OF RESEARCH & DEVELOPMENT, **BIOGEN** INC.: Thank you, Michel. Our team at **Biogen** has worked so hard for so many years and with the disappointments, criticism and even ridicule, but we believed in each other and had faith that if we follow the science, always with the goal of doing what's best for patients, we would get here. I am very proud to be part of the **Biogen** team.

We stand on the shoulders of many talented scientists, clinical investigators and drug developers in the Alzheimer's disease community, having learned as much as we could from their hard work, their discoveries, and the results of their clinical trials over several decades. And of course, we would not be here without the patients who volunteered to participate in clinical trials. We are so happy to be able to offer this drug to them and the many other families that are affected by this terrible disease.

Alzheimer's disease is the most common neurodegenerative disease and the most common cause of dementia. The brain in Alzheimer's disease atrophies due to neurodegeneration. The histological hallmarks of the disease are the amyloid plaques and the neurofibrillary tangles. Several decades ago, biochemical studies showed that the amyloid beta protein is the main constituent of the amyloid plaque and that the microtubule associated protein tau is the main constituent of the neurofibrillary tangle. Amyloid plaques and neurofibrillary tangles are defining pathologies of Alzheimer's disease.

Alzheimer's research has benefited from the advent of tracers that estimate the amount of amyloid beta protein in the brain by positron emission tomography or PET. On the bottom left are PET images in a 68-year-old person who is cognitively normal and a 68-year-old person with Alzheimer's disease using Amyvid, the amyloid PET tracer approved by FDA in 2012. This technology allows for the measurement of amyloid plaque burden over time in individual patients and has contributed immensely to our greater understanding of Alzheimer's disease as well as enabling drug development.

As depicted in the figure from the 2013 paper by Clifford Jack and colleagues, we now understand, based on CSS studies and imaging, that Alzheimer's disease begins many years prior to the onset of symptoms beginning with alterations in the biology of amyloid beta and the accumulation of amyloid plaques. The accumulation of tau pathology follows and the structural as well as metabolic changes associated with neurodegeneration are then

 

also seen. Thus, the temporal sequence of events is consistent with the notion that abnormalities of the amyloid beta protein pathway is a key initiating pathophysiology.

Advances in biomarker research have led the field to modify how we think about Alzheimer's disease. To quote a paper published by Paul Aisen and colleagues in 2017 in the journal Alzheimer's Research and Therapy, "Advances with biomarkers have also prompted a shift in how the disease is considered as a clinical pathophysiological entity. With an increasing appreciation that Alzheimer's disease should not only be viewed with discrete and defined clinical stages, but as a multifaceted process moving along a seamless continuum."

We licensed aducanumab from Neurimmune back in 2007. After 4 years of preclinical studies to elucidate the biochemical properties of the antibody and to define the doses and drug exposures necessary to engage the target and reduce amyloid beta in transgenic animals, we began clinical trials in 2011. After determining the maximum tolerated dose in a single ascending dose trial, we conducted Study 103, PRIME in patients with early Alzheimer's disease.

I had mentioned previously the lessons learned from the Alzheimer's research community over the years. Key among them were: one, we had to go to earlier stages of disease; two, we had to select patients with appropriate biomarkers to be sure that they actually had amyloid in the brain, which is our drug target and also necessary for the diagnosis of Alzheimer's disease; and three, we had to go to doses that would lead to a reduction of amyloid plaque.

We incorporated all of these learnings into the design of the PRIME study, that is we studied patients with prodromal or mild Alzheimer's disease, all patients enrolled were positive on amyloid PET scans during screening, and we studied a range of doses up to the maximum tolerated dose. PRIME, which read out in 2014, showed that aducanumab treatment led to an observed dose and time-dependent reduction of amyloid plaque over the course of 1 year. We believe that this was the first study to show that a drug can reduce amyloid plaques in the human brain.

Based on these findings, we began enrolling patients into the pivotal trials ENGAGE and EMERGE in 2015. These trials were terminated in 2019 prior to their planned completion. Study endpoints were analyzed based on the prespecified statistical analysis plan, and we filed for approval with FDA in July of 2020. It has been a long journey, and we are committed to continuing this journey, to continuing the EMBARK long-term extension study, to conducting the required confirmatory trial to verify the clinical benefit of aducanumab and to gathering real-world evidence in patients treated with aducanumab.

We hope that the accelerated approval of aducanumab based on observed reduction in amyloid beta plaques marks the beginning of a new era for innovation in Alzheimer's disease and believe that more treatments addressing the core pathophysiology of the disease will follow.

I will now -- I would now like to pass the call over to Nicole.

NICOLE MURPHY: Thank you, Al. With a strong focus on operational manufacturing excellence, **Biogen** is positioned to launch ADUHELM and begin serving patients. Our global manufacturing network, advanced supply chain and talented workforce will enable us to supply this innovative therapy to patients in the U.S. And if approved, eventually globally.

We have currently completed all operational readiness activities to enable launch, utilizing our extensive global manufacturing and supply capabilities across our integrated network. Throughout the pandemic, we have leveraged our strategic supplier relationships to proactively build increased critical raw material and component inventories to risk mitigate anticipated potential shortages related to COVID.

Following our 2019 announcement that we would file aducanumab with the FDA, we immediately responded by adjusting our internal asset production configuration and rapidly increased our capacity through various construction and plant upgrades across drug substance and drug product at our manufacturing campus in RTP, North Carolina. This is certainly a testament to the agility of our talent and our teams. And within just a few short months of the announcement, in February 2020, we had progressed required manufacturing upgrades and had initiated our first campaign of aducanumab in RTP.

Since then, we have continued to manufacture aducanumab in our internal plants and with strategic third-party CMOs in order to ensure adequate inventory would be available at the time of launch. I'm very happy to share, and as Michel indicated earlier, we expect to begin shipping product in about 2 weeks' time.

 

Through our strong end-to-end supply chain, we believe we will also be ready to supply aducanumab beyond the U.S. in various potential global markets, if approved. At **Biogen**, we utilize one of the largest bioreactor capacities in biotech, and we plan to leverage our **Biogen** manufacturing campuses in both North Carolina and Solothurn, Switzerland to produce aducanumab. As I previously mentioned, we plan to utilize our U.S. site in North Carolina for the initial supply of aducanumab.

RTP is a site driven by adaptability and agility and has a long track record of success with facilities that support multiple production scales and across multiple modalities. The site also has an impeccable inspection record with no major or critical observations that represented a quality system deficiency in any regulatory inspection. Our next-generation manufacturing facility in Switzerland recently received its multiproduct GMP license with the Swissmedic authorities, and we plan to file a prior approval supplement for aducanumab with the FDA later this year. If approved, Solothurn would be our primary source of drug substance with RTP acting as a critical dual source and backup as we seek to ensure a resilient supply to patients.

I'll now provide a bit more detail on Solothurn's high-throughput manufacturing capacities, capabilities and optionality for future additional manufacturing sales should they be needed. **Biogen** embarked on one of the largest state-of-the-art biological facility builds in 2015. This has been a multiyear journey enabled by an investment of approximately $2 billion, providing us with multiproduct, large-scale, high-throughput capabilities, incorporating some of the most advanced manufacturing technologies available. We are currently producing aducanumab in one of our two biological manufacturing cells, with the second expected to be fully operational within the next few months dependent upon aducanumab demand and needs. This would result in 148,000 liters of production capacity fully operational in Switzerland.

The new fully automated facility is equipped with the latest technologies, which we expect will drive process robustness intensification and allow for real-time control of quality. Compared to benchmarks, aducanumab is one of the highest fed-batch upstream processes in industry with demonstrated batches above 10 grams per liter. This is accomplished through a variety of things, including new equipment technologies, raw material optimization and enhanced cell line and media formulations. This, coupled with the latest development of high-capacity purification, is expected to enable delivery of greater than 10 metric tons of protein per year.

And Solothurn is aligned with **Biogen**'s long-term commitment, healthy climate, healthy lives, to accelerate action on the greatest challenges of our time, climate, health and equity. The facility incorporated multiple design features to maintain lowest possible emissions, reduced water and reduced energy consumption. And we plan to continue to implement new technologies as they become available to further advance our efforts in the years ahead.

We are also ready to potentially expand capacity as needed. As previously mentioned, we are currently producing aducanumab in Solothurn. We have just recently received our GMP license from the Swissmedic authorities and are currently preparing our Solothurn specific aducanumab filing for the FDA. Currently, we believe our facility in Switzerland is capable of supplying more than 1 million patients per year. And while we believe this current capacity is adequate in supplying initial patient needs, we are prepared to continue leveraging our overall network capacity across both sites in the U.S. and Switzerland, which could enable supply for approximately 2 million patients per year.

We are also actively engaged in further innovation with the aim to increase plant efficiencies and process life cycle opportunities to increase supply as well as potentially leveraging additional CMOs as necessary. Importantly, we have completed required activities to begin further expanding the current Solothurn infrastructure to add additional manufacturing cells, if required. This could enable supply for more than 4 million patients per year from Solothurn alone.

In summary, I'm happy to share we have built required manufacturing inventories to launch ADUHELM, and we are also prepared to potentially expand capacities to meet anticipated future needs in the long term. This is an exciting moment in our journey to advance innovation, quality and supply for patients.

Thank you so much for your attention. And I will now pass it over to Mike.

MICHAEL R. MCDONNELL, EXECUTIVE VP & CFO, **BIOGEN** INC.: Thank you, Nicole. We are very excited about the opportunity that ADUHELM represents. Let me now review the U.S. market and financial opportunity, accounting considerations related to our collaboration with Eisai and our financial guidance.

As Michel mentioned earlier, ADUHELM is the first and only approved therapy to address a defining pathology of Alzheimer's disease. We believe ADUHELM represents a significant long-term growth driver with modest revenue in 2021 ramping to a multibillion-dollar U.S. sales opportunity over the next several years. Today, we estimate

 

there are approximately 1 million to 2 million patients in the U.S. that have been clinically diagnosed with MCI or mild dementia suspected to be due to Alzheimer's disease, who would be amyloid beta positive, if tested.

It is important to note that we do not expect all of these patients will be treated with ADUHELM for a variety of reasons, including appropriate patient selection criteria and limited capacity of specialists. Further, we believe the majority of diagnosed patients are not currently under the care of a specialist. And as a result, we expect gradual uptake over time.

Looking at our near-term revenue potential. As we have stated in our 2021 full year guidance, we have assumed modest revenue in 2021 due to dosing titration, the need for sites to prepare to diagnose and treat patients, and the time that it will take to secure payer coverage. Titration results in less revenue per patient in the initial months of treatment and plays a role in how quickly revenue can ramp. Of note, the maintenance dose is approximately 3x higher when compared to the average dose in the first 6 months of treatment.

We expect revenue to start ramping in 2022 and beyond as we believe that detection and diagnosis of early Alzheimer's disease will increase. System capacity will increase due to greater physician focus on treating dementia, site infrastructure will continue to scale, and the availability of amyloid testing and reimbursement will increase for both PET and CSF.

While we are focused on the U.S. today, I want to remind you of the overall economics with our collaboration partner, Eisai. **Biogen** and Eisai will conduct co-promotion activities with a region-based profit split. **Biogen** will be the commercial lead in the United States and the European Union with a profit share of 55% and 68.5%, respectively. Eisai will be the commercial lead in Japan and specific Asian territories where **Biogen** will retain a 20% profit share. In all other territories, inclusive of China and South Korea, **Biogen** will be the commercial lead with a 50-50 profit share.

Let me now review some of the accounting considerations for our arrangements with Eisai and Neurimmune focusing on territories where **Biogen** is the commercial lead such as the U.S. First, it's important to note that before launch, both R&D and SG&A are recorded net of reimbursement from Eisai in our P&L. Starting at launch, which in the case of the U.S. will be Q2 2021, **Biogen** will book 100% of revenue, cost of goods sold and SG&A expense. Eisai's share of revenue, cost of goods sold and SG&A expense will be recorded through a separate expense line called collaboration profit sharing. R&D expense will continue to be recorded net of reimbursement from Eisai in the R&D expense line. All of these items will be included in income from operations. These post-launch accounting changes will be made retroactive to April 1, 2021.

At steady state, we expect the cost of ADUHELM manufacturing to be slightly higher than our other biologics products. Our SG&A expense will include the necessary investments to build out our ADUHELM infrastructure. In addition, we expect continued investment in R&D, driven in part by the post-marketing study, all of which we will manage within our overall R&D initiatives.

**Biogen** will pay Neurimmune royalties ranging from high single digits to sub-teens on annual net sales, which will be reflected through noncontrolling interest below operating income. In addition, **Biogen** will pay Neurimmune a milestone of $100 million related to the U.S. commercial launch to be recorded in the second quarter through noncontrolling interest. After cost sharing with Eisai and taxes, we expect a net impact of approximately $45 million.

And lastly, I would like to reaffirm our 2021 full year financial guidance. I would refer you to our slides for more detail on some of the critical assumptions that underlie this guidance. Our revenue guidance remains at $10.45 billion to $10.75 billion. Non-GAAP EPS guidance remains at $17.50 to $19, and capital expenditure guidance remains at $375 million to $425 million.

Let me now welcome back Michel for some closing comments.

MICHEL VOUNATSOS: Thank you, Mike. As we begin rolling out our launch in the U.S., we continue to engage with regulators around the world with ADUHELM currently filed in 6 global markets, including the EU, Japan, Brazil, Canada, Switzerland and Australia. Lastly, for **Biogen**, not only that this approval validates over a decade of cutting-edge science and hard work, it also represents a significant step forward towards building our vision of a multi-franchise portfolio, adding a new pillar of growth and value creation.

Over the long term, we aim to build on the approval of ADUHELM as we know there is more to do in order to meet the unmet medical needs of all Alzheimer's patients. This is why we're advancing a broader Alzheimer's pipeline across therapeutic targets and modalities, including lecanemab or BAN2401 and other anti-amyloid antibody that targets aggregated forms of amyloid similar to ADUHELM. In collaboration with Eisai, lecanemab is

 

currently being evaluated in a Phase III clinical study in early Alzheimer's disease as well as another Phase III study evaluating the potential therapeutic benefit in asymptomatic Alzheimer's disease and additional approaches targeting tau another pathological hallmark of the disease.

Through this pipeline, we aim to further build on the exciting approval and launch of ADUHELM to potentially establish **Biogen**'s leadership in Alzheimer's disease. 2021 is truly a transformative year for our company.

I would now like to open the call for questions.

Questions and Answers

OPERATOR: (Operator Instructions) Your first question comes from the line of Umer Raffat with Evercore.

UMER RAFFAT, SENIOR MD & SENIOR ANALYST OF EQUITY RESEARCH, EVERCORE ISI INSTITUTIONAL EQUITIES, RESEARCH DIVISION: Let me start by sharing a comment and then the questions. Congratulations to you, Michel, Al and Samantha. I know it's months and months of hard work and congrats again on that. I also wanted to mention just before I ask my question that I do think there's a disconnect between some of the words that you've shared in your press releases like responsibility, access, health equity versus the price point, especially given the primary care population, which leads me to my question, which is, can we perhaps dig into a little more detail on the thought process behind the price point of $56,000, considering it's a primary care population, considering there's no outcomes benefit?

And also, one of the things I was hoping to learn a little more was, perhaps there's a value-based pricing contract, which actually drops the net price for a certain subset of patients. But it wouldn't necessarily be easy to do that because it's impossible to tie it with CDR sum of boxes. So if you could help us understand what parameters the value-based pricing contracts would tie you to.

MICHEL VOUNATSOS: Thank you, Umer. The pricing is a very important consideration at launch. And I can tell you that we've spent many months of engaging broadly. We believe that the price is substantiated by the value it is expected to bring to patients, caregivers and society. We are obviously open to considering value base. And I know it's not easy. And I know there is not a full commitment of the U.S. market to move to value base from fee-for-service. And **Biogen** has been a leader since years having small regional, large regional or national value-based contracts in MS.

But the uptake is challenging because you can't change the market alone. One thing is the price set based on the value we believe it delivers to patients. One thing is to secure sustainability of the system by engaging and partnering with the payers and also serving the underserved population, which is absolutely at the heart of our mission. Allow me to ask Chirfi Guindo to tell you a bit more about our work and price setting.

CHIRFI GUINDO, EVP OF GLOBAL PRODUCT STRATEGY & COMMERCIALIZATION, **BIOGEN** INC.: Thank you, Michel. Thank you, Umer, for the question. Just to give a bit more background in terms of our thinking, Umer, we've been at this for months, as Michel suggested, we've consulted extensively with experts, health economists, clinicians, policy and payer leaders. And we have taken also into consideration the **Biogen** pricing principles. I will summarize those principles into 3 main categories, Umer.

The first one is really the value that ADUHELM brings to patients, caregivers, really importantly, caregivers, and society as a whole. The second element is our commitment to fund future research, not just in Alzheimer's, but also in other neurodegenerative diseases such as ALS, Parkinson's and so on. And then the third element really is affordability. So we want to make sure that there are -- that ADUHELM is affordable for patients and sustainable for health care systems. With that in mind, we have voluntarily committed to not taking any price increase over the next 4 years. That's a really important commitment we're making. And we're also remaining open-minded. So we're going to monitor, we're going to learn over the next 4 years to see how the uptake takes place.

I would also highlight, Umer, that we consider ADUHELM to be a specialty product, right? So this is a product that is most likely to be initiated by specialists. It is not a primary care -- a typical primary care product in that sense. With that in mind, we have looked at analogs. There is no perfect analog in this space, but we have certainly looked at biologic -- specialty biologics recently launched in the United States, such as, for example, cancer immunotherapies. We've also looked at the psoriasis biologics recently launched. And we have priced ADUHELM at roughly 1/3 the level of the cancer immunotherapies and roughly 25% below the average level of psoriasis biologics. So we consider this to be a really responsible price, and we consider this to be a price that is sustainable for the system.

 

OPERATOR: We'll go next to Marc Goodman with SVB Leerink.

MARC HAROLD GOODMAN, MD OF NEUROSCIENCE & SENIOR RESEARCH ANALYST, SVB LEERINK LLC, RESEARCH DIVISION: So what will you tell the doctors about how long that the patient should stay on the drug? I'm just curious about your interactions with the payers and what the payers are saying about how long they'll pay for the drug.

MICHEL VOUNATSOS: What an important question and the fascinating part of science that yet did not deliver its full answer. We see benefit in our long-term extension of our Phase I PRIME B study 5 years after dosing. And this is certainly an era that we need to continue to investigate. Al will add more color.

ALFRED W. SANDROCK: I agree with you, Michel. We continue to see reduction of amyloid plaque over many years in the extension study. We also heard from patients, many of them testified at the FDA Advisory Committee that when aducanumab was stopped after years of treatment, that they didn't feel quite as good and they felt worse. And then they felt better when they were restarted. You heard that testimony. And so -- and I also agree that this needs further study.

MARC HAROLD GOODMAN: And the payers are not going to limit you to a short period of time, for instance, like the 18 months that were in the studies? The discussions are basically the payers are going to pay for many years?

ALFRED W. SANDROCK: I see no reason to limit it to 18 months based on the data we have at hand.

OPERATOR: We'll go next to Matthew Harrison with Morgan Stanley.

MATTHEW KELSEY HARRISON, EXECUTIVE DIRECTOR, MORGAN STANLEY, RESEARCH DIVISION: I was hoping you could just comment on some of the mechanics around near-term launch. So for example, how you think not having a J-code for maybe the first 6 months will impact uptake and what you think about the need for an MRI within the past year, what proportion of patients you think may have that? And then any other factors we should consider as we think about maybe the first 6 to 12 months of launch?

MICHEL VOUNATSOS: Thanks for the good question. I'm very pleased with the progress our U.S. team was able to make over months. We are ready to launch. And obviously, we have some launch assumptions. And we assume that at least at the outset, the specialists will be front and center in collaboration with the primary care, and gradually, we will expand. We are ready in terms of sites, manufacturing, advocacy support.

We are absolutely determined to engage the customers based on the entry criteria of our trial. So we're more focused on where we have the data, which is the early stage of the disease, but we know that these are assumptions, and it will take a few weeks in order to validate those. Alisha, the President of the U.S. **Biogen** Organization, will give a bit more color. Alisha?

ALISHA A. ALAIMO, PRESIDENT OF **BIOGEN** U.S. ORGANIZATION, **BIOGEN** INC.: Thank you, Michel, and thank you, Matthew, for your questions. So 2 answers for you. The first, as you asked about the J-code, which is actually a very insightful question. We do expect the product-specific J-code to be fully implemented by early 2022. Now with any new infusion product, there's always a time when a J-code -- there's always a time when we have to wait for the J-code to be available. And typically, what sites do is they will use a miscellaneous code. Until then, we will launch a number of initiatives to help sites manage their potential concerns.

However, another important part of your question is that our teams have spent this past year understanding and profiling the landscape of potential sites of care for an amyloid beta-directed antibody to treat Alzheimer's disease. Because this will take a multidisciplinary approach to treat a patient with ADUHELM, rather than segmenting prescribers, we segmented sites of care, and we're very rigorous with our methodology. We profiled approximately 1,200 accounts which we believe at some point had a relationship with the large majority of the patients who have a clinical diagnosis of Alzheimer's disease.

Now the really great news is that we expect a core group of these sites, that they will be ready to move really quickly. Now we believe, and you heard Michel say, that there are over 900 accounts ready. Let me tell you what ready means. Ready means that they have the required capabilities, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy. Now that ADUHELM has been approved, we have local teams throughout the entire country that will prioritize the 900 accounts to support site activation, while our expectation is that more sites are going to become ready in parallel. And our teams are laser-focused on getting this product to as many appropriate patients as possible. I hope that answers your question.

 

OPERATOR: We'll go next to Michael Yee with Jefferies.

MICHAEL JONATHAN YEE, EQUITY ANALYST, JEFFERIES LLC, RESEARCH DIVISION: Let me extend my congrats as well to Al and the team. Maybe Al or someone on the team could address the concept of the patient journey, specifically as it relates to a requirement for a PET scan, the broad label where neurologists appear to be able to treat sort of whoever they think is appropriate per se. And then IV capacity and how that would work? And it would seem to be no more different analogous to TYSABRI or OCREVUS or something like that from neurologist. So maybe you could address that patient journey along that way.

MICHEL VOUNATSOS: Thank you, Michael. As you saw in the label, basically, the regulator is giving the responsibility for the physician for addressing the clinical aspect or the biomarkers to determine the diagnosis. And I think this is very important to notify. Alisha, you want to say a bit more about the patient journey?

ALISHA A. ALAIMO: I will. Specifically, I will comment, Michael, on the amyloid confirmation because what I can probably take a little bit from your question is that you think that, that potentially could be a bottleneck or that there will be a vast majority that will be doing it. So you are correct, the label does not require confirmation of amyloid pathology. The necessity of testing, as Michel has said, has been left to the judgment of the prescribing physicians and as the label states, ADUHELM is an amyloid beta-directed antibody.

Since there hasn't been an approved therapy that is amyloid beta-directed, amyloid confirmation isn't a routine clinical practice of today, and there is currently no reimbursed test for amyloid. Therefore, the majority of patients have not yet been amyloid confirmed. But **Biogen** believes access to this testing should be easily available and affordable. Therefore, we've established a program, as you heard Michel say in his opening remarks, with Mayo Clinic Labs and Labcorp to help physicians and patients access cerebrospinal fluid diagnostic laboratory testing.

Also, as Michel had referred to, we are continuing to work with the coalition of health care and advocacy organizations to support a pathway to PET reimbursement from CMS, and we believe we will need both the CSF test and the PET reimbursement.

OPERATOR: We'll go next to Jay Olson with Oppenheimer.

JAY OLSON, EXECUTIVE DIRECTOR & SENIOR ANALYST, OPPENHEIMER & CO. INC., RESEARCH DIVISION: Congratulations to everyone at **Biogen** for having the perseverance to get ADUHELM approved. My question is related to the diagnostics available for early Alzheimer's. And I was wondering if you could compare and contrast amyloid CFS (sic) [CSF] testing with amyloid PET imaging. It seems like both methods are equally accurate at diagnosing Alzheimer's, but some patients may prefer PET imaging because it's less invasive, even though it might be less accessible and more expensive. And then you may have regional differences, like I've heard that Europeans are more receptive to CFS (sic) CSF testing compared to patients in the U.S.

MICHEL VOUNATSOS: Thank you for the important question. It's fascinating to see the geographical differences into accepting CSF test versus alternatives. Critical to see how technology is progressing fast, and I want to believe that soon we'll have also a blood diagnostic and this will make things much easier. Al and Samantha will add to this very important topic, because it is a broad population, as you know, and to ease diagnostic in addition to the clinic is critical with a biomarker.

ALFRED W. SANDROCK: Thanks, Michel. Yes, we and others in the field have been very interested in understanding the correlation, the concordance between PET imaging and CSF. And I'm happy to say that all of us find a very high concordance. In our hands, it's up -- it's greater than 90% if we compare, for example, amyloid PET scans versus CSF. And other people have confirmed that. And so either option, I think, is available. And in our clinical trials, you're right, we tend to get more CSF from European sites than we'd get from American sites.

MICHEL VOUNATSOS: Samantha?

SAMANTHA BUDD HAEBERLEIN, VP OF CLINICAL DEVELOPMENT, **BIOGEN** INC.: Yes. Thank you, Al. To expand on that, in our EMERGE and ENGAGE studies, we did do -- we tested 4 concordance between CSF and PET and the sensitivity and specificity was in the 90s. So from a technical standpoint, it's absolutely correct. These 2 methodologies are literally selecting the same patient population. But there are definitively geographical and cultural differences, which is why we believe it's really important to have both methodologies. And as Michel said, hopefully, in the future, also blood test. Alisha, maybe you'd like to comment on the availability of the 2 tests.

ALISHA A. ALAIMO: Yes. Thank you. And Jay, you referenced something very interesting in your question. You talked about maybe a patient preference. I'd like to tell you a little bit why we need both PET and why we need the CSF testing. We need PET because the lumbar puncture will not be for everyone. About 30% to 40% of the

 

patients might have contraindication with taking blood thinners or anticoagulant. And the reason why we need the LP is because there are going to be rural areas of the country who will struggle with getting the ligand of the cyclotron in the sufficient amount of time due to the half-life. So for example, Hawaii will have a big problem with getting the ligand there. So there are areas of the country who are going to need the CSF testing.

OPERATOR: We'll go next to Cory Kasimov with JPMorgan.

CORY WILLIAM KASIMOV, SENIOR BIOTECHNOLOGY ANALYST, JPMORGAN CHASE & CO, RESEARCH DIVISION: I'll add my congratulations to the team on this pretty momentous approval. Wanted to follow up on pricing. What's your expectation for the out-of-pocket cost for a Medicare patient? And how concerned are you about Medicare budgets and the backlash the industry may face over this price point? And how much did that factor into your consideration of choosing this price?

MICHEL VOUNATSOS: Thank you for the question. And obviously, as you're well aware, there is a -- the coverage will be fragmented the way it is between commercial, Medicare, Medicaid. And my colleagues will give more details on the budget and the way we engage with CMS and the authorities as good partners. And Alisha will add too on what it means as per the different segments of the Medicare plan. We anticipate that 80% of the lives will be covered by Medicare, approximately. Medicare is also fragmented in terms between Advantage, fee-for-service. Chirfi, on the overall sustainability, critical.

CHIRFI GUINDO: Yes. So thank you for the question. So we believe that the real budget impact of Alzheimer's in the United States, according to the Alzheimer's Association, is about $600 billion a year. So the real question is, what would happen if you have a treatment that might have a meaningful impact on the total cost? That's kind of how we would like to frame the conversation. Having said that, as we discussed earlier, we believe that with our responsible pricing, our willingness to engage and learn in the coming years, we will be working with CMS. We will be working with the private payers to make sure that there is sustainability in the total budget.

The last thing I'll say before I hand over to Alisha is we do not foresee a kind of a hockey stick effect, which was seen in other areas, other product introductions. This is going to be a gradual increase, as Mike mentioned, because you need infrastructure for care and you need a testing and the patient journey that was alluded to. So the budget overall is one that will be predictable, and we will work with the payers to make sure that it is sustainable for the system.

ALISHA A. ALAIMO: Thank you, Chirfi. And obviously, this is a very important question. I love that you asked it. Because as you know, the cost that's typically in the headlines is always the wholesaler acquisition cost. However, patients really want to know what their out-of-pocket costs will be. Patient out-of-pocket costs are highly dependent on their insurance coverage. Now keep in mind, as Michel has said, the majority of the Alzheimer's patients are going to be over 65 or older, and they're expected to be covered by Medicare either through fee-for-service or Medicare Advantage. So here's a couple of differences for you.

Most Medicare fee-for-service enrollees also have secondary coverage, and this limits their out-of-pocket exposure, which is a good thing. Patients who are covered by Medicare through a Medicare Advantage plan have a maximum annual out-of-pocket cap. And this will also vary by plan that each patient is on. Now for the eligible commercially insured patients, we do have in place co-pay and infusion cost assistance programs that may reduce the out-of-pocket costs to as low as 0. **Biogen** and Eisai are committed to providing access to ADUHELM for patients across a spectrum of financial situations.

OPERATOR: We'll go next to Paul Matteis with Stifel.

PAUL ANDREW MATTEIS, CO-HEAD OF THE BIOTECH TEAM, MD & SENIOR ANALYST, STIFEL, NICOLAUS & COMPANY, INCORPORATED, RESEARCH DIVISION: Great. Let me add my congratulations. I wanted to ask what percent of the 1 million to 2 million target patient population is treated at or within a referral of these 900 centers that are ready at launch? And what percent do you think will be treated at or within a referral of a center that can kind of viably give this drug and navigate all the logistic considerations a couple of years from now?

MICHEL VOUNATSOS: Another fascinating question. And as you can anticipate, we will discover in the coming weeks a bit the dynamic and how the patients will be pulling and asking for access. We had already many, many calls and patients moving to the specialty centers. Alisha will give a bit more. But we'll have the opportunity to update you on what we see in a few weeks from now and beyond. Alisha?

ALISHA A. ALAIMO: Yes. Thank you, Paul, for the question. Now there have been a lot of numbers that have been thrown around about patient populations. And once you account for getting a clinical diagnosis and testing

 

positive for the pathology of amyloid, we believe that there may be 1 million to 2 million patients, as you have said. Now not all those patients will go on ADUHELM for a variety of reasons. They need to be the appropriate patient. However, as I referenced earlier in an answer, we profiled 1,200 sites. Those 1,200 sites, which are centers of very high volume and the ones that have the infrastructure and capabilities in place, do account for the large majority of already clinically diagnosed patients.

So we believe, right now, we have absolutely the right footprint at launch. We are covering a large proportion of those patients. And as we launch and as we learn, we will be readying sites in parallel to the other sites coming online. So we have taken a very rigorous methodology, we've targeted and been very laser-focused on who we're calling on.

MICHEL VOUNATSOS: Excellent, Alisha. And be aware that we have partners in Eisai that have tremendous experience in the field, and we are ready to expand. But for the launch, we have really a very rigorous segmentation so that we secure that the foundation is strong around the specialist and gradually, we will expand.

MICHAEL HENCKE: Operator, I think we have time for about 2 more questions.

OPERATOR: We'll go next to Terence Flynn with Goldman Sachs.

DANIEL BENJAMIN ZIMENT, RESEARCH ANALYST, GOLDMAN SACHS GROUP, INC., RESEARCH DIVISION: This is Dan on for Terence. Is there any initial perspective you can share on the design of the confirmatory trial and plans for enrollment if it includes the placebo arm?

ALFRED W. SANDROCK: Terence (sic) [Dan], yes, this is Al. We are still in discussions with FDA, with our advisers, and we will be disclosing the details of the planned confirmatory trial at a later date.

MICHAEL R. MCDONNELL: And I'll just quickly add to that. You'll see in our reaffirmation of guidance today that we reaffirmed our guidance for the year, which included an R&D estimate of about $2.3 billion to $2.4 billion. And we manage our R&D budget holistically, and that will include the confirmatory trial. It'll all be managed within the context of our overall initiatives in R&D and our business model.

OPERATOR: We'll take it from Phil Nadeau with Cowen.

PHILIP M. NADEAU, MD & SENIOR RESEARCH ANALYST, COWEN AND COMPANY, LLC, RESEARCH DIVISION: Let me add my congratulations on this landmark approval. One question from us on your discussions with payers, particularly Medicare. What do you expect the insurers to do to limit access? Do you expect them to have prior offs? Will patients need PET scans before they can get reimbursement? What gates in your preliminary conversations have you encountered that insurance might put up to limit reimbursement to appropriate patients?

MICHEL VOUNATSOS: So before Alisha gives you more details, I just want to say that this is now more than a year that we're engaging with public and private payers. And we are pleased with the level of engagement. And obviously, now we are even closer to secure that we do things as well as we can. Alisha?

ALISHA A. ALAIMO: Yes. Thank you, Michel. And thank you, Phil, for the question. This is a tough one because it's not one we can really speculate on at this stage, but I do have a couple of things I can share with you. Prior to launch, our teams have been working closely with both commercial and government payers. And what I can tell you is that our commercial teams will be discussing patients consistent with those studied in ADUHELM's clinical development program with their customers. Now we've already talked about the majority of patients being on Medicare. And for Medicare fee-for-service, coverage is automatically presumed with FDA approval, and we expect most Medicare Advantage and commercial plans to define their medical policies, which is in reference to your question, within the first several months after launch.

Now we do believe patients should have access to ADUHELM, which is why innovative contracting is an important part of our launch approach. We have engaged, as you might have seen in our press release, with a small number of strategic partners, including Cigna and the Veterans Health Administration, on innovative or value-based contracting. For example, Cigna and **Biogen** intend to enter into a value-based contract to ensure there is a streamlined path to access treatment for patients consistent with the population in which ADUHELM was studied. And with the VA, we are finalizing a multiyear agreement in order to support access to ADUHELM for veterans who are historically underserved and racially diverse. Our market access teams are continuing to engage with the payers to communicate the clinical data for ADUHELM, so they are able to make the appropriate decisions in the days ahead.

 

MICHEL VOUNATSOS: Thank you, Alisha. Thank you for being with us today. As you can sense, the **Biogen** team is ready. We are looking forward keeping you posted as we progress with the launch of ADUHELM in the near future.

Thank you all for your attention.

OPERATOR: This concludes today's call. Thank you for your participation. You may now disconnect.

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