Good afternoon, and welcome to the Merck session of Cowen’s 41st Annual Health Care Conference. We’re very pleased to have Merck back with us again this year. Representing the company is Frank Clyburn, who is Chief Commercial Officer; as well as Peter Dannenbaum, who is the global Head of Investor Relations. So we appreciate you both being here with us today.

Merck had a solid year in 2020. Frank, as you peer into 2021, what do you see as the pushes and pulls to the year? What do you think will maybe go better than expected? What do you think could be a little bit more challenging?

Sure, Steve. So thanks for having us, and it’s great to be here this afternoon. As we look into 2021, we first remain, Steve, very confident in our growth pillars because they remain intact. And we highlighted guidance that was 10% top line growth at the midpoint of ’21 in our guidance range, which we think demonstrates really strong underlying demand for our key products: KEYTRUDA, GARDASIL, BRIDION and Animal Health.

We do expect, Steve, to your question, to some of the headwinds to have a negative impact to the business in ’21 from the COVID pandemic, but to a lesser degree than what we saw in 2020. Specifically, we highlighted a 2% negative impact on ’21 revenues, and we expect that to be more pronounced in the first half of ’21, primarily on our vaccine business, particularly in the U.S.

As you can see and recall, obviously, as we were coming out of December and in January, a lot of hospitalizations, cases spiking. So the first half of the year, we’ve called that out. And we do expect a more normal environment from where we are today in the second half of ’21. It’s also good to note that the first quarter of ’21, remember, we’ll be comparing performance to the first quarter of ’20, where we did not see any negative impact from COVID in the first quarter of 2020 given the timing of the pandemic. So that’s something also, obviously, just to keep in mind.

We did announce that we’re withdrawing ZERBAXA. So that’s something that I would highlight as well. And some of the lockdowns that we’re seeing in Germany and Japan are having an impact on physicians being able to access the health care system as we start this year. So those are some of what, I would say, some of the challenges early on.

However, I do want to emphasize that our overall growth pillars and our current demand and momentum around those pillars do strongly remain intact. And we think as we continue to move in the second half of ’21, and as you think about longer term, I think the story remains consistent. We feel very confident in our growth going forward.
Great. So let’s dig right into the products. So let’s start out with the most important one, KEYTRUDA. So you recently had some very compelling data in the CLEAR data. So how will KEYTRUDA plus LENVIMA be positioned in first-line RCC relative to KEYTRUDA plus Inlyta? And what is the sales message that’s delivered to educate physicians relative to your regimens versus I-O/I-O regimens?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes, Steve. And we were very excited to share the KEYNOTE-581 data recently at ASCO GU. The combination of KEYTRUDA plus LENVIMA in RCC we see as very strong data. If you look at the combination, not only do you see a benefit in overall survival, Steve, you see very strong median progression-free survival, strong response rate. So the efficacy measures across the board are very impressive.

In addition, it’s also important to note that this combination showed data across all 3 subgroups, in IMDC risk groups, which is also important, which is not necessarily the case with all regimens. So we feel really good about the KEYTRUDA-LENVIMA data. We want to remind everyone that the KEYTRUDA-Inlyta data, also 426, is very strong data.

And physicians, Steve, use VEGF receptors differently. They’re used to using them in different situations. So what this will enable us to do with KEYTRUDA being foundational now in RCC and will lead to new patient share, we will now have another option, if approved, to offer to physicians. And we think having 2 tyrosine kinase inhibitors to offer to physicians with KEYTRUDA being foundational really broadens out the opportunity and options in RCC for us. So we feel really good about our position.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

And do both regimens, the KEYTRUDA plus LENVIMA and KEYTRUDA plus Inlyta, get the same amount of sales force attention and support? Or are you leaning one way or the other?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. We’re not going to get into the specifics of what exactly the strategy. What I would say is, obviously, we have our partnership with Eisai with LENVIMA, where we do monetize half of that asset based on our business development activities. But for us, for the physicians, we’ll clearly, upon approval -- if approved, 581, we’ll put a lot of focus and efforts there to make sure people are well aware of the tremendous data you saw from the CLEAR trial.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. And what’s the detail to educate physicians of your regimens versus an I-O/I-O regimen?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. So I think, clearly, I-O/I-O regimens and RCC have had a really strong impact. What we have been focused on is differentiating based off of very strong and durable benefits with our combination, very strong overall survival, if you look, and you don’t want to do cross-draw comparisons per se, Steve.

But if you look at progression-free survival, overall survival, strong response rates in all risk categories. We think that is a very strong offering for physicians in RCC. And that’s been really our focus to really make sure that physicians are well educated in that area.
Okay. Let's move to lung. Is this a fully penetrated tumor? Or is there more room to go? Is there room for the new entrants, including the recently approved one from Sanofi? How does -- how do we go into lung cancer from here? How does it grow from here?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes, Steve, in lung, and I'll separate a little bit of the U.S. market from some of the x U.S. markets because it is a little bit of a different dynamic. In the U.S., KEYTRUDA has clearly established itself as the standard of care in non-small cell lung cancer across, what I would say, pretty much many -- most of the segments in non-small cell lung cancer, both non-squamous and squamous histology.

In the 50 PD-L1, 50 and above, Steve, we have very strong share penetration for KEYTRUDA monotherapy, not a lot of room of growth in that segment. As you look at the PD-L1-negative population in the 1 to 49 segment, there is still opportunity for growth in those 2 cohorts or segments. We get about approximately 8 out of every 10 eligible patient. If you were to exclude those with EGFR ALK genomic aberrations. So we penetrated well in the U.S., but still some opportunity for additional growth there.

In the x U.S. market, significant opportunity because we're much earlier on in the penetration, in particular, in Europe, where we have not only approval but reimbursement across our lung regimens. So you'll see lung continue to grow, particularly in Europe, also in Japan. In some of our other x U.S. markets, the penetration is not as high. So we feel very good about our overall position in lung, having 5 overall survival trials.

And even now, if you think about it, Steve, recently, we just highlighted some additional KEYNOTE-024 data. You're seeing long-term data follow-up in lung, which is really important to give physicians confidence that they're getting good durability, and that was well received as well. So overall, x U.S., significant, I think, opportunity for additional growth. U.S., higher penetration for KEYTRUDA, still some growth in the segments that I mentioned.

Great. Question along the lines of KEYTRUDA life cycle management. So KEYTRUDA will be patent-protected for another decade or so, lots of room to grow. What's the bigger opportunity? Is it combinations? Or is it the adjuvant setting? And I appreciate that, that both of these are big opportunities. But as you look at the size of these opportunities, which do you think is larger?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Steve, I would say, and it may not be the exact [thing] you're looking for Steve. I think it's significantly involved, and here's why. Within the combination setting, we have a number of opportunities in front of us. And if you think about just what we even highlighted recently, we just talked about KEYTRUDA, LENVIMA and RCC, and you think about the combination seen on endometrial and other targeted therapy combinations that we have.

We have, we think, a very significant opportunity if the data reads out, for instance, in a cancer type like prostate cancer, Steve, which is significant size, right, as far as prevalence goes. And we have a number of trials in that area. We also are working on our co-formulation approach and strategy, where we have our anti-TIGIT molecule we're combining with KEYTRUDA in a co-formulated form, as I mentioned, in non-small cell lung cancer. So the combination strategy and the significance of our breadth there, we think, offer significant opportunities for us.

Earlier-stage disease, we have 20 registrational trials. We have significant data readouts coming over the next couple of years and interim in KEYNOTE-091 in lung. So as you move to earlier stage of disease, clearly, that is a very significant opportunity as well. If the data pans out, and we think that both the combination strategy we have with other agents, our co-formulation strategy we are building and working on in earlier lines of therapy, give us significant opportunity and runway for growth going forward.
Stephan Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Great. One more question, then we will move to the TIGIT molecule. But we and others have estimates for PD-1, PD-L1, 3, 4, 5 years down the road at $50 billion-plus. $50 billion-plus. And we have Merck capturing about half of that, roughly. What's the first thing you think about? Or what comes to your mind first when you hear estimates like that?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Well, I'm not going to, as you imagine, Steve, provide any specific comments on -- or product guidance per se. What I would say is that we do believe KEYTRUDA has the opportunity to be the -- one of the largest drugs in the history of our industry. And we think that our vast clinical program, including early-stage disease and combinations, as I've just mentioned, give us significant opportunities for future growth.

If you think about now, Steve, 28 indications across 17 different cancer types, and I don't think we've ever seen anything like this. It's foundational, if you think about lung, bladder, head and neck, renal cell carcinoma. We've introduced a Q 6-week regimen to help with patients and with adherence.

And also, if you think about the opportunities we have globally, in Europe and Japan and China as well. So what I say is that we feel extremely confident with the opportunity we have in front of us. We're continuing to explore KEYTRUDA, as you know, in numerous combinations and, as we mentioned, in earlier lines of therapy.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. Maybe we could chat about TIGIT for a minute. And I know that people like yourself don't want to look at cross-trial comparisons, but unfortunately, it's what I do for a living. So when you look at what's in the clinical domain, how do you feel about the Merck product? Do you think it's fully competitive? Do you think it's better? How would you characterize it?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. Well, I'm not going to go into the specific attributes and the structure for safety. We feel we're very competitive. We're excited about our anti-TIGIT molecule. Our clinical team in MRL is extremely excited. We've seen demonstrated efficacy and, in that setting, and we're moving forward in a Phase III study and a co-formulation with KEYTRUDA, comparing it to KEYTRUDA, Steve.

So we feel very good about our position. And I think if you look at what we've been able to do in the clinical space, we believe that we have very strong capabilities, tremendous execution. And we feel really good about our TIGIT molecule, as well as, I would highlight, other I-O agents that we're looking to formulate as well. So for us, we're looking at that, plus other co-formulated opportunities going forward.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

I must admit, I was unaware you were co-formulating it. Has this been a fairly recent disclosure by Merck? Or has the company been talking about this for a while?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. I think -- I'm not sure there's a specific disclosure, but yes, we have mentioned it's co-formulated, Steve.
Okay. Let’s talk about another potential target within I-O, and that’s anti-CTLA-4. Merck wasn’t the biggest fan of CTLA-4 for a number of years, at least it appeared to us to be that way, but has recently had advanced its own CTLA-4 to Phase III in renal cancer. What prompted Merck’s change in thought on CTLA-4?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Well, based on findings, Steve, from KEYNOTE-598, which we have just shared, we evaluated our internal CTLA-4 development program. And we’re looking at various tumor types to focus also a co-formulation combination with KEYTRUDA. We see this still, though, as an important asset, Steve, in our pipeline.

And it does remain one of the assets that we are advancing in Phase III in a co-formulated manner in RCC, in combination with LENVIMA as well. And then also, we are exploring it in combination in hepatocellular carcinoma. So while we did disclose and obviously took a really close look at what we saw in KEYNOTE-598, we still see this as an important asset, and we’re moving it forward in the areas that I mentioned.

Okay. Let me just go back to the co-formulation thing. So what you’re saying, though, is that there’s going – you’re going to be marketing a vial that has KEYTRUDA plus TIGIT in the same vial, same solution, administered at the same time in the hospital, in the same IV bag. That’s how it’s going to be packaged. Is that correct?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes, pro forma. Yes, Steve.

And the rationale for the need to co-formulate it is what?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Why? One, clearly, the most important aspect is to see the combination and the magnitude of effect and impact it can have on all of the key efficacy parameters, Steve. So that hasn’t changed, looking at this co-formulated product, studied, and looking at the impact on overall survival -- progression-free survival response rates. The co-formulation brings, if successful, a significant patient benefit, Steve.

So imagine for patients that need to get infused, to have a combination now, instead of having to go for 2 separate infusions. Like today, we now have one infusion. So it brings significant patient benefit. And it also brings significant health care system benefit, reduction in time and share, reduction in infusions, et cetera. So it has a significant benefit for patients, significant benefit for health care systems. And obviously, if the combinations are successful, we think it clearly can help many more cancer patients going forward.

Okay. Let’s move to some other exciting drugs in the Merck portfolio, and one of those in development is islatravir. Clearly, the data suggests this drug could be a game changer, but perhaps what’s needed is another drug with similar long-lasting profile or duration. So how do you go about producing a cocktail to optimize the value of this asset?
Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes, Steve, I'm glad you highlighted and brought up islatravir. This is a product that we are extremely excited about within Merck and in our pipeline. And the reason why is because we also think islatravir has the opportunity to be foundational in both treatment and in prep.

And let me just give you a couple of highlights and then answer your question specifically, Steve. If you look at the profile of this product with unmatched antiviral potency, a remarkably long half-life, which will be -- enable the drug to be developed in daily regimens as well as other extended-dosing regimens, and I'll come back to that just here in a second, strong barrier to resistance helps this to allow it to be used with 2 drugs, potentially in a 2-drug regimen compared to 3-drug regimens that are commonplace in HIV. So the profile of islatravir, we feel really good about.

In fact, we just -- there's been some titles announced here today in CROI. This weekend, we'll be sharing some of our data in combination upcoming with 8507. We think that's a nice opportunity, we think, prep for oral monthly. We also would be highlighting some of our subdermal platform, I should say intervention using the NEXPLANON technology we have, Steve, to potentially see this be used even maybe in a yearly form for prep. So we think islatravir can be foundational and used in the treatment and settings or, I should say, treatment and prep settings.

The combinations -- we clearly are exploring internal combinations. We clearly are open to exploring external combinations as well, driven by the science. And obviously, we're spending a lot of time with our scientists thinking to our strategy there. But once again, very excited about islatravir moving forward.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. Maybe we can move to a recent approval, that is VERQUVO. And Merck has long aspired to sustain a presence in cardiometabolic after the patent expiration of JANUVIA. Is VERQUVO the mainstay and cornerstone of that strategy? Or is this a stepping stone to get there? And we don't know what the new strategy will be post the JANUVIA patent expiration.

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. So VERQUVO, Steve, we look at this as a really important opportunity for CHF patients, Steve, going forward. I wouldn't say it's a stepping stone per se. What we're looking for is we already have a presence in the space with Adempas, if you recall, for CTAP. We are committed to the area, Steve, of cardiovascular and cardiometabolic research, where we still think there's high unmet need for innovative treatments.

We're evaluating several cardiometabolic assets that are in clinical development, including in NASH and in pulmonary arterial hypertension. So that's how we see VERQUVO. It was just approved. The launch is just underway, Steve. And I would say that it would be more of a slow build because you're going to have to get, obviously, market access for the product as we go forward, but we are excited about the opportunity.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Could this be a blockbuster?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

I'm not going to speak to the -- whether or not it could be a blockbuster, Steve. What I will say, it would be an important product, we think, for those patients that still have a significant unmet need in chronic heart failure with a worsening event.
Okay. What sort of marketing support does JANUVIA get currently? And how does that change heading into the patent expiration?

Yes. So right now, in JANUVIA, and I'll use a couple of examples, Steve. In some markets around the world, we have pretty much gone to more of a digital model, Steve, where we engage with prescribers in diabetes through digital channels and not much in-person or in visit, or I should say, in contact with our sales force anymore. So we've made some of those changes.

In the U.S., we have our team that supports JANUVIA, but they also support other products as well. So they will continue to support JANUVIA, but they will be launching new products, for instance, VERQUVO. There'll be other products that are in their sales bag as well. So think of it as more of an allocation for JANUVIA, but other products that make out the portfolio for those sales teams.

Okay. And does this stay that way up until the day of the patent expiration? Or is that phased down over time?

Yes. It depends on the market. It depends on the opportunity. As I mentioned, for us, we have been focused on building and putting our resources to where our greatest growth drivers are. And I think you see -- seen, Steve, in our SG&A and our resources, and this has been a big part of our strategy, we've been focusing much more of our commercial resources behind oncology, behind vaccines, behind our hospital and specialty areas where we see significant growth opportunities. And we clearly will support JANUVIA up until the time where we don't think that the return makes sense in certain markets around the world, but our shift has been much more in the areas that I mentioned as far as resources.

Let's move to another product that is now filed, I think, that was announced just the other day, and that is gefapixant. Maybe you can frame the opportunity in chronic cough?

Yes. So gefapixant, if you think about the chronic cough market, what I would say is it's 10% of patients complain of some type of chronic cough, Steve, and 20% to 30% of those are what I would say is kind of persistent, right? So if you think about trying to understand the market opportunity, we feel good about gefapixant, but we also know that this will take a -- some time to build awareness.

This is a new market. This is a first-in-class new mechanism, Steve, that we will be introducing. So it's going to take a lot of education. It's going to take awareness of this new product and molecule, but we feel good about the opportunity. But clearly, it's a market that's going to need to be built.

And this is where Merck, I think, excels. We've done this before in diabetes. We've done this in respiratory disease. I would say we've done this in oncology. So we're going to have to educate and make people aware of gefapixant, but feel good about the opportunity in front of us.
Okay. I'm actually a little bit surprised to hear that awareness building is necessary because I would think, if you're a chronic cough sufferer, it probably dominates your life. You're probably aware that gefapixant is coming, and you'll probably call your doctor on a week to get it. So I would have thought it would have been different, but that's just me. What's the next opportunity for gefapixant after chronic cough?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. So we are studying -- I think we have some data, I believe, Steve, coming out in, call it, I think and it's in endometrius -- or endometrial pain. That we have -- that study is underway, and then I think there'll be some other things that we're looking at as well.

Okay. Okay. Merck has -- and I know you're not necessarily responsible for the pipeline, but Merck does have a BTK in the pipeline. And BTKs are a pretty hot area these days. But the Merck BTK doesn't necessarily look like one of the more selective ones in development. So what's the high-level strategy behind developing this product? Is it to have a foot in the door of this class? Or does Merck see something in it that is unique and special, and we, on the outside, don't quite see it?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. So I think what we have said, Steve, we're excited about our ArQule deal and our BTK inhibitor. We see this as a really nice opportunity for us to move forward in providing additional options in hematologic malignancies. So for us, I think we've said that we believe it's a selective molecule. We feel good about the profile of the product. And it's an area that, clearly, we're building out a presence in heme, and we think this will be really important for us in the future.

Okay. We only have a minute or 2 left. Another hot area, at least in investors' eyes, is KRAS inhibitors. Does Merck have a small-molecule KRAS program underway?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

We do. We have a partnership with Taiho, us, Astex for the KRAS target. We also have a partnership and some work that we're doing in these early, early stages of preclinical, Steve, with Moderna as well. But KRAS, we do see as an important target going forward.

Okay. Any important data coming at ASCO or AACR you'd like to call to our attention at this early juncture?

Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Nothing I would call to your attention yet, Steve, except just to say we will continue to have a very strong presence at those conferences. Obviously, Oncology at ASCO is a really important meeting for us. You'll see additional, obviously, KEYTRUDA data, but you'll also see some of our earlier data from other assets. And it's obviously a really important meeting for us as we continue to build out our oncology franchise broadly.
The other thing I just would want to mention, Steve, which we haven't had a chance really to talk about is some of the most recent deals. VelosBio, our business development deal for antibody-drug conjugate in targeting ROR1, our collaboration now with Seagen for another antibody-drug conjugate, LIV-1. So obviously, our presence continues to grow in that area.

**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Yes. We've been watching this probably half a dozen interesting targets that Merck very quietly has licensed in the last year, and they all look like they're best-in-class. So that looks exciting. Last question, Frank, and then we'll let you go. What's the one thing that you feel investors don't appreciate about Merck? And if we did appreciate that, we might have a different view?

**Franklin K. Clyburn** - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. I think the one thing I would say, Steve, is that we feel, I would say, in both the near-term and long-term, that we have a very strong growth profile and opportunity. We've spoken a lot about our key growth drivers, obviously, in KEYTRUDA, GARDASIL, BRIDION and what we kind of say we have in hand right now. I think the one thing is really the future in the pipeline that we have, Steve.

I think you've mentioned it, we've done over 120 business development deals over the last year. We are building out a very significant portfolio and pipeline. We've just done a deal, for instance, Pandion Therapeutics, I would highlight, Steve, as an example, where we're getting a diversification into immunology.

We've highlighted islatravir. We've talked about some of our other vaccines in the pipeline as well. So I would think the one thing I would say is our business development efforts, the expansion into other areas, and our pipeline we still feel is maybe underappreciated. And we think that we're in a very good position overall as a company.

**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Great. Well, to keep you on time, we need to end here. Frank, Peter, I want to thank you for your time this afternoon. This has been a great rundown. And we'll watch with great interest the success of Merck over future years. So thank you for your time.

**Franklin K. Clyburn** - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Thank you, Steve. Thanks for your interest. Awesome.

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

Yes. Thanks, Steve.