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PRESENTATION

Andrew Simon Baum - *Citigroup Inc., Research Division - Global Head of Healthcare Research and MD*

Good morning, or good afternoon to those of you in Europe.

This is Andrew Baum from Citi's global health care team, delighted to introduce our next session.

As you'll see from the roster of familiar faces above me, we have the management from Merck, namely Roy Baynes, the Chief Development Officer and Chief Medical Officer; and Peter Dannenbaum, the Head of Investor Relations. Many thanks, both of you, for joining us.

We've got about 45 minutes. I want to keep it a free-flowing discussion. (Operator Instructions)

QUESTIONS AND ANSWERS

Andrew Simon Baum - *Citigroup Inc., Research Division - Global Head of Healthcare Research and MD*

So maybe a leading question, to start. A criticism that we get from investors, and obviously we've been a very long-term bull of immuno-oncology and Merck in particular, is that there is too much dependency on KEYTRUDA. The durability of KEYTRUDA is questioned in terms of biosimilar entrants. And more than that, the absence of visible pipeline drivers further increases that centrality, as well as the spin coming up later in the year. So I wanted to give you an opportunity to say whether you think the investor base really has a fair opinion of the true extent of Merck's pipeline, because from my perspective, I can see an awful lot of activity in terms of clinical trials. And I know trials that you have ongoing, but you disclose far less data than perhaps some of your peers when it relates to Phase I, Phase II. And I understand why you do that from a competitive point of view, but do you think Merck has that balance right, i.e., to minimize competitive risk but at the same time benefiting from it in the share price? How do you think about that consideration?

Roy D. Baynes - *Merck & Co., Inc. - Chief Medical Officer*

Well, I'll just take an R&D perspective, I mean, to start with, and that is that we're very pleased with where we are with KEYTRUDA. KEYTRUDA is really a remarkable product and transforming the cancer care landscape. This has a number of consequences. Obviously, it becomes widely used across many different tumors. Our strategy has led to obviously development of significant precision medicine tools to enable patient selection and understand resistance, and that's provided tremendous entrée into potential combinations which might be beneficial. So as we look at that, we have over 20 different internal molecules that we are combining with KEYTRUDA, many of which have pretty impressive effects in early-stage trials. The other consequence of having a molecule such as KEYTRUDA is that pretty much anyone in the oncology space who has a promising molecule is eager to explore the combination. And so we have a very large extramural collaboration program identifying combinations. So just from the idea of a KEYTRUDA concentration, that is actually not a bad thing scientifically and has helped us enormously in terms of changing the landscape of cancer care.

That having been said, we're not just an oncology company. We have a pretty broad portfolio. In fact, the visible pipeline is a largely derisked pipeline with candidates in a number of important therapeutic areas, and we'd be happy to step through some of those if there's an appetite to do that. Obviously, we span cardiovascular medicine, neurosciences, vaccines, infectious disease. I've spoken obviously to oncology. We have a tremendous track record in cardiovascular medicine and an impressive array of molecules in the inflammatory and respiratory space. So as you look across all of that, there are significant late-stage development programs across most of those therapeutic areas that, as I say, are largely derisked. And we believe that there is tremendous growth drivers outside of just the KEYTRUDA story, but we're very pleased with the KEYTRUDA story. It truly has transformed the care of a cancer patient. And I must say, every time we get an additional indication or approval and we update the label, it's quite chastening to read that label. That label now reads like a textbook of oncology, and it's been a great privilege and pleasure to be able to contribute to that.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And my question, just to clarify, wasn't in any way meant to understate the importance of KEYTRUDA because that's self evident [in its case].

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes, sure.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

It's really somewhat to bring out some of the features that indeed you mentioned, and you touched on very promising data from early-stage compounds. And most investors, when asked to discuss that, they'll think back to the initial STING data you presented a couple years ago, which was there was the initial data on TIGIT which was dose-ranging data and a whole bunch of cold tumors in monotherapy as well as combo, but it was a small data set and people might shrug their shoulders. So that is the perception. I guess what I'm driving at is when does that change. And I know that you have the forthcoming ESMO forum coming up, and you are showcasing some data there with both TIGIT; and as well the ILT4, the LILRB2.

So without you wanting to -- without wanting to make you disclose that data set, perhaps you could talk to your level of excitement that you see in TIGIT and where you think it fits in given that we have the Roche Genentech data set out there as some kind of anchor. And then perhaps you could talk to ILT4, where you've been clearly expanding cohorts, suggestive of significant activity. And I note the poster there. So over to you.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Well, thanks, Andrew, yes. So let's just talk about STING, first of all, because you raised that. STING has been intriguing target. I think it's been largely misunderstood. The approach that we had taken with STING initially was intratumoral injection. There's no question that STING has an intratumoral effect, and I think it's asking a lot of a molecule to really expect it to have huge abscopal effects in and of itself. So we continue to explore STING. And we have a number of different STING candidates, where we are looking at potentially an oral STING. We are looking at a systemic STING. We are looking at an intratumoral STING. So that program continues at pace. We actually have a Phase II study ongoing right now in the head and neck cancer arena looking at intratumoral. We also, as you mentioned -- again, I'll highlight some data at the upcoming ESMO meeting. And talking about TIGIT for just a moment, obviously an exciting target: Our asset, we believe, is well developed. It has all the characteristics of what appears to be an effective molecule. We have conducted obviously some Phase I data, and we will be presenting some data at ESMO looking at this situation as it pertains to IO-naive non-small cell lung cancer in combination with KEYTRUDA. We're also looking at IO-experienced patients. And we have commenced a pretty substantial program. A number of these are umbrella-type trials looking for signal detection with TIGIT, and based upon some of our encouraging data in the non-small cell lung cancer field, we do anticipate a Phase III study commencing early in '21. So TIGIT is certainly an area of focus for us.

ILT4 and, a closely related molecule, ILT3 basically address the whole question of the myeloid suppressor population of cells, which is thought to be a potentially important negative immune regulator. And we will be sharing some of our very initial data. Again, these are early data, so I caution that we are obviously looking at heavily pretreated patients in a lot of these circumstances, but we are very excited by what we see with ILT4. And that program is obviously moving ahead. This is in addition to many other candidates. I think everyone is aware of our CTLA-4 program, which is moving ahead in a number of different indications, and this has been carefully developed to maximize efficacy and minimize toxicity. We have mentioned previously a LAG-3 program. And as I said, we have some -- more than some, 20 assets which are internal which are moving forward into the Phase I and Phase II studies, so it is a very broad portfolio. And we will be talking about it more as data start to emerge.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And so just picking you up on the Phase III starts in 2021, which is I think the first time you've addressed that; and it's not a huge surprise, obviously. Which indication are you pursuing? Is it -- I'm assuming it's non-small cell lung cancer, but is that in combination with KEYTRUDA? Or is that as part of a -- on top of a KEYTRUDA backbone?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Right. The trial itself is not yet posted. We haven't had fulsome discussion of that yet, but your surmise around the indication is correct.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

So non-small cell.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Got it. Okay, that's helpful. And then in terms of that -- your CTLA-4 -- I forget which number because I wrote it down but I misplaced it. I'm sure it's top of your mind, but compared to ipilimumab and the therapeutic window that you believe that you have achieved, what does that mean in terms of ability to dose higher? And therefore, is there any potential for superior efficacy than we've seen with ipi-based combinations?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. The CTLA-4 field has been fairly complicated. There has been a lot of energy around CTLA-4, but to date, if you look for the convincing Phase III data that established unequivocal efficacy of the CTLA-4 PD-1 combination using the marketed products, that's kind of hard to find. I mean there have been approvals, but indeed many of the KOLs would argue that they have not necessarily met the high bar of demonstration of contributions. And clearly there is a toxicity issue. So we have developed 1308, which is our CTLA-4, in a thoughtful way to try and minimize toxicity. And we are seeing encouraging efficacy signals, and we certainly will be exploring this more broadly. I think the jury is still out, though, as to whether the addition of a CTLA-4 to a PD-1 overall is going to be transformative. That's the key question to be answered.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And we'll see that CTLA-4 data or the initial tranche of data from that CTLA-4 trial. Where we'll see that, world lung? Or we're going to have to wait into ASCO next year.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. We haven't disclosed where we plan to communicate that, but we do have a fairly substantial emerging body of early data.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Okay. Let's come back to oncology in a bit but just take a break -- to break from it for a short while. HIV: So Merck, unquestionably, is one of the leaders in antiviral therapy; and a founding father of many of the categories of HIV drugs, including integrase inhibitors. You have, as we've pointed out, a few years ago now -- was islatravir, an incredibly potent, differentiated drug because of the pharmacokinetics as well as the potency. Your first opening gambit is the daily doravirine combination, which has received relatively little attention from the market because there are already 2-drug regimens which were already approved, but when I look at the data that you may deliver for this drug, I can see a point of significant differentiation but yet I don't hear Merck talking about it. So I'm interested whether you share my view.

And that is that we know that both TAF, as well as integrase inhibitor, is associated with weight gain and, you would imagine, particularly among black female patients given what we've seen in previous trials. And of course, your 2-drug regimen has 9 of those, and you're comparing it to Biktarvy. Isn't it very likely, when you run the trial, you will show very significant delta in weight and potentially metabolic between the 2 arms? And [is it of itself of] relevance, particularly in relation to the competitive position against the existing incumbent, Dovato, before we even start talking about long-acting formulations and so on and so forth?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. Well, I think your assessment is spot on. Indeed, islatravir is a remarkable drug. It's got properties which are very important. You've highlighted potency and you've highlighted pharmacokinetics. I would also highlight that it has a remarkable resistance profile. It also penetrates tissues remarkably well. Obviously, that could be very important as it pertains to certain indications. And it combines well with other molecules, so all in all, it has the potential to be a transformative agent in the HIV space. You've highlighted the once-daily treatment, and you picked up clearly on the early signals that we do not see the weight gain associated with some of the other agents. Would -- I will just caution that those are early trials. And obviously we would like to see that replicated in large controlled experiment, as you have suggested, but it does have the potential to be differentiating, for sure.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And that data will read out 2021, right, the initial Phase III trial?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

We currently are expecting a 2021 date, but [these progs] -- obviously, we've been through COVID and we'll just have to see what the impact is, but that's the current thinking, yes.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And then on islatravir's PrEP, where you don't need to partner it, which is a separate discussion we'll come on to. GSK, by running a trial in developing world, managed to show superiority versus standard of care, but it took them many patients and a very long time to do that. You and I have spoken previously about whether there may be certain [accelerated] development routes for this drug, including things like the Pearl Index. Do you think the FDA is open to discuss this? Or does the fact that GSK demonstrated superiority mean, well, if they can do it, then you should do it? And therefore, [were you to develop a partner set], you have to do a superiority trial versus tenofovir. How is that -- where are we on that?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. So we haven't disclosed our strategy around PrEP. We are moving ahead with PrEP. I think the FDA has been clear that they're looking for a controlled trial in females and a controlled trial in (inaudible) male population. And we have been working closely with the FDA to optimize design so that this can indeed be executed with a reasonable sample size and a reasonable duration of trial, but we have not disclosed details yet but only to assure you that this is moving ahead.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And I'm assuming that -- and the PrEP, I'm assuming, won't be in the form of a daily tablet. It will be with one of the other formulations, presumably the depo.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Well, the pharmacokinetics of this agent are intriguing. They are very favorable and the intracellular half-life of the metabolites are actually extraordinarily long. So we do believe that there is a definite potential here for a potentially [Q month] oral agent.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

All right. And then moving to the big commercial opportunity, which is the therapeutic one. The challenge is -- as you have been investing in, is finding an agent with suitable pharmacokinetics to take advantage of islatravir's. And obviously you've been exploring prodrugs, tenofovir. You've been exploring next-generation integrase inhibitors. How far are we away from being able to initiate a registration trial with less frequently dosed islatravir-based combination of therapeutic setting?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Right. So as you remarked earlier, Merck has had a remarkable history in that area of the various classes of HIV agents. Obviously, we've been a leader in protease inhibitors. We've been leader in integrase inhibitors, clearly in non-nucleoside reverse transcriptase inhibitors. And we have explored a number of possibilities. We are advancing a internal Phase II candidate, and in addition, we're also very mindful of the external environment. And so clearly, we are not adverse to partnering as well in this space, but I think rest assured the -- less frequent-dosing treatment paradigm, initially probably Q-week, will be looked at. And then there are obviously agents that we might look to partner with for even longer intervals of -- between application.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And by that, I'm assuming -- given you rejected cabotegravir some years ago, I'm assuming that leaves capsid inhibitors as being the obvious partner of choice to extend the dosing window.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes, we haven't disclosed who the potential external collaborators might be, but we're obviously exploring all possibilities.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Got it, okay. That's what I had on HIV. Perhaps we could go back to oncology for a little bit, and then we'll move off on to some non-oncology targets. So 2 licensed drugs which you've conducting very extensive programs have been LYNPARZA and LENVIMA. And both have demonstrated positive data, including an immuno-oncology at -- well, one in the immuno-oncology setting, one not yet. Could you talk to your level of confidence of using PARP as maintenance treatment post KEYTRUDA in non-small cell lung? And how that has changed with time. I'm interested because, when I speak to your counterpart -- or roughly your counterpart at AstraZeneca, your partner company -- José is doubtful, I think it's fair to say, that maintenance setting with PARP will work in non-small cell lung because of the absence of biallelic mutations of DDR or loss of heterozygosity. And as a result, he's somewhat skeptical. Obviously, you've initiated the trial a year or 2 ago and you have a different view, so I -- could you help me understand whether this is because you're betting on a different mechanism that basically -- do you think it's really unrelated to that? There's an immunostimulatory activity. What underpins the need or the conviction to test the hypothesis?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. So I think PARP inhibition is a still incompletely understood field. I think the prevailing theory of mechanism of action relates to synthetic lethality, and obviously then you get into all the questions of loss of heterozygosity and that as a key underpinning. What's interesting is, if you actually look at the cellular signatures of a patient on PARP inhibition, they actually look to all the world like platinum. And so there is a counterview that indeed PARP inhibitors are indeed a orally available, potentially less-toxic form of platinum-type therapy. I think it's well described that a number of the settings where PARPs have been quite active are in the settings where patients were initially platinum sensitive, and that would certainly be consistent with an alternate hypothesis. We do have some early Phase II data that have spoken to the efficacy in certain tumor types unrelated to loss of heterozygosity. And so I think the question has to be answered that it's clearly a very tolerable approach, and I think it's a very worthwhile question to ask. And so consequently, we are conducting a few randomized trials to try and get a definitive answer.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And there's an ongoing trial called PIPSeN out of Gustave Roussy. It doesn't have a checkpoint in it. It's chemo doublet followed by PARP maintenance versus chemo doublet. Were that trial -- and it's been running for a while now -- but it's a proper trial that's sizable and well run, et cetera. Were that trial not to show benefit for PARP maintenance, to what extent does that influence your opinion? Or you think the fact that there is no checkpoint agent within PIPSeN mean that actually it's not a useful data point in weighing the probability of success.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. I think we'd have to look at the data and understand it and obviously understand the size of the trial, the patient selection. And clearly, ours are all combined with checkpoint inhibitors. So that's the other sort of idea here which we've added into the mix.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

So let's take a break from oncology for a second and go to gefapixant, which doesn't get much attention. You recently presented the data. It's clearly an unmet medical need. The magnitude of improvement in the primary end point isn't huge, but obviously, as I said, it's a material unmet medical need. And there is the metallic taste. How -- do you think this is enough given the paucity of treatment options that are available is the first question. So what's your level of confidence that it's good enough to make a dent in a unpenetrated market?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. So I think that the whole area of chronic cough is clearly a field which is emerging. And obviously there are many different names applied to the syndrome, but for clarity: These are folk who no underlying cause has been found for cough, that have high rates of coughing through the day have been a fairly debilitating symptom. As you rightly say, there are no really approved agents. There's been very little progress in this field. And

treatment is generally with off-label applications of either low-dose opiates or alternatively other nerve modulators. So the P2X3 pathway is a purinergic nervous system pathway. There is some evidence and actually quite persuasive evidence that quite a lot of the patients who have this entity of chronic cough, which is not due to some secondary cause, have a hypersensitive purinergic nervous system and it's believed that the P2X3 pathway is important. So we've actually conducted 2 Phase III studies, and we have shown unequivocally that there is a very meaningful reduction, at the 45-milligram dose, of cough rates. The absolute reduction is on the order of 60% to 70%. It's important to recognize -- this has been known for many years. This was also known from our Phase II program, that there is a placebo effect in this which is fully understood, but despite that, we have an effect size which clearly is superior to simply the placebo effect observed. It is also important to note that, as was presented, the median duration of coughs in these patients was on the order of 11 years. That's a remarkable disease burden for patients to have to carry around, namely chronic cough that is sort of endless and ongoing. We knew from our Phase II program that, once patients have been in the Phase II, when a second Phase II opened, they were clamoring to participate because clearly the drug had a salutary effect [on their symptomatology].

So we're very encouraged by this. We have 2 Phase III studies we -- with positive primary end points. They also have very strong support of quality-of-life data going with them. And these are clearly trials which are in a lead position. The competition is quite a ways behind. The taste perseveration is clearly an adverse effect, but the fact that a majority of patients with taste perseveration decided to stay on therapy speaks to the perceived benefit-risk that patients experience with this agent. So it is a new field. Clearly there's a lot of work to be done to flesh out the detail of that field, but this is a very large number of patients. The current epidemiology of this suggests that as many as 10% of patients in the world -- or people in the world have chronic cough. And about 1/3 of those, there's no identifiable cause, so we're talking about a fairly substantial patient population for whom the available therapies are really simply inadequate. And we're very encouraged by the Phase III data, which as you say were presented last weekend.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

So from a -- I would imagine, if I was at the agency, I would have -- yes, my significant concern would be, given this is a diagnosis of exclusion, the risk is that it could be given to patients who have some sinister organic disease which may camouflage that. And obviously one thinks of non-small cell or small cell or other diseases which results in chronic persistent cough which might be masked in the same way as a PPI might mask gastric cancer. How does Merck deal with that? And what is the -- what can Merck do? What does the regulator do? And who is the principal prescriber? Is it the pulmonologist? I'm guessing it's not the primary care practitioner, but that whole infrastructure as you go from where you are now through the regulator and to the market, how do we -- could you help me along that journey?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. So I think the professional societies that recognize the entity of this chronic cough syndrome have been quite deliberate in how they thought about this. They have put a time window around this, and there's a strong recommendation that the major secondary causes are excluded during that time. So in our discussions with regulators, there was an agreement that we would put a time window around the inclusion in the study. And that would be a very meaningful surrogate for patients, having had appropriate clinical workups and potentially therapeutic trials, to interdict some of the known underlying causes. The fact that the median duration of patients on this trial was on the order of 11 years speaks to the fact that there is indeed a substantial cohort of patients who actually have chronic cough and where all these secondary causes have been largely excluded. So I think that time window is of some importance. That begs the next question, and that is, is that time window too stringent? Because chronic cough clearly starts at some point along the way. And what is the minimum time it should be explored? And we are doing some additional work to try and define a time window which might be even more appropriate for patients with this debilitating cough syndrome.

As to the prescriber, I think there's no single answer to this. In various jurisdictions there are various degrees of awareness of chronic cough. There are chronic cough clinics in many countries. And in your own country, chronic cough is a well-recognized entity. And the phenotype of the physician looking after these patients varies. This includes, for example, pulmonologists, allergists, asthma specialists. Because ultimately a lot of folk with chronic cough get referred to one of the specialists categories that actually are responsible for some of the underlying cause excluding. So the typical things that you exclude are obviously concomitant medications such as ACE inhibitors. You exclude gastroesophageal reflux disease, upper respiratory issues of a postnasal drip variety and hypersensitive airways as in asthma. So all of these things get worked up, and so you can imagine there is some heterogeneity of the physician cadre that actually looks after this patient population. And obviously we have to work very closely to

address those groups. I will just say that the trials enroll very quickly. And in our experience, at least my experience, rate of enrollment is a good proxy for pent-up demand. And so leveraging the folk who have participated in our clinical programs will be very important as we begin to map out what that patient journey really looks like.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

So when -- it's a drug that doesn't and hasn't historically received much focus from the investor community because of the diagnosis exclusion perhaps; the unfamiliarity; and perhaps some awareness of the adverse event burden, although not serious, troublesome and unpleasant or could be unpleasant for the patient, but listening to you, it sounds like the commercial and medical importance of it is perhaps far greater than is externally perceived by the market. Is that a fair conclusion?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

I think, for that percentage of patients, that's a very true statement. Again just to emphasize: If you've been troubled by troublesome cough continuously through the day for 11 years, that's a pretty major burden to walk around with.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Yes. I understand. So we're in the sort of the last innings of the call, so over the last 10, 15 minutes or so, we should talk about COVID, which here again, despite Merck's legacy in antivirals and as a vaccine manufacturer, you singly are overlooked by the market. You have been relatively quiet in your disclosures over the progress of your various vaccines. And obviously it's a deliberate choice. It's not accidental. But starting with the 2 vaccine and the vector -- virus vector vaccines that you're using, first question. In light of the case of transverse myelitis reported to Astra yesterday and assuming it is transverse myelitis and assuming it is triggered by the fact they were using an AAV-based vaccine, is that of a concern for you? Or is your experience with Ebola make you relatively relaxed that actually this is not something that's necessarily going to be problematic for you? So thoughts on [safety and platform].

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. I certainly wouldn't make that overarching statement. I mean this is why you have to do large Phase III clinical trials, why they have to actually address meaningful numbers of patients. Because, remember, we are vaccinating, in any cases, patients who would otherwise be normal, and so perceived safety is obviously really important. And I think we have to proceed with very deliberate caution and ensure that we indeed have a safe profile. You do make the point that both of our vaccines are based on established platforms. So one candidate, V591, is based upon a measles vaccine platform. And we know that this vaccine has been into literally tens of -- or hundreds of millions of patients, so it's not like this is a first starting for this particular replicating viral platform. The other one, as you rightly comment, is based upon our vesicular stomatitis virus platform. And again, that is a well-validated platform. It is the basis of our Ebola vaccine. And so when we decided to look at deploying potential COVID vaccines, we really wanted to work with platforms that we have a lot of confidence around. And as a consequence, we picked these 2. The other idea here is our hope is that we might have a single dose exposure. As you can imagine, with a raging pandemic, multiple doses are less desirable than single dose. So that was another idea behind the 2 platforms that we have chosen, and we are progressing both of these platforms.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And the decision not to use a protein subunit vaccine, was this because you believe that it's you need CD8s and these -- a viral vector is better positioned to get CD8s? Or entirely a different set of reasons.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

I think these are both well-validated platforms well recognized to produce both humoral and cellular immunity. Most of the vaccines that you're seeing developed are targeting the spike protein, which is thought to be fundamental to the cellular uptake of the virus. And so the idea here was, as I said, to use well-validated platforms that create broad immunity that potentially lend themselves to single-dose application.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

The only reason I was asking is because the majority of protein subunit vaccines don't typically produce high-CD8 titers. And I was trying to -- I was wondering whether this was you thought this element of immunity was particularly important versus humoral immunity, but I understand that. That's fine. And then on the Emory-Ridgeback antiviral, could you update us on when we will get data from -- well, I've lost track of -- I think you're running the Phase II, so I think we're pending data from the Phase II, but you tell me. And when we expect to hear.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

So this molecule known as MK-4482 was in-licensed and partnered with Ridgeback. This molecule is in a series of Phase II studies right now. We have not disclosed any data from those; and we are moving ahead into a larger Phase II/III trial. One of these will address an outpatient population. One of these will address an inpatient population. And we are optimistic that we will be able to have this up and running toward the end of September or early October.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And how large will that be?

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

These will be Phase II/III trials and they will be of significant magnitude. We haven't disclosed the absolute size yet, but that will obviously be posted when these trials come online. And obviously we've been working with regulators to get agreement on the protocols.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

So potential data for Q1 of -- early part of Q1 2021.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Yes. This will obviously be driven by the rates of enrollment. And clearly, execution of these trials is going to require really top-notch on-the-ground information because, as you know, the sort of outbreak sort of waxes and wanes in different jurisdictions. And so ensuring that you're maximally deployed to enroll patients is going to be pretty important.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Let's just step sideways and talk strategy for a second. So look, on the basis of KEYTRUDA, you've -- clearly from not having had a legacy in oncology, you've become the dominant player or certainly one of the dominant players in the space. The rise of immunology as causal in many noncongenital diseases at oncology has encouraged many of your peers to intensify their efforts in the space, helped by a favorable commercial environment. You had some autoimmune drugs, but you divested many of them some years ago. What is the appetite to reengage within autoimmune either on the biologics side or on the small molecules side? So that's one question. And then in a similar vein, whilst you do have a presence in hematology in Hodgkin's and now the acquisition of the -- or ArQule in CLL, it's very small. And obviously Bristol Myers, your competitor, is -- dominates that

field. And it's still a substantial chunk of the oncology market, so what's the strategic commitment to increase your footprint in hematology either through BD or organically? So autoimmune and hematology.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Right. So firstly, just to be clear: While we may have divested certain molecules that we saw as been potentially not first in class or not necessarily industry leading, we have retained a very substantial discovery effort in the immunology, inflammation areas. So we remain very active in the autoimmune and inflammation area.

I think, the hematology question, just to clarify. Actually, it wasn't BMS that have the hematology profile. It was really Celgene that...

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

I'm -- new Bristol, let's call it.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

New Bristol, okay. And having said that, our philosophy has always been one of go after great drugs rather than necessarily try and build franchises. I think our view is always that great drugs will build great businesses. Great businesses don't always necessarily build great drugs. So again, our view of the world is, if we come across meaningful targets that look as though they could be first in class and have unambiguously large effect sizes, we will build a capability around that. As you rightly comment, we have a very active position in Hodgkin's and in primary mediastinal B-cell lymphoma. In that regard, the 204 data were really quite spectacular. And as you commented, we did bring in the noncovalent BTK inhibitor, which is looking quite promising in addressing the area of BTK-resistant B-cell malignancies that have developed specific mutations. We will continue to look at potentially important first-in-class molecules that are likely to have an unambiguously large effect sizes. So we don't preclude anything, but the whole idea here is finding great drugs.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

And just since you mentioned the BTK inhibitor. I was with Jake Van Naarden of Loxo, who was claiming that the specificity of their molecule results in what they believe is a superior or broader therapeutic window than you see with the ArQule molecule. And I was just interested in your observations, whether -- I would be surprised if you agree, but I'll pause...

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

In God, we trust. Everyone else must show data. So when we see the data, we'll comment.

Andrew Simon Baum - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Very good. All right. So listen, I think we've reached our allotted time. Roy, it was a pleasure. Peter, thank you for joining. And then to investors, thank you for your interest. (Operator Instructions)

Next session, with Novartis, starts in approximately 5 minutes.

Many thanks to both of you. Have a great week.

Roy D. Baynes - Merck & Co., Inc. - Chief Medical Officer

Thank you, Andrew.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Thank you, Andrew.

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