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EDITED TRANSCRIPT

MRK.N - Merck & Co Inc To Acquire Cidara Therapeutics Inc

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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Co Inc, Rahway, New Jersey, USA Investor Event announcing the acquisition of Cidara Therapeutics. (Operator Instructions) This call is being recorded. If you have any objections, you may disconnect (technical difficulty)

I will now turn the call over to Mr. Peter Dannenbaum, Senior Vice President, Investor Relations. Sir, you may begin.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Thank you, Denise. Good morning, everyone. Welcome to Merck's investor call highlighting the announced acquisition of Cidara Therapeutics. Before we get started, I'd like to remind you that some of the statements that we make today may be considered forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of our company's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1A and the 2024 10-K identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck & Co Inc, Rahway, New Jersey, USA undertakes no obligation to publicly update any forward-looking statements.

During today's call, slide presentation will accompany our speakers' prepared remarks. These slides and our SEC filings are posted to the Investor Relations section of our company's website. Our agenda this morning includes Rob Davis, Merck's Chairman and Chief Executive Officer, who will

lead off our presentation. Rob will be followed by Dr. Dean Li, President of Merck Research Laboratories; Chirfi Guindo, Chief Marketing Officer, Human Health; and Caroline Litchfield, Chief Financial Officer. Q&A will follow the presentation.

With that, I will turn the call over to Rob.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thanks, Peter. Good morning, everyone. We continue to successfully advance our science led strategy through new product approvals and launches, strong clinical execution, important data readouts and the addition of novel innovation through our business development efforts. With the strong momentum we have across our broad pipeline, we're increasingly confident in our sustained ability to positively impact patients with our medicines and vaccines and in our potential for long-term growth and value creation.

Today, we're very excited to speak to you about our acquisition of Cidara Therapeutics. We've been closely tracking the Cidara team's progress in developing CD388, an innovative first-in-class investigational long-acting antiviral agent designed to prevent influenza infection in individuals at higher risk of developing influenza complications. Influenza infection still poses a substantial public health threat with significant associated mortality, which Dean and Chirfi will speak to in a minute. And we're pleased to add CD388 to our pipeline to address this serious unmet need.

Merck has a long legacy of bringing forward important medicines and vaccines in the infectious disease and respiratory spaces, and CD388 represents a complementary addition to our portfolio. We're excited to welcome the strong science and talented Cidara team to Merck and look forward to benefiting from their additive skills and further contributions. CD388 has received FDA fast track and breakthrough therapy designations and is currently being evaluated in a Phase III trial. Should the trial results meet our expectations, we believe CD388 will be an important new option in the prevention of influenza. Given the size of the addressable population and unmet need, we see a greater than $5 billion non risk-adjusted commercial opportunity. We expect CD388 to be another important contributor to growth as we enter the next decade.

More broadly, this transaction is yet another example of our company acting decisively when compelling science and value align, and we're confident in the benefits it will provide Merck and our shareholders. We're proud of the success we're having in bringing novel innovation through business development, and we're well positioned financially to complete this transaction while continuing to pursue additional opportunities. In the coming years, we'll increasingly benefit from the rapid transformation of our portfolio that is now firmly underway.

We look forward to a future with a far more diversified set of growth drivers with CD388 adding to the greater than $50 billion revenue opportunity we've highlighted in the past. We continue to successfully advance and augment our pipeline, the deepest and broadest we've had in recent memory. And I am very confident in our ability to positively impact patients and achieve long-term growth.

With that, I'd like to turn the call over to Dean, who will speak more about the strength of the science and clinical data underpinning CD388's profile. Dean?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Thank you, Rob. Good morning, everyone. It is great to be here to provide more detail following Friday's announcement. CD388 represents a compelling scientific opportunity with the potential to address a significant public health need. It aligns well with our strategy of adding the best external science while complementing our portfolio of products and pipeline candidates targeting respiratory diseases.

Influenza continues to pose a significant global health threat causing widespread illness, morbidity and death each year, especially in older adults, high-risk adults and those with compromised immune systems. There is a high burden of disease in the United States alone. The latest data from the CDC indicates that the 2024, '25 season, there were up to 82 million people infected with influenza, resulting in as many as 1.3 million hospitalizations and 130,000 deaths. There is a significant unmet medical need, especially for those individuals at high risk and those who are immunocompromised. And as we look at the current options available, there are clear limitations.

Current seasonal flu vaccines have limited efficacy, which varies year-to-year. These variations are predominantly caused by viral antigenic drift as well as mismatches between the seasonal vaccine formulation with circulating strains. Efficacy varies with age, immune status and influenza type. The level of protection from vaccine tends to be lower in the elderly and immunocompromised populations due to less robust immune responses, putting them at increased risk despite vaccination. There are available antivirals, but they must be initiated within 48 hours of symptom onset, which limits utilization. Given these dynamics, influenza is a major driver of morbidity and mortality, and new innovative options are needed to address this burden.

CD388 is a potentially first-in-class, long-acting, strain agnostic antiviral which demonstrated clinically meaningful rates of influenza prevention in a Phase II study. It is a multivalent conjugate of the approved neuraminidase inhibitor, zanamivir linked to an Fc hybrid domain of human IgG1 that has been engineered for an extended half-life. It is not a vaccine. And unlike flu vaccines, efficacy of CD388 should not vary season to season nor be dependent on immune response. CD388 is designed to provide a full season of coverage from influenza strains A and B.

And given its mechanism, it has the potential to be complementary to flu vaccines. CD388 is a novel, late-phase candidate with a differentiated mechanism of action. The Fc conjugation of zanamivir enables an extended half-life allowing for a single season dose to confirm protection.

In preclinical models, CD388 improved the antiviral activity of zanamivir, demonstrating potent universal activity across influenza A and B viruses, including high pathogenicity and neuraminidase inhibitor resistant strains. The molecule has a high barrier to resistance based on in vitro data and has potential to provide increased protection in high-risk and immunocompromised individuals.

Now to the Phase IIb results. The primary endpoint of prevention efficacy of protocol-defined influenza-like illness events at 24 weeks was met with statistical significance at each dose group. The remarkable 76% efficacy at the highest dose demonstrates the potential for once per season protection against all strains of influenza in individuals. All secondary endpoints also met statistical significance in each dose group. There was a low incidence of anti-drug antibodies observed at all doses demonstrating CD388 low immunogenicity.

CD388 was well tolerated with no safety signals observed and the rate of injection site reactions was similar to placebo. The Cidara team has successfully initiated the Phase III ANCHOR study. The trial is rapidly enrolling with the design focused on individuals at high risk for complications of influenza, including those 65 years of age and older and those that are immunocompromised.

Similar to the Phase II study, the primary endpoint is prevention efficacy of influenza-like illness. An interim analysis is scheduled after the first flu season to assess the potential need for an increase in sample size. Finally, I'd also like to echo Rob's comments and highlight Cidara's strong clinical achievements and the success they've had in advancing the science in this important disease area.

With that, I will turn the call over to Chirfi, who will highlight the commercial opportunity in more detail.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Thank you, Dean, and good morning, everyone. As you heard from Dean, our team is excited about the opportunity to advance a potential first-in-class, once-per-season, strain agnostic long-acting antiviral agent for influenza. We see a complementary fit with our existing portfolio and pipeline, given our strong presence across a range of diseases in which individuals are high risk for poor outcomes from influenza.

Influenza is a persistent public health challenge, impacting both individuals and health care systems. Severe outcomes from influenza are concentrated in high-risk populations, including people with underlying illnesses or those aged 65 and older. Beyond the direct burden of disease, the broader consequences of influenza include increased risk of infection and exacerbation of chronic underlying conditions, all of which increase the risk of hospitalization and death. Approximately 50% to 70% of influenza-related hospitalizations and 90% of influenza-related deaths occur in people aged 65 and older.

Vaccination coverage rates are high among high-risk and/or immunocompromised individuals. About 70% to 80% are estimated to receive a traditional flu vaccine today. However, even with that level of coverage, significant risks remain. In fact, 9 out of 10 people who are hospitalized

with influenza had at least one underlying health condition, individuals with COPD, PAH, atherosclerosis and metabolic disorders or those with weakened immune system due to diseases such as HIV or cancer are all at increased risk of developing serious complications from influenza.

More broadly, seasonal influenza is known to burden health care resources. Flu seasons are routinely associated with billions of dollars in health care spending and lost economic output. As we consider the population that CD388 can potentially serve, we expect there to be approximately 110 million individuals in the United States alone at higher risk of influenza complications who would benefit from the protection offered by long-acting antiviral.

This includes approximately 85 million individuals who are living with high-risk conditions or are immunocompromised and approximately 25 million individuals age 65 and older without additional comorbidities who may benefit from additional protection beyond what the current vaccines offer. We believe CD388 will be highly differentiated in the market based on its efficacy in preventing influenza-like illness as well as its potential to provide strain agnostic coverage with seasoned long protection.

In summary, we're eager to put our commercial engine to work behind the potential first-in-class, once per season, strain agnostic antiviral for the prevention of symptomatic influenza in high-risk individuals. CD388 is complementary fit with our current portfolio, covering respiratory vaccines, infectious diseases and other areas that address high-risk patients. We will be well positioned to deliver on its full potential and are excited to build upon the great work done by the Cidara team. Based on a strong clinical profile, the significant unmet need in a large patient population and our commitment to working with customers to operationalize this novel antiviral agent, we believe CD388 represents a greater than $5 billion commercial opportunity.

And with that, I'll turn the call over to Caroline.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Thank you, Chirfi. Merck is in a strong financial position, allowing us to announce the acquisition of Cidara while retaining significant capacity to pursue our capital allocation priorities, including future business development should additional attractive opportunities arise.

As Chirfi highlighted, given the substantial unmet need for influenza prevention in a large at-risk population and the significant protection CD388 provides, we believe it has greater than $5 billion in revenue potential and can be a meaningful driver of growth beginning later this decade and continuing through the next. CD388 strengthens and complements our expanding respiratory pipeline and portfolio. We are confident that this transaction has the potential to create meaningful value to shareholders.

Turning to the financial details of the transaction. Merck has agreed to acquire all outstanding shares of Cidara Therapeutics for $221.50 per share. This results in a total transaction value of approximately $9.2 billion. We intend to finance the transaction primarily through new debt and commercial paper issuance and there will be no impact to our credit rating. We expect the transaction to close in the first quarter of 2026, subject to Cidara shareholder approval and regulatory approvals.

We expect the transaction to be accounted for as an asset acquisition, which will therefore result in a charge recorded to next year's research and development expense of approximately $9 billion or approximately $3.65 per share. In addition, we believe this transaction will negatively impact EPS by approximately $0.30 in the first 12 months, roughly one-third of which represents investment to advance CD388, and the remainder is the assumed cost of financing. The impact of these charges will be reflected in both our GAAP and non-GAAP results.

Our balanced approach to capital allocation remains unchanged. We will use our strong balance sheet and growing cash flow to continue prioritizing investments in our rich portfolio and pipeline. We remain committed to funding and growing our dividend over time and we preserve the ability within a strong investment-grade credit rating to pursue additional value-enhancing and innovation-driven business development transactions, which remains an important priority. Finally, we intend to continue share repurchases this year at the same pace that we've previously communicated.

In summary, the success we are having in advancing and augmenting our pipeline, including through science-led business development, like the acquisition of Cidara makes us increasingly confident about our prospects to deliver important innovation to patients, long-term growth and value creation to shareholders.

I will now turn the call back to Peter.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Thank you, Caroline. Denise, we're now ready for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Carter Gould, Cantor.

Carter Gould - *Cantor Fitzgerald LP - Analyst*

Great. Congrats on the deal. Good to see you. I wanted to touch on the manufacturing side, which I noticed wasn't in the slide deck. Cidara's go-to market strategy has leaned heavily on WuXi manufactured products from China with new CDMOs potentially serving as a backup. Is that still a fair assumption in your hands? Or should we anticipate US domiciled facilities, either CDMOs or your own that will need to be ramped up to be the main source of product by the time of launch for CD388?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. Thanks for the question, Carter. So to answer your question, long term, we will be the manufacturer of the drug and it will be in a US site. Obviously, we'll have to work through the transition with WuXi over time. But given the investments we've been making, we've announced some recently, along with our existing manufacturing footprint and frankly, expertise in the CMC that would be needed for this, we are quite confident in our ability to manufacture and move that forward.

Operator

James Shin, Deutsche Bank.

James Shin - *Deutsche Bank AG - Research Analyst*

As we get ready for CD388 data and pending launch, our discussions with the timing of discussion with ACIP and the status of that whole, I guess, panel, does that impact the launch?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

This is Dean. This is an antiviral that's BLA, that's a biologic that's in the adult population. At this point, there is no concept that this needs to go through the ACIP and relationship to being launched.

Operator

Vamil Divan, Guggenheim Partners.

Vamil Divan - *Guggenheim Securities LLC - Equity Analyst*

So maybe two, if I could. So one, just curious. interesting you have RSV antibody also, now you have this antiviral. I'm curious, has there been -- has the shift in sentiment we're seeing around vaccination in any way impacted your view sort of the infectious disease base to kind of pursue these sorts of opportunities as opposed to maybe vaccination opportunities? And second, just curious, if you see an opportunity for this technology moving beyond influenza into other infectious disease opportunities in the future?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Maybe I'll start and then Dean can jump in on broader applications of this technology. As we look at this, first and foremost, what we're excited about is this is a first-in-class antiviral, which really is a new mechanism for treating people with infectious disease as a result of pneumococcal -- or sorry, seasonal flu mixing our portfolio with the seasonal flu.

So I would not say that our view of what is happening around vaccinations is any way affected either our view of vaccinations or what drove us to this. Why we like this is it's very complementary to what we have in infectious disease. It's very complementary to what we have in the vaccines portfolio and the fact that it's a long-acting antiviral, you can think of actually drugs in dealing with HIV and PrEP as an example, which we're developing. You can think about other areas, other antivirals that are out there, LAGEVRIO, as an example, these are areas where we think it's very complementary. And the science is what drove us here, not something in what is the view of vaccines in the current public stance.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. I would just add scientifically. There has been innovation in the sort of commercial flu vaccine area but from a basic technological approach, I haven't seen any true ability to markedly improve the response to influenza viruses. There were different technologies more recently that we're deployed in flu and you do not see a step function change in being able to improve the efficacy of a flu vaccine.

Given that, that is where the unmet needed, and that is why using a longer-acting viral agent especially a biologic because you're putting an antiviral on an Fc is really an attractive arena for us. As for other areas where you would conjugate something to an Fc in infectious disease and outside of infectious disease, there are applications to it. And this application of this technology is not so distant from those used in terms of antibody drug conjugates.

Operator

Daina Graybosch, Leerink Partners.

Daina Graybosch - *Leerink Partners LLC - Analyst*

I wonder if you could talk a little bit more about the Phase III trial and whether you need to show trends in protection for all three major circulating strains in influenza A and B? And do you see any risk to capture the total events needed or any specific strains? If you could help us understand that.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

So I should just simply say that we've been in close contact with Cidara's team. We're very comfortable with the plans, and we're very comfortable with their relationship with the FDA. Outside of that, I would be a little bit hesitant to speak on the details of their clinical trial and some of their details of that until we are the full owners of this asset.

Operator

Alex Hammond, Wolfe Research.

Alexandria Hammond - *Wolfe Research LLC - Equity Analyst*

Two for me. So the first one is, looking forward on M&A, are you focused on the same therapeutic areas and target size of $1 billion to $15 billion? And how should we think about the cadence of additional potential trials? And then in light of payer emphasis on real-world evidence, what post-approval studies are planned to kind of quantify CD388's cost offset in the immunocompromised populations? Thank you.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. Maybe I'll start, and then Chirfi can jump in on the second part of the question or Dean, either one. So as it relates to M&A, I would say, first and foremost, we're very excited about this. The ability to affect seasonal influenza is meaningful. And as we've said, it's aligned and very complementary with our existing therapeutic area of focus.

And as you think about going forward, you should assume we're going to continue to follow the same strategy we've been following from business development. We always ask first, is there a significant unmet need where we see interesting science that can address it, does it strategically fit within our portfolio. And in that regard, as we've talked about in the past, we continue to look at oncology as an area for further opportunity, immunology, cardiovascular, cardiometabolic or cardiorespiratory and then any broader opportunity that would present itself.

The $1 billion to $15 billion range is still our primary focus. But as we pointed out, we are willing to go larger than that if we see an asset that brings the scientific benefits I've talked about and is aligned to the portfolio. We continue to believe there is no need for a cost synergy-driven type of transaction. I feel very good that we're on pace to address the growth we need. If we continue to make the progress like we've been making, we are very well positioned. So we want to do more, but we will be disciplined and you'll see us follow the same strategy we followed to date.

So with that, I'll turn it over to maybe Dean and then he can -- Chirfi, if he wants to add anything you can.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. I mean, I would always say real-world evidence is always very important. But I think the focus is on the clinical studies. The FDA has -- and Cidara has announced that they only need one Phase III trial, not two Phase III trials. And so I think the focus is on making sure that the Phase III trial, which is powered to detect a 60% efficacy hits.

And upon hitting that or depending on where that is, it will change how you would do your real world evidence, but you would clearly do real-world evidence. Other people will do real-world evidence for this as well.

Operator

Steve Scala, TD Cowen.

Steve Scala - *Cowen and Company LLC - Analyst*

I have two questions. First, what is the likelihood that resistance will eventually develop to zanamivir? And secondly, Dean, you mentioned the interim look after the first flu season that could trigger a sample size increase. Should we assume that will occur in Q2 of '26? And could this interim also lead to early stoppage for efficacy or early stoppage for futility?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

So I would say that the history of these antivirals and preclinically and what was known clinically, I would say the chances of resistance is relatively low. So that would be the first. And then in relationship to interim analysis, we will look at the interim analysis as to determine whether we're on the right path. We'll know what the attack rate will be in relationship to influenza and we'll make choices accordingly. As you note, depending on how things are, we could expand it. And I would imagine that there is a chance that you could see some degree of futility at an interim analysis, but I think that would be highly not likely.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - *BMO Capital Market - Analyst*

Two for me. So looking at the Phase III trial design, I note that it's -- I see that there's a note that says it's not designed to assess effect on mortality. Is that going to be something you will need eventually to gain reimbursement? And can you also kind of discuss why you decided to take on all the risk by not including some sort of a CVR with this Phase III clinical trial ongoing?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Well, so I would just say that this molecule -- I mean, this is an antiviral that is known to be extremely effective, and you're adding an Fc. So you have a pretty good idea of what the -- with the pharmacokinetics and pharmacodynamics are. So I think also with the positive Phase II studies that is -- I think the FDA has shown its excitement for this mechanism in relationship to showing a mortality in the clinical trial per se. That is not what's in the clinical trial at this point, but I'll let Chirfi speak to how payers may think about that.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

No, we believe that the value proposition will be compelling. You saw on the slide that Dean commented on earlier. You're talking about 82 million cases of illnesses in the last season, as an example, leading to 1.3 million hospitalizations and between 20 million and 40 million medical visits, right? And unfortunately, 30,000 to 130,000 deaths due to influenza. So as you think about that, we believe that we will have a compelling value proposition, which will then allow us to pay -- to price and secure reimbursement for the appropriate protection.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And then in terms of the deal construct, we are very comfortable with the valuation that we have given for this acquisition. What we see is a first-in-class once-per-season strain agnostic antiviral agent. We see it having a high probability of success of making it across the finishing line and therefore, feel we've paid a full and fair value for an asset that has the potential to be over $5 billion as we move forward.

Operator

Chris Schott, JPMorgan.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Just can you talk a little bit more about the commercial model for the product here? So just how quickly assuming successful data do you think this product can ramp? How much education is required, et cetera? And is there anything you can say about price assumptions that are supporting that $5 billion target? Should we think about this kind of conceptually price like we think about a flu vaccine? Or is it something that's very different pricing just given the efficacy profile?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Thank you, Chris. I think the beauty of this asset is that it fits in nicely with our existing commercial model, if you think about the population that we're intending to protect at least initially. You're thinking about cancer patients, COPD patients, arthrosclerosis patients and the like. So these are patients who are typically in health systems already. So we will have the opportunity to reach them in a way that is effective within our existing infrastructure. So that's the first comment I would make to your question.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And if I may, Chris, add in terms of pricing assumptions. It's obviously early to be getting into the details of the exact strategy. As we look at this opportunity, though, there's a significant number of people that currently get a flu vaccine and are not getting the protection they need, and we can provide significant protection to those people with this therapy in advance.

As Cidara did pricing research in the marketplace, they had seen better price points up to $600 was very effective with the potential to have patients take this and not be subject to any access restrictions. So we will look at that research to determine what's the right price point for ourselves. And in addition, as we look at ex US market, we would expect to see fairly comparable prices to the United States. So -- but serving a smaller population. So we're excited about this opportunity, both US as well as the potential ex US.

Operator

Geoff Meacham, Citi.

Geoff Meacham - *Citigroup Inc - Analyst*

Thanks for the question. Congrats on the deal. Dean, it sounds like the regulatory review of this could be outside the purview of ACIP. I wanted to ask how much of the utilization or reimbursement could be guideline driven? And also just thinking about how payers would view kind of cost benefit relative to traditional flu vaccines?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes, I'll just make a scientific a comment, and then I'll turn it over to Chirfi. I mean, you just look at our portfolio, OHTUVAYRE with COPD, WINREVAIR with PAH, enlicitide with secondary prevention in the future, KEYTRUDA, sac-TMT, tulisokibart, diabetic macular edema, HIV. Those patients are not ideally or optimally protected against influenza and they need to be. So that's the excitement from our standpoint.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

And so we also know that for the high-risk individuals and those who are immunocompromised, traditional vaccines really do not offer adequate protection. You're talking about 5% of -- or up to 35% protection for the high-dose vaccine in this case. So we believe that our value proposition will be compelling. So should the Phase III data pan out and we're confident in our ability to bring this protection to those who need it most.

Operator

(inaudible), Wells Fargo.

Unidentified Participant

So a couple of questions. One is what is the base case assumption you have for the timing of the launch of this vaccine? And then the second one is on commercial, Chirfi. How similar or different do you think it could be from your [RSV mAb] launch in terms of positioning and then getting reimbursement and everything?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I'll take the first question. First, I just want to continue to emphasize this is not a vaccination, right? This is an antiviral. I mean, the way a correlate, it's not a precise correlate, but when we talk about HIV PrEP, we're talking about an antiviral that protects you and those individuals who high risk. This is the same general idea. Clearly, one is in HIV, and this is an influenza.

In relationship to the questions that you have, we're very comfortable with what Cidara has said in the past. But having said that, I would just simply say that until we have full control of the asset and all of this, I would just -- we may update that in the future time, but we are very comfortable with what the assumptions are behind Cidara and what they have said publicly.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

So just to add to the second point of your question. So the RSV mAb our (inaudible) obviously addresses infants. So this is for adults. And the big difference really is the size of the opportunity. You're talking about potentially 110 million people just in the United States, 85 million of them who have high risk or are immunocompromised and then 25 million who are 65 years and older who are all candidates for -- to receive this prevention. So this is a meaningful opportunity, over $5 billion as we have forecasted it.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Sanford C Bernstein & Co LLC - Equity Analyst*

I have two, if possible. One, I just wanted to probe a little bit more on that commercial model. Can you just help us understand a little bit more about where you anticipate the point of administration being? Is it with kind of those specialist environments for those particular patients? Is it more in the primary care setting? Or is it more in the retail pharmacy setting?

And then the second question is at Caroline, I think you made a point about the parameters of this deal and you're feeling very comfortable with the returns for what's being paid. Can you just clarify, given your comments on kind of US pricing versus ex US pricing, is US revenue enough for this deal to be a positive return on investment? Or do you need kind of that ex-US expansion to take place as well?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Maybe I'll take the first part, and then Caroline, you can take the second one. So thank you for the question. As we stated earlier, we believe CD388 is complementary with our current portfolio and pipeline, covering respiratory vaccines, infectious disease, HIV in particular, but also other areas such as cancer, COPD, PAH, atherosclerosis. These are all areas for which we have or are building infrastructure. So we do not anticipate that CD388 will require additional -- significant additional resources to support this launch because of the call point overlaps in this particular case.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And in terms of the return, Courtney, as we've valued this business, the US is the more significant part of our valuation. As we've looked at ex US, and seen prior precedents, we see the opportunity to price somewhat consistently to the US market in the G7 plus market, supporting a smaller population, and so we are very confident in the valuation we've given. We do feel that ex US, we will have a market. And we do feel that there could be upside, quite frankly, to the US market should the point of administration of this increase beyond the traditional points of administration that we're currently including in our valuation.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

So maybe I'll add to that. Just on the point of administration. In our model, we have factored in that these patients who are going to be prioritized really are already part of the health care system. So they will have access to CD388. And so that is what's baked into our model. But should there be a pharmacy opportunity at a later stage, that will present an additional opportunity but we have not factored that into our model at this stage.

Operator

Daina Graybosch, Leerink Partners.

Daina Graybosch - *Leerink Partners LLC - Analyst*

We talked a lot about this not being an ACIP. Is this actually fall under the USPSTF preventative services like PrEP? And is that an opportunity in the future to expand access?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I think all of those things would be considerations. I think as you noted, what guidelines and who would recommend. What I meant in relationship to ACIP is it's not formally under their requirement to actually opine and that's the current precedence. But in terms of other guidelines, I think it will be important to target other guidelines and to ensure that they -- if the data holds the way that we think that they recommend it for the patient populations that are most in need.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

You're talking about high risk and immunocompromised patients. So those are going to be really prioritized.

Operator

Steve Scala, TD Cowen.

Steve Scala - *Cowen and Company LLC - Analyst*

Are there significant drug-drug interactions between zanamivir and drugs commonly used by older people? And what clinical data has been generated to date of CD388 in older adults and immunocompromised adults?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. So I would just say that in the data that has been publicly available in relationship, I do not believe that substantial DDIs have been seen or ADAs have been seen. In terms of your other question, you're in relationship with what data, that requires detailed subsegmentation of the Phase II that has already been advanced, but we think that this drug, this antiviral with an Fc will have low ADA and will have limited drug-drug interactions with those drugs that these other patients are taking.

Operator

There are no further questions at this time.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Great. Well, thank you all very much for your time and interest this morning. We appreciate it and a lot of good questions. Please reach out to the IR team if you have any follow-ups, so we look forward to catching up with you soon. Thank you.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thank you.

Operator

Thank you. That does conclude -- we appreciate everyone's participation. Have a great day, and you may now disconnect.