Biogen Inc.

Biogen Inc. presents at Jefferies 2024 Global Healthcare Conference

Wednesday, June 5, 2024 12:30 PM

Event Participants

Analysts 1
Michael Yee

Executives 2
Michael McDonnell, Priya Singhal

Michael Yee Analyst

All right, good. So welcome, everyone. Thank you for joining us on our next fireside discussion. Up here, we have two members of the senior management team of Biogen. To my far left is Priya Singhal.

She is Head of Development. So we're going to have lots of great R&D questions. maybe hit on Alzheimer's a little bit and a whole bunch of other pipeline programs; as well as the CFO, Michael McDonnell. Great to have you with us.

Obviously, Over the last year or so, it's been a great focus around the launch of LEQEMBI with your partner, Eisai, as well as an acquisition that you guys made. We'll talk about SKYCLARYS. And obviously, it's just been so much focused around Alzheimer's. I feel like everything else sort of falls under the wayside. But it is important.

Michael Yee Analyst

And so I would love maybe Mike or Priya, you could just start off a little bit from a high-level perspective about your perspective on the LEQEMBI execution this year. And whether you guys feel that this is going to pick up, accelerate, get better? How do you guys feel about LEQEMBI?

Michael McDonnell Executive

Sure. So thank you, Mike, and thank you, everyone, for joining us, and thank you to Jefferies and to Mike in particular, for having us here at this -- at the conference. And just a quick reminder that Priya and I may make some forward-looking statements today, and actual results may differ. I refer you to our SEC filings and our risk factors for further information. As it relates to LEQEMBI, I would say, first and foremost, the launch continues and progress is

gradual and that is exactly what we expected from the beginning.

This is truly a pioneering effort. This is something that hasn't been done before. You may have seen in the first quarter, we did start to see some progression in patient uptake. We ended the first quarter or we reported in the first quarter about 2.5x the number of patients that we reported in the fourth quarter. Interestingly, about 70% of the patients thus far have come through some of the smaller networks, the, call it, top 100 integrated delivery networks have only delivered maybe about 30% of the patients, and we found that some of the smaller centers have maybe been a little bit more nimble in terms of being able to get patients through the process.

The #1 bottleneck continues to be getting patients in to see neurologists and to see specialists. Reimbursement is going well, getting patients through PET scan, getting them diagnosed. We're finding the smaller centers are a little more nimble, but some of the larger integrated delivery networks are now making progress, and we are seeing forward progress on that. And that's important because a lot of them have satellite locations. And once they get their protocols in place, you may see further progression and proliferation and ability to get more patients on drug.

All of the KPIs continue to go in the right direction. We're not seeing instances of physicians pulling patients off of drug due to lack of utility or for other reasons, it's all progressing, but it's progressing in a gradual way. And I would say that the other thing that's important to remember is that we're not just in the U.S., a lot of the focus as is appropriate is in the U.S., but we also now have an approved product in Japan, in China, in South Korea, and we have 13 other locations that are currently under review. So we continue to believe that LEQEMBI can be a very important and meaningful sizable opportunity for both Eisai and for Biogen.

Michael Yee Analyst

So if -- certainly from a financial community perspective, which is the audience of the conference, and on the webcast, people would look at it and say it's steady and gradual, but the absolute numbers are still relatively small, certainly relative to Biogen size and to the potential blockbuster opportunity. So is there things that can happen over the next 6 to 12 months? Are there things happening that you think will accelerate that? Or you think it's $1 million of growth per month steadily which would not necessarily be where people would like to see it?

Michael McDonnell Executive

Yes, hard to say there aren't a lot of analogs for this one. But probably our best prediction would be more gradual and steady. There's maybe a few catalysts out there that could potentially bend the curve more meaningfully, blood-based diagnostics would be one example. And those exist today, they're not widely used. That's probably the better part of a couple of years away before those are being used commonly to diagnose and get reimbursed.

So as best we can see, again, there are not a lot of analogs. We see this continuing to progress at a gradual pace, and that's consistent with what we had always expected.

Michael Yee Analyst

Is it made -- like talk to me about anything else, would it be -- you're saying it's not PET scan stuff, right? That's not a gating factor?

Michael McDonnell Executive

Now we've been able to see patients getting through PET scan. The biggest bottleneck has been actually getting them in to see specialists. And there's a large addressable population here. This is not a demand issue but many of them are looking to be treated for the first time. And just getting appointments with specialists as a starting point can take a number of months just out of the game.

Michael Yee Analyst

Okay. So your advice, not guidance, is steady growth, and people are tracking IMS numbers and watching this. It's steady. But nothing necessarily that would say it should be an acceleration?

Michael McDonnell Executive

Steady and gradual is how we're seeing it and we'll obviously be reporting all the information that we can on a quarterly basis.

Michael Yee Analyst

Okay. Maybe Priya can talk about the path for subcu. Now on subcu, many people would believe that obviously, longer term, that, that could instill confidence in the market because that would be an easier to administer product. But recently, that was separated into a maintenance type of filing and an induction filing. Can you talk about the maintenance status?

How would that be implemented when it's approved? And then for induction, what are the things necessarily there to file? And how important would that be?

Priya Singhal Executive

Sure. And maybe I can start off with what am I excited about with LEQEMBI, which I think is really the overall product. The clarity we have from our Phase III study, the open-label extension the fact that we achieved bioequivalents, which we demonstrated at CTAD, all of these are really first. And I think that our approach to LEQEMBI with Eisai has always been providing optionality to patients, number one, and that's where subcutaneous formulation comes in. And the second is making sure that we are addressing the full disease where maintenance comes in.

And finally, I think looking out for all different patient populations where we are thinking about presymptomatic AD and our AHEAD 3-45 trial. So I'll come back to your question about subcutaneous formulation. So we initiated a rolling review submission for the maintenance subcutaneous filing, we received fast track designation for this BLA and it is under review right now. The one component that is outstanding is generating 3-month immunogenicity data, and Eisai has communicated that, that will be complete by the end of Q3. So we expect that, that's when the filing will totally be complete.

We have already requested priority review, but the answer to that can be expected when -- once the filing is complete, about 60 days within the filing completion. So if that's true, we would expect an approval decision or a filing -- outcome decision from the FDA in 2025.

Michael Yee Analyst

My math would say by mid-25 for the...

Priya Singhal Executive

Yes. That is our -- that is an estimate, and depends on whether it's priority or standard review as I said.

Michael Yee Analyst

For a maintenance setting?

Priya Singhal Executive

For a maintenance setting. And you asked about how that could change?

Michael Yee Analyst

How would that work?

Priya Singhal Executive

Yes. How would that work? How it would work is really that after the patients complete their initiation or induction phase with intravenous LEQEMBI, they could switch on to an auto injector, which is included in this filing for subcutaneous formulation, which would be administered weekly. And it could be at home or at a medical facility. The exact timing of transition from induction to maintenance.

We are still discussing it with the FDA, but it's in the 18-month to 24-month time frame.

Michael Yee Analyst

Yes. Okay. So to be clear, post month 18 to 24 months of use.

Priya Singhal Executive

That's right.

Michael Yee Analyst

So my actual math would be, well, you could always switch off people from clinical trials, too. But certainly, people who started all the early people started early on LEQEMBI could be about 2 years, they could start swapping over. And again, it's a long-term thing.

Priya Singhal Executive

Exactly.

Michael Yee Analyst

So. Okay. I kind of asked a question on that. I promised you that an analysis that have been done around devices that investors get very nervous about devices and drugs. Is this an auto -- tell me about the auto-injector how fast is it?

What does it entail? Is it used currently for any other drug?

Priya Singhal Executive

It is an auto-injector that we used in the open-label extension subcutaneous substudy. It has about 1.8 ml of drug. It's a weekly injection of 360 milligrams. And that is really what I can share at this point.

Michael Yee Analyst

Is it -- I need to think about that. It's weekly 360?

Priya Singhal Executive

Yes.

Michael Yee Analyst

It's not -- because it used to be two injections, I think, per week. But this is now moving to an auto injector. So it's not two subcu needles. It's one auto-injector.

Priya Singhal Executive

Yes.

Michael Yee Analyst

That's new, I think.

Priya Singhal Executive

No.

Michael Yee Analyst

There was always an auto injector.

Priya Singhal Executive

It's maintenance. And I think that is a different dose from induction. That's the difference.

Michael Yee Analyst

So it's one auto-injector device. Is it a long time? Is it very quick?

Priya Singhal Executive

It's quite quick. It's a few seconds.

Michael Yee Analyst

Few seconds. And that device is novel to this product? Or is it a device that's being used in other approved things, which should sort of help derisk the actual device?

Priya Singhal Executive

Yes. I don't know that we've shared that information. I can come back to you on that.

Michael Yee Analyst

Okay. Okay. All right. But it is in a device. Okay.

And in the induction setting which, people would believe could help accelerate adoption, I don't know, tell us about what's required there to file.

Priya Singhal Executive

Yes. Just for the maintenance, I think that what we believe is that patients as this is a new space with the dementia care and Alzheimer's care, doctors really want to see their patients. So we think that this could be a nice combination where they are -- they have access to their patients in the first part of the induction and then they can slowly transition patients to maintenance subcutaneous. And we think that, that could really help from an infrastructure perspective, but also patient convenience and prescriber convenience perspective.

Moving on to induction. What we saw was that we observed a higher rate of exposure, a higher exposure as well as a higher rate of clearance. And so what that had us thinking about is how do we now optimize this dose to really benefit patients from all perspectives. So that is the exercise that's currently underway. And as of now, Eisai has communicated that we would expect a regulatory decision from the FDA by Q1 of 2026.

which is the fiscal year of 2025.

Michael Yee Analyst

Right. So the guidance from Eisai is on the approval timing, which is Q1 of '26. So by math, that's filing by first half '25, which is around the corner.

Priya Singhal Executive

Sometime in '25. That is correct.

Michael Yee Analyst

And what is required to file, it's some more work because you guys are going to lower the dose.

Priya Singhal Executive

Yes. Yes, there is more work to be done. That is underway currently. We haven't shared all the details of what that work is, but we'll do so at the appropriate time.

Michael Yee Analyst

But it's a lower dose and that may make it a more convenient injection or something because

this also use the auto-injector, same thing?

Priya Singhal Executive

Yes. Well, we're evaluating the total package here. But I think the idea here is that we can optimize dose and it could be a shorter duration of treatment, could have other benefits as well.

Michael Yee Analyst

Okay. All right. So overall, do you think that this is very important for adoption of the drug that it would accelerate things and something to look forward to such that by the continued momentum and uptake of these centers, plus subcu that you think over a 3-year period, do you think we're going to be in a different spot?

Priya Singhal Executive

We could be. I think that there are several things that are happening in parallel. So one is that because we've been out there with LEQEMBI, we are developing the infrastructure, the market, the paradigms. IDNs are looking at their protocols, how do they implement this new DMT for early Alzheimer's disease. And in the meanwhile, we've seen quite a bit of momentum with the blood-based biomarkers.

So by the time this comes to fruition, we believe some of these things could be in place to really provide additional momentum. And I think that by that time, neurologists will also probably be more familiar and comfortable with the new treatment paradigm, which they haven't been thus far.

Michael Yee Analyst

Okay. Two other things going on in this space, and then we'll move on. The European filing had a speed bump because of some regulatory changes in Europe around the Scientific Advisory Group, SAG. And my understanding is that we need to get a SAG scheduled and done. Where do we stand with getting a new Scientific Advisory Group and getting this back on the agenda, so we can get this drug approved.

Because right now, we're kind of in limbo.

Priya Singhal Executive

That's right. So I think overall, we are -- remain in regulatory review in the European Union with EMA. The original SAG neurology or SAG-N was a nulled or canceled. The findings from that were canceled by the European Medicines Agency in -- from a court ruling that was independent of LEQEMBI. And it pertains to identifying conflicts of interest for SAG-N members and attendees.

So really, this was about an unrelated finding. But in subsequent to that, EMA indicated that they also believe that for LEQEMBI, there may have been some SAG-N members that had competing interests. So they canceled it.

Michael Yee Analyst

So let me be clear. So are all SAGs being reorganized or only because your SAG also could have identified some conflicts of those people on it. that they wanted to redo yours. Is it the whole SAG for everybody or just that?

Priya Singhal Executive

This is applying to all SAGs, but exactly what time point they bring in those all SAGs versus the ones that occurred before or after we don't have insight into that. but we were informed of this. And yes, a new SAG has to be formed and put into place.

Michael Yee Analyst

Is that like for the neurology group, it's a SAG for neurology?

Priya Singhal Executive

SAG-N.

Michael Yee Analyst

So they want to do a new SAG. So can we get one going?

Where do we stand with that?

Priya Singhal Executive

Yes. We are waiting for that, and we'll communicate more as that becomes available. But right now, that's what we're waiting for. What Eisai has communicated is that they expect the European regulatory decision to be done by Q3.

Michael Yee Analyst

Repeat that again. Eisai expects the regulatory decision by Q3?

Priya Singhal Executive

Yes.

Michael Yee Analyst

So to give that guidance, that has some confidence that there's going to be a SAG, and that there's going to be a decision and a vote by the third quarter?

Priya Singhal Executive

Well, we expect, yes, that it will be scheduled imminently. I don't expect that the EMA is waiting, but you can imagine that they have a lot of different things that...

Michael Yee Analyst

You do expect a SAG to be scheduled imminently?

Priya Singhal Executive

We expect it to be scheduled, yes.

Michael Yee Analyst

She said imminently. That's how it's resonating with me. Okay. All right. Also, in the U.S., getting back to the U.S., so Europe it sounds possibly imminent.

In U.S., there's a PDUFA -- an Ad Comm for your competitor June 10, I think.

Priya Singhal Executive

On Monday, yes.

Michael Yee Analyst

Monday. Okay. We'll see how many people are going to sit around for all 9 hours watching that. But I don't know what to expect out of that. They're going to talk about a lot of things.

I am is very familiar with the data. And I think there are some risks to it. What do you guys expect? What have you heard? And do you expect that they're going to get approved and launch?

And is that going to disrupt your progress?

Michael McDonnell Executive

So a couple of comments, and then Priya can add. This is a -- obviously, we can't speculate on what the Ad Comm will do or what the regulatory process will be like for the Lilly product. But what we would say is that this is not a demand issue. This is a very large addressable market. I'll repeat what I said before, we continue to believe that this can be a very large opportunity for both Biogen and for Eisai.

We would welcome a second product. In fact, we think it could help open up the patient care pathways a bit and some of the process that needs to be put in place and the infrastructure that needs to be built out could accelerate.

It's important to remember that a lot of neuro specialists are not used to prescribing for Alzheimer's patients. Heretofore, there was not a lot that they could do for them. And so having a second product in place may actually help accelerate awareness and create a bit of a buzz effect, so to speak. So we'll see how it all plays out, but we look forward to just continuing doing what we're doing.

Michael Yee Analyst

Okay. Yes. I mean, if two drugs are out there on the market approved it's kind of hard to ignore that from a patient or physician perspective. Okay. So let's move from that to SKYCLARYS.

So SKYCLARYS was off to a great launch. He's off to a great launch. And the Street views maybe the commentary around 2024 is more of a moderation of that. There was good growth in the first quarter over the fourth quarter. Do you expect continued sequential growth in the

United States and also Europe is coming on too.

So what is the outlook for SKYCLARYS look like?

Michael McDonnell Executive

Sure. And thank you for remembering Europe. It's important to remember, Europe, when we underwrote the transaction, we estimated that perhaps 50% or so of the revenue would come from the U.S., about 40% in Europe and then 10% from other parts of the world. And so in the U.S., we talked about 1,100 patients who are on SKYCLARYS when we did our first quarter call. That's about 24% of what we estimate the U.S.

patient population to be around 4,500. The original bolus of patients where the drug came out. There had been a manufacturing impurity that had to be resolved. So there was a bit of a pent-up demand of patients just waiting to get on treatment. And that's pretty much played through now.

And so we're now kind of in the second wave of finding patients and investing our time and assisting those patients, find physicians and get on drug reimbursement going well. And that launch in the U.S. continues to progress in line with our expectations.

Michael Yee Analyst

Do you steady growth in the U.S.? Like all these people who came on over the last year, people think 8% hopefully small percent would come off and then you're coming on. So there's this Wall Street perspective on [indiscernible]?

Michael McDonnell Executive

Yes. No, we do continue to see more patients coming on drug on a steady basis. But I would just repeat what I said before, which is that there was that original bolus that has now been worked through. So now it's kind of more of a steady state finding the patients, bringing them in, and continuing to progress in the U.S. Europe, I'm pleased to say that, that launch is off to a very good start.

We now have patients on drug in four countries, in Germany, in France, in Austria and in the Czech Republic, and we expect to be somewhere between in 20 countries with patients on drug by the end of this year. So very pleased. And we also have a pediatric study. About 10% of the population is under the age of 16. And so we're hopeful to be able to complete that study and offer SKYCLARYS to that population as well.

Michael Yee Analyst

In Europe are you booking revenues for all four of those? Because like in France, that's new information. I mean certainly in Germany, I would expect that there could be uses France from early access programs or can you explain that you can book revenues from all those?

Michael McDonnell Executive

Sure. It's a good question because it's a complex environment and every country is a little bit different, but we are booking revenue for SKYCLARYS in Europe.

Michael Yee Analyst

But no price agreement per se?

Michael McDonnell Executive

The price agreement in France, I think, is still ongoing.

Michael Yee Analyst

Yes. Yes. It's an accounting thing based on an estimated price. Okay. But there is revenue there.

So I expect there will be growth of SKYCLARYS because you now have booking revenue in Europe.

Michael McDonnell Executive

That's the plan.

Michael Yee Analyst

Okay. Maybe one or two last questions in the last 2 minutes. One on pipeline. For you or Priya there were some pipeline setbacks over the past Angelman also, I think, ataxia. What would be the one or two things you would look forward to for the next 6 to 12 months on the pipeline that you think attention to?

Michael McDonnell Executive

Sure. So I'll start quickly and then maybe you want to comment on Angelman's and anything else. The first thing I would say is that we have a very keen focus right now at Biogen under Priya's leadership, along with Dr. Jane Grogan, who joined as our Head of Research just a few months ago on making sure that we prioritize the programs with the highest probability of success. And that is something that we are very, very focused on.

The HI-Bio acquisition is, I think, an excellent example of that. We are very much looking forward to welcoming a number of the -- many of the HI-Bio employees to the Biogen family likely next quarter when that transaction closes. But that gives us three very good shots on goal, two indications that have completed Phase II on that still is in Phase II. It helps diversify. We remain very committed to neuroscience but this also helps augment that going into immunology.

It's an area that we know well. So we're pleased with the ability to diversify. And it's a manageable amount of capital allocation. It's obviously a meaningful amount of money that we're paying to get into that space, but we would estimate that we probably have another $8 billion to $10 billion of capacity for incremental BD over, say, the next 2 years.

Michael Yee Analyst

I'll comment on it. So on the HI-Bio deal, it was a little unclear to me is that a IgAN area of focus? Or is that a lupus thing or -- and would you want to add on to that?

Michael McDonnell Executive

Yes, do you want to comment on that?

Priya Singhal Executive

Yes, I can talk about that. So overall, we are very excited about the proposed acquisition for HI-Bio. And the reason is that they have been focused on immune-mediated diseases. In this case, they've got three indications with clear biomarker support as well as clinical evidence that they are planning for Phase III. During our diligence, we've looked at all of them.

We are very excited about the antibody-mediated rejection data, 82% in patients who had resolution versus 20% in placebo. A small trial but a very high unmet need with no real options. Primary membranous nephropathy, the commonest cause of nephrotic syndrome. Again, excellent data, they've concluded Phase II. They have orphan drug designation as well as breakthrough designation.

And then IgAN, as you mentioned, which is very important as well, while it is a crowded space in terms of development, I would say it is unique because of the mechanism of action of felzartamab, which is the product we're talking about. And this is a fully human monoclonal antibody anti-CD38. And we believe that it's a unique direct mechanism of action, for example, in IgAN that competes quite favorably in terms of efficacy with the BAFF and the APRIL inhibitor.

Michael Yee Analyst

Is this combinable or would be direct competition to the APRIL and BAFF drugs that neighbors like Vertex across the street from you guys?

Priya Singhal Executive

Right now, it's hard to say whether it would be combinable. And as of now, what I can tell you is that we believe that in the efficacy space, we're very equal. Like it's a 50% UPCR, 50% UPCR. But most importantly, the APRIL and BAFF, we believe in engaging with nephrologists and prescribers, they would need to be chronic therapies, whereas with IgAN and anti-CD38 felzartamab, there is a possibility that patients could get a significant drug holiday. And this is because the data out, which they just presented in Stockholm at the annual Renal Congress shows that at 24 months, so about 18 months after the last dose, patients have durable stabilization of eGFR.

So that is very encouraging. Of course, all to be confirmed in Phase III studies. So we really believe that we're bringing in a pipeline and a program. And that's just the leading asset. We're looking at all the other...

Michael Yee Analyst

So Mike, that kind of gets you into that space, you would look at other tangential or shouldn't we just think about neuro per se?

Michael McDonnell Executive

No, I think we're going to look at -- continue to look at neuro. We'll look at areas like immunology. We'll look at rare disease which we've done pretty well with SPINRAZA and now SKYCLARYS. So I think that we'll look to...

Michael Yee Analyst

You can do more tuck-in things?

Michael McDonnell Executive

We can. We can. Absolutely can. And part of that is due to the Fit for Growth initiative, which we don't have time to cover, but we are confident that will produce $1 billion of gross savings by next year. And that's incremental free cash flow, and it's also providing a lot of good margin expansion.

You started to see evidence of that in the first quarter.

Michael Yee Analyst

Very good. Priya, Mike, thank you guys very much.

Michael McDonnell Executive

Thank you. Thanks for having us.

Priya Singhal Executive

Thank you.