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Carter Lewis Gould *Barclays Bank PLC, Research Division - Senior Analyst*

PRESENTATION

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Great. Good morning. My name is Carter Gould, senior biopharma analyst here at Barclays. I am pleased to welcome Pfizer to the stage. Today, we actually -- this is a great setup because we're going to continue the immunology theme after the last talk, and we have the entire I&I squad here from Pfizer: Michael Gladstone, Global President, Inflammation & Immunology; Michael Vincent, SVP, Chief Scientific Officer, I&I; Michael Corbo, who's Chief Development Officer in I&I.

Before we get started, Bryan Dunn from the IR team is going to make a few opening comments.

Bryan Dunn - *Pfizer Inc. - Senior Director, Investor Relations*

Hello, everyone. Just as a reminder, the discussion with our I&I leadership team today could include forward-looking statements. These statements are subject to risks and uncertainties that could cause actual results to differ. If you have any questions or want more information, please see our Form 10-K or 10-Q filed with the SEC. Thanks.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Great. So maybe before we just launch into the Q&A, maybe to -- this is going to be a recurring theme. Michael Gladstone here, just maybe some opening comments on kind of where you see the I&I franchise at this point on the back of Arena closing late last week and sort of the state of the state of Pfizer I&I.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Great. Thanks, Carter. Welcome, everybody. Good to see you. We're happy to be here. What gets us out of bed in the morning is helping to end the suffering for patients who suffer from immuno-inflammatory diseases. We're passionate about the patients. We're passionate about the science, and we're also passionate about the business opportunity. These patients have a need for diverse options. They need multiple therapies. And the good news is their future is bright because we have a strong and robust pipeline, and we're also open to acquiring scientists, as you indicated, Carter. Many of you know we just recently closed the Arena deal. So we're really excited to bring along their excellent science into Pfizer. And also, they're very engaged colleagues. So there are great opportunities around. We continue to innovate here because patients continue to need options. And with that, thanks for the opportunity to open, Carter.

QUESTIONS AND ANSWERS

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Perfect. Great. So maybe a follow-up on that. Just I think the Arena deal served as a reminder to a lot of people around sort of your guys' presence and your ambition in I&I. Maybe to put a finer point on that, when you think about where you guys want to be as a franchise, looking out 3, 4, 5 years, can you maybe help frame that for folks? And I think one of the things that also was a standup from the Arena deal was your willingness to take on more risk than maybe we've seen in the past from companies entering BD in I&I.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Yes. First and foremost, we're excited about the opportunity with I&I because really the opportunity for growth is really sound. And that opportunity from growth stems from the unmet need. If you look at a couple of different categories, if you look at atopic dermatitis, for instance, 60 million patients around the world suffer from AD but yet only 4 million patients are on some form of systemic therapy. If you look at rheumatoid arthritis, you've got 20 million patients who suffer around the globe from rheumatoid arthritis. The standard of care there is T&S. And the fact is the vast majority of these patients don't achieve remission. So there's an opportunity there.

If you look at IBD, 3 million patients in the U.S. alone have IBD. T&S is the standard of care there and nearly half of those patients don't achieve any remission or don't -- half of those patients fail, I should say. So the opportunity is strong here, and we're excited about it moving forward. And I think the key thing here is all these patient populations are heterogeneous, and they need multiple options in order to go through their course of therapy.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. So maybe moving on to etrasimod here in the deal having closed, can you talk for a second around when you think about what really got you excited about this asset. Clearly, the Phase 2 data was very compelling from a response from remission standpoint. But when you think about -- like I said, what got you excited, but also kind of like the sensitivity of this marketplace to that level of response rate and like just given the lack of options today, how sensitive is it to like a numerical mid-teens type benefit versus placebo? Or are we just in an environment where there's just a dearth of options or anything that gets over the finish line is going to have an impact on (inaudible)?

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Great. I'll start off, and then probably ask it to one of the Mikes for some additional commentary. First of all, what made us excited about the Arena deal was just, quite frankly, that we had the opportunity to expand the number of patients that we were able to treat significantly with that new mechanism. We know that there's a need. In terms of our ability to act before data, we're confident in our ability to assess the science. And we also wanted to act quickly because the clock is ticking for launch on etrasimod. And every month we waited also gave us less time to prepare the market. So put those 2 things together, our confidence in the molecule and the fact that we wanted to act quickly, the reason why we jumped on it. From a commercial standpoint, there's such a great need for patients out there. As I indicated before, the standard of care treatments don't work all that well. And there's a real spot for patients, physicians and health care providers for etrasimod. I'll pass it to one of the Mikes.

Michael Corbo - *Pfizer Inc. - SVP, Chief Development Officer, Inflammation & Immunology*

Sure. I think if you think about the risk that we took, and again, we're taking the risk on behalf of patients and our shareholders. So the risks we're going to take are going to be responsible ones. And looking at the robustness of their Phase 3 design, we decided that looking at blinded data was a reasonable thing to do. You have an objective measure in endoscopy, which is relatively consistent when you look at the more contemporary studies. We have good modelers. We have good gastroenterologists. And also after meeting the Arena team, we have confidence in their ability to conduct trials. So wrapping all that together, we felt that this is a reasonable risk. It's a prudent risk, and it's one that can get patients' drug faster.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. And just to be clear, you were able to see blinded data on both efficacy and safety?

Michael Corbo - *Pfizer Inc. - SVP, Chief Development Officer, Inflammation & Immunology*

That's correct. And when I look at safety, I just assume everything is the drug. And we also have cardiologists looking at that. Obviously, there's a CV component to this as well. We also feel strongly that there was not a need for titration based on their history with data and history with regulators. So that also increased confidence. But we brought all of our safety folks to bear across Pfizer, which is great because we have a number of therapeutic areas with expertise.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. When you think about segmentation in UC, we often kind of fall back on to lines of therapy, but maybe drilling down a little bit more into that prebiologics segment, it does seem like there are some -- I kind of fall back on to I think about what that median patient's journey is over the next 4 or 5 decades. And the appropriateness then of an oral agent seems like a pretty compelling option. So I don't know if there's any further detail you can talk about how when you think about the -- just the segments in that opportunity and if there's specific opportunities that kind of like jump out at you.

Michael Corbo - *Pfizer Inc. - SVP, Chief Development Officer, Inflammation & Immunology*

I can speak to the GLADIATOR trial. Maybe -- and then, Mike, if you want to talk about some of the other agents and then you want to talk about segmentation, but I'm already talking. So we do have the GLADIATOR trial with Arena, which is a prebiologic population. It will always depend on benefit risk. And from what we've seen already, we think this is a viable option potentially. So if you could be bringing somewhat a more advanced therapy prior to reaching the biologic, let's call it the cycle that patients have to potentially live through with anti-TNFs, you potentially are going to alter their trajectory. And that's really the goal here. So once we get those data in, obviously, it will be a benefit risk discussion with regulators. But if we could get more advanced therapies early, potentially, we're going to really reduce the suffering on the back end for the patient.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. And when you then think about how much you're able to sort of guide that evolving treatment paradigm with -- in the space, how do you think about that, particularly when we think about all these other kind of mechanisms kind of evolving, some of which you guys have a stake in, some of which you don't? And to the extent you can shape like this, it really hasn't been a space where we've had really kind of strict kind of guidelines in the past.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

I'll speak just briefly and then turn it over to you. I wouldn't anticipate super strict guidelines moving forward either because of the patient types and the types of diseases they have and the need for these multiple mechanisms that aren't necessarily going to be sequential the way we think about them in other diseases.

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

Yes. I mean I think you point out the development has been primarily focused on the most severe patients. And really GLADIATOR is, I think, one of the first examples where a program has started to look at how you might slot a therapy into an earlier line. And if you're looking out 4 or 5

decades, I think the therapies that are currently used for the more mild and moderate patients are really substandard, and patients would benefit from access to more advanced therapies.

Looking deeper into our pipeline, we would love to get to a day where we can predict who's going to respond to a particular therapy. We have a TL1A program, as you're probably aware, where we've seen a nice response in the overall population, but we're also exploring potential biomarkers that might identify a patient population that responds more strongly and could enable a more targeted effective therapy that people, I think, usually associated with oncology as opposed to inflammatory diseases.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

So I want to come back to TL1A in a minute. Maybe just to wrap up with etrasimod. Obviously, the drug is being developed in a number of other indications, including Crohn's, atopic derm, EoE as well. To the extent that those indications really kind of entered your thinking when you did the deal and if any of those kind of really pop out as more credible or more likely to succeed than others?

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Yes. As we thought about -- I'll turn it over to Mike in a bit. As we thought about the opportunity overall, we looked at etrasimod first and the rest of the assets. But also within etrasimod, we're interested in all the potential indications. But ultimately, the science is going to drive that. It was -- the deal was valued on etrasimod largely you see with anticipation and hope and risk adjusted for the other one.

Michael Corbo - *Pfizer Inc. - SVP, Chief Development Officer, Inflammation & Immunology*

Yes. And Crohn's is a significant component as well. With ozanimod data, we have proof of mechanism. We're hopeful then that, that same differentiation that we hope and anticipate UC would be translated to Crohn's. The Phase 2 data in AD, I think, was an operationally challenged study. So our intent right now is to keep allowing that to advance, understand the effect size better. I'm sure the drug works. I just don't know how well it works. So we've -- we're working together with the Arena folks to ensure that we can estimate that effect size during the study, right? There's ways you can do that in an adaptive fashion. So in EoE, we're just going to wait for the Phase 2 data at the end of this year. We'll make science-based decisions on all of it.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. Perfect. Maybe come back to TL1A now and make sort of the transition there. I guess the first question is really around you talked -- you made a reference to sort of patient stratification or really finding the appropriate patients here. Can you talk a little bit about the key biomarker here and how you're sort of potentially incorporating that into patient selection as we think about future development?

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

Yes. I mean, TL1A is a mechanism that has come up in a couple of different contexts. First, I would point out some of the work looking at expression profiling and disease tissue that's highlighted upregulation of TL1A in patients who are poorly responding to existing standard of care therapies. In addition, there is a literature around the different HAP types driving higher levels of TL1A secretion. So you could take a couple of different approaches to trying to understand which patient population is going to respond best to your drug. It's always a little more believable if you have a hypothesis going in. So in our Phase 2a study, we kind of understood a little bit about what we might look for.

And like all small studies with any combination with larger studies. But we were very encouraged to see that one of the biomarkers that we preselected did associate it with a higher level of response, and actually the majority of the patients that needs to be replicated. I guess what I would say is it's a fairly treacherous business to try to preordain what a biomarker is going to tell you about responsive therapy or not. And it's always at least the way we approach it. We like to be data-driven. As I said, it's always better if you have a hypothesis going in. But in this case, we

did have a hypothesis going in. The preliminary data looked positive and we have to confirm on a larger study, which we'll be reading that data out later this year.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. And when we think about that data readout, should we think that we're just going to get the induction in the maintenance data sometime later this year? Or is there the opportunity to maybe read out the induction data earlier?

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

So we'll be seeing the induction data internally reasonably soon. We haven't made a decision at this point as to whether we'll release the data in piecemeal or whether we'll do it in one pop. But definitely the data will come out sometime this year.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. And then when you think about differentiation versus other approaches targeting TL1A, how do you think about that and maybe the key nuances we should sort of keep in mind?

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

It's a relatively well-behaved biologic, I would say. And the -- certainly, biologics can be differentiated from one another. What we've seen so far of the space, we think our antibody is well behaved and really doesn't have any particular deficits that make it an opportunity for someone else who wants to combine us with the same mechanism with the different antibodies.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. Maybe just sticking in UC, as we think that around just bigger picture when we think about combinations, sort of -- what are sort of the foundational pieces or thought process that kind of really sort of guide that decision-making process? Whether it's with your own internal programs or mix and matching with other people, are there like sort of pillars that you kind of build upon and will guide you throughout the process?

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

I mean I think the basic principles of combination therapy are pretty well established in the context of inflammatory diseases, certainly, in rheumatology, gastroenterology. I think when it comes to targeted therapies, there's been less progress perhaps in understanding how to combine those. Our fundamental principle is to look for orthogonal mechanisms, mechanisms that don't overlap in one particular arm of the immune system. Maybe I'll point to our current combination study in rheumatoid arthritis, where we have a first-in-class IRAK4 inhibitor with a first-in-class JAK3 type inhibitor. Those are 2 very distinct mechanisms that one targets the innate immune system, one targets the adaptive immune system. Bringing those together in a very selective way, we think, has the potential to drive greater efficacy while not having the same kind of safety liabilities that maybe hitting the same pathway like an IL-1, and the TNF historically has been challenging.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. And when you think about those initial combinations, do you think that we're going to see those really kind of pop up more sort of prebiologic or post biologic in line kind of with how we've traditionally seen for our development in the space?

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

I mean it's all going to depend on the benefit risk profile as is always the case. Another -- I think another component is the format, to be particularly honest. A fixed dose combination with 2 small molecules gives you the flexibility of having unique pricing for the combination relative to the 2 individual agents. In the biologics space, we're quite interested in bringing together different epitopes into the same molecule to kind of get around some of the complexity of dosing different molecules, IV or subcu, to drive the same efficacy.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. Maybe turning back to the commercial portfolio for a few minutes. Maybe just an update kind of how you -- sort of Xeljanz and how it sort of stabilized after, let's say, a colorful 2021.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Yes. No, thank you for the question. 2022 is going to be a transition year for Xeljanz, and the good news is we have a label. We know what we're working with. And the other good news is that when we talk to our health care providers or key opinion leaders for that matter, when people understand the data and they understand the data of the indication of what patients are appropriate for Xeljanz, there's an adjustment period. But then almost all of them or the vast majority of them view returning to growth for Xeljanz. So I think we're going to see some adjustment here during 2022 as the health care providers learn and understand which patients are right for Xeljanz. And I can tell you that we're really on the front end of this. We're on our front foot. We're educating doctors in every possible way we can from symposia to individuals to field medical because we know the quicker they get through that curve, good for patients, good for society, but also the quicker they get through, the more they start to think about returning to growth. And the fact is the JAKs really have and Xeljanz really has a great place in the treatment paradigm for appropriate patients.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

And then maybe just a range of scenarios as we think about the regulatory review in Europe and how that might play out.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Yes. So when we think about the Article 20 in Europe, a couple of things to think about. First, you think about abrocitinib, what would the impact be on abrocitinib. And I can tell you that while we can't predict that EMA has been reviewing 1133 data for quite some time, even before the approval of CIBINQO. And also, you're looking at 2 very different patient types. The 1133, data older patients, comorbid. Some smoking. When you look at the atopic dermatitis patient set, it skews much younger. These tend to be healthier patients. So there's a little bit of a difference there. Mike, I don't know if you want to speak further to Article 20.

Michael Corbo - *Pfizer Inc. - SVP, Chief Development Officer, Inflammation & Immunology*

Sure. We've been speaking with PRO-ACT since May of 2019 with Xeljanz. And we've had extensive discussions working very closely with them. All of the analyses we've been doing on Xeljanz have been absolutely consistent with everything that they've been interested in because that was the start of it. All the analysis for abrocitinib, they followed suit because we knew where their interest was as far as events and special interest, et cetera. So the filing contained all the data that they would have been asking for. In fact, in the Article 20, all we've done is purely update what we have provided in the dossiers themselves.

I think PRO-ACT right now, their drive is they see inconsistency in labels across the JAK class and now their interest is where do we go from here? They can take the simple approach and do what the U.S. did, which is a way to just limit the use or do you optimize the use. And from our perspective, if you look at abrocitinib and Xeljanz, we do know that the majority of risk is in those patients over 65 or whoever smoked. Now I don't know the

data in anyone else's, but if that's consistent, typically PRO-ACT and CHMP take a very scientific approach to things. If they can take a targeted approach like that, they're more likely. If it is more dispersed, it's more likely that they'll go to a simpler approach.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Maybe it's a good segue to abro and we think about the launch, which is early days. Maybe just talk about sort of initial reactions there and how we should think about access and the pace at which they might open up over the course of '22.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Yes. Thanks for the question. It's exciting. We've just released our field sales force on CIBINQO. And the feedback that we've gotten is very encouraging, both from key opinion leaders and field-level prescribers. And I think the way to think about this is, let's put yourself in the position of the patient. It's really, really a tough disease that impacts so many elements of their life. And there are so many patients that are unsatisfied with the current treatment. So they've been talking to the physicians. Their physicians have been waiting for CIBINQO and now it's here. And so we're hearing just excitement from them, that finally we have a more efficacious option for patients. And qualitatively, we're feeling very good about where we are. Access is going to open up over time. We think that patients need multiple options. And also, as you look forward to 2023, once launch is well underway, you have sort of a marketplace event in a big biologic going LOE, which will provide opportunities for payers to think differently about the category. So we're excited all the way around.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

That's a great point. And I mean we spoke a little bit about last night at dinner around these massive LOEs coming up and how it may serve as sort of a reset point for the industry. I guess when we think about -- that's not putting in sort of absolute dollars, but just qualitatively, when you think about just the magnitude of that from a reset point in terms of your relationships with payers, can you maybe just help frame that for the folks on the call?

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Okay. Yes. I think what we've heard from some payers is that they're looking at that as an opportunity to reset how they look at rebate streams for the entire category. Some of them are discussing an option to diversify sort of the companies that they contract with and would receive rebate streams from. And again, there's a pretty good range with the way payers look at it. But I think overall, it represents an opportunity for a variety of manufacturers. We also participate -- will participate in that space with our own biosimilar. So the market is going to stay interesting and vibrant in the days to come.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. Maybe just the last sort of 90 seconds left. Spoke a little bit last night around your PDE4. It sounded like a lot of excitement there and still have a strong view on the world of topicals. Maybe just high level, walk through that program and what makes you most excited?

Michael Vincent - *Pfizer Inc. - SVP, Chief Scientific Officer, Inflammation & Immunology*

Yes. Maybe I'll take that. That's still a relatively early program, but going back to the Anacor acquisition, we recognized early on that the cytokine profile of -- the first agent in that class was somewhat limited and not having any coverage for IL-13. So we immediately began working on designing another molecule that was more potent. And we were fortunate enough to find that a molecule that has extremely potent IL-13 activity. We formulated that in a topical formulation, done an initial study, first in healthy volunteers and then both atopic dermatitis and psoriasis, and we were very encouraged to see what we think might be best-in-class activity at an extremely low dose that has essentially no systemic exposure. So

the topical market, there's no question that dermatologists like to have a good topical option, always a limitation is safety and being able to use it in a liberal way. And we think the PDE4 mechanism really hits the mark on that profile.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Perfect. Well, that's the end of our time. I'll leave it there. Thank you all. Thanks for Pfizer for participating, and have a great day.

Michael Gladstone - *Pfizer Inc. - Global President, Inflammation & Immunology*

Thanks, everyone. Thank you.
