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David Reed Risinger *SVB Leerink Holdings LLC - Senior MD*

PRESENTATION

David Reed Risinger - *SVB Leerink Holdings LLC - Senior MD*

Great. Good afternoon, everyone, and thank you so much for joining us for a discussion with Pfizer's hospital leadership team. It's very much my pleasure to welcome Angela Lukin, who is the Global President of Pfizer Hospital; Annaliesa Anderson, who is the Chief Scientific Officer of the Hospital Group and is also in charge of Bacterial Vaccines; and Jim Rusnak, who is Chief Development Officer for Hospital and also for Internal Medicine. We also have with us Chris Stevo, who is the Chief IR Officer for Pfizer.

And once again, I wanted to thank the participants and for the Pfizer leadership team members for joining us today.

QUESTIONS AND ANSWERS

David Reed Risinger - *SVB Leerink Holdings LLC - Senior MD*

I thought it would be great to kick off at a high level, Angela, by asking about the pivot from defense to offense. I mean, clearly, your business has largely resolved its manufacturing issues. And it would be great for you to set the stage for the vision for the Hospital segment.

Angela Lukin - *Pfizer Inc. - Global President, Hospital*

Sure. So look, we see ourselves as an important growth driver as part of the overall Biopharmaceutical division. As you mentioned, we have -- look, we have a breadth and depth of a portfolio of 300 medicines across 14 different therapeutic areas, and one of the largest portfolios of antimicrobials in the industry, including 100 medicines that are on the WHO essential drug medicine list.

So when we think about the breadth and the depth of the portfolio, it's very much a channel strategy to help to ensure that the hospitals have the products that they need. Obviously, our multi-stores, value-add and novel are key aspects of our business. But as we continue to look towards the future, obviously, looking at bringing in through business development or through our own development new molecular entities that really serve critical unmet needs in the hospital. For example, our recent acquisition of Arixia and Amplyx as just an example of a potential global anchor brand in the antibiotic space and a potential global anchor brand in the antifungal space, really building upon the expertise and the capabilities that we already have.

And so as we start looking towards the future with Hospital business, obviously, Paxlovid is going to be a big game changer overall. But our core underlying business is really significant, and we continue to look through either our own research and development or through business development to bring in assets that complement the portfolio we have today and also have the potential to address significant unmet needs in the marketplace that will bring breakthroughs that will really change patients' lives.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

That's great. Yes. And clearly, Pfizer's ability to execute globally with respect to the COVID vaccine has been super impressive. So I mean, if it wasn't already clear to the world for outside entities that are looking to maximize the value of their novel anti-infectives, right? I mean, clearly, you're super well positioned. So your segment's run rate is a little bit over \$7 billion. Could you provide some other figures just to help frame the business today in terms of maybe number of employees, magnitude of R&D efforts, et cetera?

Angela Lukin - Pfizer Inc. - Global President, Hospital

Yes. So look, we have over 3,000 employees that span across commercial, R&D, product development that really supports the Hospital therapeutic area. I mentioned before around the 300 medicines in 14 different therapeutic areas, very much taking that portfolio approach when we go to the hospitals. 190 molecules, 10 different types of delivery systems. And we've gone from one new molecular entity and asset to building -- starting to build that portfolio there.

But I think as we think about the impact, and look, we started experiencing some of the impact of COVID very early on in 2020 with the first wave. And we started seeing uptick of many of our core products that are used in ICUs like Propofol and Precedex that are used for patients who are being intubated or patients who are in ICU. And we began to see this massive surge of need in the market in which we began to very quickly scale up.

And just to kind of give a relative number, during that first wave, when we looked at the impact that we had on COVID patients around the world that were hospitalized, it was roughly 1 in 5 patients have been touched by an HBU product who were COVID positive. So even our core portfolio was really important with COVID.

And actually, now we're really even more excited for the opportunity to bring a potential antiviral in the therapeutic to really address those patients who actually do become sick with COVID and, in a very different way, help them, treat them and play a much more major role in combating COVID-19 around the world.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

That's very helpful. And so could you talk about the growth prospects for the segment ex Paxlovid? So clearly, the hope is that the pandemic is going to start to fade soon, and you'll have a little bit of tough comps. But any way to frame how to think about the business excluding Paxlovid? And clearly, Paxlovid is going to be an incredible driver and will provide lots of extra cash flow for Jim to consider putting to work. But if you could comment on that, that would be great.

Angela Lukin - Pfizer Inc. - Global President, Hospital

Yes. I mean I'll just say, look, we continue to be -- we have been a growth driver, particularly over the last 2 years since the setup of the organization. And we continue to be one as we look forward to the future. Obviously, we continue to develop our pipeline and look for opportunities of growth. But beyond that, just to share that we are a growth driver, and we're looking to increase that impact beyond just Paxlovid, but the core business as well.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Great. Very helpful. So now I wanted to turn to Paxlovid. And I was hoping that you could talk about the innovation. So how the company was able to bring it to market so quickly and what enabled that super rapid development?

Angela Lukin - Pfizer Inc. - Global President, Hospital

Yeah. So maybe I'll turn that over to Annaliesa to talk a little bit about the innovation that really drove Paxlovid.

Annaliesa Anderson - Pfizer Inc. - Senior VP and Chief Scientific Officer, Bacterial Vaccines & Hospital

Thank you, Angela. Yes. So at the beginning of the pandemic, we were working on the vaccine, and we knew it was going to be critically important to also help patients who weren't able to get the vaccine. And at the time, actually, we didn't know that the vaccine was going to work. We were driving everything forward. We didn't have a traditional antiviral unit as one would normally think upon.

But what we did have is excellence in medicinal design. And also we had the Vaccines research and development organization with a lot of viral expertise. And so what we were able to do was kind of sit down and work through what did we really want for a treatment, and it had to be orally bioavailable. It had to be highly selective and specific. And it had to be designed in a way that we don't see potential rapid resistance.

And so we worked with the Medicinal Design Group and the -- across Pfizer, the other organizations to be able to really rapidly use our investments in digital and artificial intelligence to rapidly design structures that could be used for treatment that would fit the criteria that I mentioned. And actually, within the first 4 months, we had made approximately 600 compounds. And at that point, we realized that we did have some that had some of the properties that we were looking at.

And so we were able to trigger early investments in clinical trial material manufacturer and really take out things that are often the critical -- on the critical part, like manufacturing the materials. We were able to run things in parallel. For example, nonclinical studies with toxicology studies and specificity studies, all the things that you do before you start clinical studies. And often, we do sequentially. So we did them in parallel. And we're able to then start our first in human studies in -- within a year of starting the program.

And not only that for those first in human studies, we were able to conduct them in under 2 months to be able to determine what Paxlovid was going to look like regarding its dose and the addition of the ritonavir to help ensure that we have very high concentrations of nirmatrelvir, which is the active component of Paxlovid, for patients to help treat disease rapidly.

So those are some of the components. And then over to Jim, who can talk a little bit more about the development program and how we managed to really do those efficacy studies in such a compressed amount of time to be able to -- without compromising safety, get the Paxlovid to the people who needed it as quickly as possible.

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Thanks, Liesa. So we basically took the baton from Liesa's team, and we took the results from the Phase 1 and quickly developed a Phase 2/3 program. It was a seamless program. And it was 3 Phase 3 studies: the EPIC HR study for the high risk, the standard risk study, and then also the post-exposure prophylaxis trial. And each one of them were initiated in very close sequence: July, August and September of last year.

But for the EPIC HR study, that one began about mid-July. And by the time we came to the November time frame, we were reporting out on that trial of the interim analysis, which is about 1,400 patients in the early December time frame. We then had concluded the results of the trial with 2,200 patients. And really, how that was achieved was just fantastic teamwork on a global basis, 350-plus investigative sites and over 20 countries, just internally, externally, huge partnership because of the commitment and the need for patients.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

That's great. Well, congrats on that extraordinary success, and also thank you for what you've done for society. And actually, speaking of that, with respect to what you've conveyed for the potential number of courses in 2022 and beyond, could you just remind the audience what you've stated and whether that could be revised upward in the wake of this morning's news that EMEA seems to be hesitating on Merck's molnupiravir.

Angela Lukin - Pfizer Inc. - Global President, Hospital

Yes. Sure. So the guidance that was issued just recently was about \$22 billion in revenue, and I believe the way that Albert and Frank talked about it was part of that, part of that \$22 billion was the 30 million treatment courses that were based on definitive supply agreements or binding agreements with the markets. But it also included other countries and other volumes that are different and be more advanced stages in terms of that.

In terms of the way that countries are thinking about this, I think they're really thinking about it from an HR, the high-risk population point of view. And really, what we've seen is actually countries that have actually launched the product coming back and saying, actually, you know what, I think we're going to need more. The U.S. launched with 10 million, they came back for another 10 million. U.K. launched with wanting to have 250,000, they now have 2.75 million.

So I think we're beginning to see kind of how countries are thinking about what they're looking to purchase. But obviously, as we move forward, those -- that \$22 billion in guidance was based on that snapshot and that moment in time in terms of where countries were. And obviously, we are still in negotiations with over 100 countries through this process. And I'm sure as we continue to move forward, and the data, whether it be the standard risk trial or the PEP trial as those data read out, I would anticipate -- if they are positive, obviously, I would anticipate that we would continue to seek greater volume and greater desire from countries not only to address the high-risk population. But if approved and if authorized, obviously, the other 2 important indications that will be following soon after.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

And when are those 2 readouts, please?

Angela Lukin - Pfizer Inc. - Global President, Hospital

So maybe, Jim, I'll turn it over to you to talk about the other 2 trials and the estimates around the data readout?

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

So the post-exposure prophylaxis trial should be reading out in the second quarter of this year. For the standard risk protocol, we're actually increasing the sample size so that we can get a better statistical power for our key secondary endpoint around hospitalization and death. And as a result, we will open -- reopen enrollment this quarter and expect those trials to -- that trial to read out in the third quarter.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

And could you remind us how you define standard risk?

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Yes. So standard risk in that trial was basically 2 broad categories. One were unvaccinated patients that didn't meet high-risk criteria, so for all of the other comorbidities. But also for patients that were at high risk but were fully vaccinated and essentially had a lower risk or more of the standard risk of hospitalization. Those were included in that trial.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

I see. Okay.

Angela Lukin - Pfizer Inc. - Global President, Hospital

And sorry, Jim. Sorry, just maybe just as a follow-up, maybe just to remind, when we think about our high-risk indication, it does include a portion of that. Can you maybe just talk a little bit about that?

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Yes. So whenever the EPIC HR trial was read out, although that trial did only enroll patients that were unvaccinated, whereas our SR trial enrolled patients that were at high risk but fully vaccinated, the EUA actually covers both of those population without regard to vaccination status. So that part of that SR population is already encompassed underneath the EUA.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Okay. That is very helpful. And then looking ahead, Annaliesa, could you comment on the opportunity for potential development of maybe a next gen that does not require ritonavir boosting?

Annaliesa Anderson - Pfizer Inc. - Senior VP and Chief Scientific Officer, Bacterial Vaccines & Hospital

Yes. So certainly. So first of all, regarding the ritonavir boosting, just a reminder, it's a low dose of ritonavir that we use, and it's for a short period of time. So pharmacists and physicians are very used to prescribing drugs with -- that have potential drug-to-drug interactions and find ways of dealing with it, including changing doses or maybe the holiday of the particular drug that may have the DDIs.

And remember, this is a life-threatening disease that we're dealing with. And ultimately, it's really up to the -- it's between the health care practitioner and the patient to look at the risk benefit.

But saying that, and of course, we are providing tools and education to health care providers to help them determine whether or not there is a risk for patients. And we also think that from the analysis that we've done, it's really a small proportion of the population that are -- have potential contradicted therapies that they're already on.

But saying that, they're still patients, and we still need to make sure that we can provide treatment courses for the majority of the population. And so we are looking at potential second-generation programs where we wouldn't need to use the ritonavir.

The other reason for looking at second-generation compounds is with most anti-infectives, in fact, all anti-infectives, eventually, you can see resistance. We think the Paxlovid, we've raised the bar on potential resistance developing because of the way that we've designed the molecule. We have a very close structure of the drug to the actual substrate of the target protease. And so it makes it much harder for the protease to change and cause resistance to happen.

We also, because of the ritonavir, we're able to go in a very high dose level so that we're really kind of swamping the virus with the medicine to prevent the resistance from happening as well as having a very short treatment schedule. So overall, we're pretty confident that we're not going to see rapid emergence of resistance. And also that there is a small population of people that may be contradicted due to DDIs, but we don't see that that's a problem for the overall population.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Got it. Very helpful. Maybe we could step back. Just Angela, could you provide a little bit of a framework for availability of Paxlovid in the U.S. and in Europe? Because obviously, providers and physicians and patients are desperate to get their hands on Paxlovid. So it would be helpful to just understand where the rollout stands and when you expect the product to be broadly available without sourcing challenges?

Angela Lukin - Pfizer Inc. - Global President, Hospital

So look, I think we, from the beginning, said obviously, because of the long lead times around being able to manufacture Paxlovid and we made investments very early on, what we said from the beginning, it's going to be a ramp-up and a buildup. And I think we've seen that.

I'll give the U.S. as an example. Our deliveries since we've launched in the EUA not that long ago, it was right before the end of the year, right? We've distributed about 365,000 doses. And of those doses, 80% of them have been ordered by pharmacy. And in some cases, we have states ordering at 100%.

Obviously, we continue to ramp up and do everything we can to accelerate the doses. And I think as we start moving into March and April, we're going to see a significant adjustment of that. But I think it's also been helpful for us to really understand where are some of the major issues or concerns that are coming up. And sometimes with a slower ramp-up, you get an opportunity to see them and hear them and also be able to make adjustments.

So we've been working very hard together with the U.S. government as well as with health care professionals to make sure that we're addressing their questions and concerns like how do I prescribe it? How do I think about DDIs? Where do I identify where the product is? Because obviously, states and governments have decided how best they would like to allocate it and in which pharmacies they want that available.

So during this time in which we have a little bit more supply constraint because we're still ramping up, I think that we're already starting to see some of those sites start to expand to others. And there's a lot of work being done on our side as well as the U.S. government around public service announcements.

I just saw ours in New York talking about the importance of not only vaccination, but now having antiviral therapy like Paxlovid and others. And we're starting to see those types of PSAs and the work that was done with the U.S. government to identify a locator tool that just type in your ZIP code, and you find out what pharmacies in your area have it and how much product.

So I think there's been a lot of work that was done since the launch to be able to identify maybe where some bottlenecks might be and help to provide greater clarity for patients as well as for doctors about Paxlovid. And obviously, as supply continues to ramp up in the March and April time period, I think we're going to see even greater expansion into other sites and more physicians prescribing.

So that's where we are currently. But obviously, as we move now into the next couple of weeks into March and April, we're going to start to see some supply expansion. And those tools that we talked about, I think, are going to be helpful to physicians on being able to identify which pharmacy has it and how much they have. So when they send the prescription, it is filled.

I will also just say in addition to that, we are seeing a very rapid turnaround from pharmacies in terms of, in many cases, same-day delivery of the medicine, again, contactless delivery, but same-day delivery. So really helping to ensure that patients stay within that 5-day window.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

That's great. That's very helpful color. So Jim, I wanted to turn back. We had some discussion on the 2 studies that are going to be reading out. Could you just provide a little bit more color on EPIC-SR? It's called standard risk, but I think it also may include low risk. I'm not sure. And what your expectations are for that trial? And then after you comment on that, then I wanted to discuss the post-exposure prophylaxis trial.

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Yes. So again, for the standard risk study, we initially designed the program around the high risk. So the standard risk, it did include those which would then be lower risk. And we had that second population of fully vaccinated high-risk patients, so 2 separate cohorts.

And in the fourth quarter of last year, we did release some data on the interim analysis of that. And what that data showed was that while the primary endpoint wasn't met, which was a novel symptom-based endpoint, we had a very strong result on a key secondary endpoint for hospitalization in that, that was directionally the same as what we saw in the high-risk study.

And because of that, we've decided to expand the population really to look at not those high-risk patients that are fully vaccinated, but the lower-risk patients, irrespective of vaccination status, and collect more data on that key secondary endpoint of hospitalization and death. That would be very useful for physicians and possibly for regulators.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Got it. And could you remind us how much did you increase the trial size?

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Approximately 800 subjects. So we were around 1,200 previously, and now we'll be approximately 2,000.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Okay. And so as a result of that, does that give you greater confidence in hitting the primary endpoint? Or is it still a bit of a show me?

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

So the primary endpoint is very unlikely to be met because it was a very flat result across this novel endpoint, which was a symptom-based endpoint that was -- that came out of our relationship with NIH and NIAID. It was 11 different symptoms that were measured over 44 days. So one had to be asymptomatic on each of those 44 separate measurements.

And it really wasn't able to discern well on the symptomatology. And we will be looking at other measures for that in subsequent trials, but we don't anticipate the primary endpoint to be met. We do, however, have a lot of optimism on the key secondary endpoint of hospitalization and death, which is why we're actually investing in a study that has already failed its primary endpoint.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

That's very helpful color. And then for the post-exposure prophylaxis, maybe you could just comment -- provide a little more comment beyond what you had discussed before? Any other nuance that we should be aware of?

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Yes. So this trial actually has a very interesting feature in that it has not only a 5-day treatment course but also a 10-day treatment course. So this is for your household contacts of patients that have been recently diagnosed with COVID-19.

So in addition to the placebo and 5-day, we also have a 10-day treatment course. We do anticipate that, that will be reading out in the second quarter of this year. And with many antiviral agents, there is a lot of efficacy that is demonstrated in post-exposure prophylaxis trial. So we are cautiously optimistic about what the results will show.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Got it. Okay. And then sorry to bounce around so much, but I'm trying to keep it lively here. So Angela, could you comment on thinking a bit longer term, right, it's possible that if we're all fortunate and the pandemic does wane, there could be potentially less demand for Paxlovid in 2023. However, governments are likely going to want to continue to stockpile Paxlovid. And so how do you think about the potential for longer-term sales between those 2 different buckets, if you will?

Angela Lukin - Pfizer Inc. - Global President, Hospital

Yes. So look, as we look across both Comirnaty and Paxlovid, right, because they're both impacted. As we move from a pandemic to an endemic, obviously, those revenues will be different than what we're experiencing now. However, we do believe that they're going to be durable revenues. Our current focus, obviously, is ensuring that we have consistent supply right now for those patients in those markets. But as we start to look towards the future and as we've seen with this virus, there -- as additional variants of concern continue to proliferate in the global marketplace, I think there'll be even more reliance on antivirals until new vaccines have an opportunity to come back and formulate to address those concerns.

So -- and given the potential pan-corona's activity of Paxlovid as well as its efficacy and safety profile of what we see currently, we continue to believe that it's going to be a very important and valuable tool for governments, not just in treating SARS-CoV-2 infected patients, but also thinking about future pandemic preparedness, obviously, subject to clinical success and regulatory approval.

But we do believe that this is a durable business, a very important unmet need and an important business that we're going to need to sustain. And as Annaliesa talked about the second gen and what we're doing with the vaccines, we're always trying to stay 1 step ahead of this virus to make sure that we are ready and prepared to the best of our ability. But obviously, even as we move into an endemic phase, there will continue to be need for products like our vaccine, of course, and of course, our antiviral.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

That's very helpful. And then as you look to potential competition to Paxlovid, could you provide any comments and thoughts? And do you think potential competitors may have to run head-to-head trials versus Paxlovid?

Angela Lukin - Pfizer Inc. - Global President, Hospital

I mean, look, our focus right now, honestly, is about continuing to reinforce the profile that we have with Paxlovid. I think our focus is less on competition and more really at this point about serving the unmet need in the patient population.

Obviously, we want to stay ahead of this virus. So we want to make sure we're continuing to adapt and to improve the profile of what we can for the product. But we believe based on the fact that it's an oral, the 5-day, the great profile that we've seen already in the high-risk population, we want to continue to reinforce that.

And so from a competition point of view, I'm not commenting so much on the competition. But I'm really focusing really more about what we can do as Pfizer in terms of staying ahead of this virus and about making sure that we've got the medicine that will best help address patients around the world, whether it be on SARS-CoV-2 or some other variants of concern that may develop over time.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Got it. And we only have a few more minutes, but I did want to step back to a higher level because, obviously, you're working on a lot beyond just Paxlovid. So I guess this question is for Annaliesa. Could you talk about innovation more broadly? And what you're most excited about in terms of pipeline candidates that we should be focused on from outside the company?

Annaliesa Anderson - Pfizer Inc. - Senior VP and Chief Scientific Officer, Bacterial Vaccines & Hospital

Yes, certainly. So within Hospital, obviously, we have perhaps Paxlovid and the potential follow-on program there. But also, we have a number of other really exciting programs that are in development. And as Angela mentioned earlier, really looking at what we could bring in.

And if you kind of forget about coronavirus and COVID-19, essentially, the next thing that we worry about is antimicrobial resistance. And so we have a number of compounds, the ATM-AVI as we call it, the aztreonam-avibactam, which is targeting beta-lactamase-resistant bacteria. And these are bacteria that the CDC have really highlighted as serious concerns because of the lack of treatment options.

Likewise, we're going to be bringing forward an oral version of the beta-lactamase inhibitor that we purchased through our acquisition of Arixa. And again, this will provide opportunities to prevent hospitalization to people with common UTI infections where they're resistant to all the drugs that are available. So really important medical advances.

Likewise, looking at our antifungal portfolios, bringing forward novel antifungal compound for people who have very limited options, the treatment at the moment. So a lot of really exciting things going on in the anti-infective space.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

Wonderful. Well, we are out of time. So I think we should wrap it up there. Sorry that I wasn't able to get to more questions from the web. But I wanted to thank you again for taking the time. And once again, congratulations, and thank you for all of your progress.

Angela Lukin - Pfizer Inc. - Global President, Hospital

Thank you.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

All right.

Jim Rusnak - Pfizer Inc. - Chief Development Officer, Internal Medicine & Hospital

Thank you so much, David.

David Reed Risinger - SVB Leerink Holdings LLC - Senior MD

We'll sign off.

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