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EDITED TRANSCRIPT

MRK.N - Merck & Co Inc to Acquire Terns Pharmaceuticals Inc

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OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

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PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Company Incorporated, Rahway New Jersey USA Investor Event announcing the acquisition of Terns Pharmaceuticals.

(Operator Instructions) This call is being recorded. If you have any objections, you may disconnect at this time. I would now like to 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, Amanda. Good morning, everyone. Welcome to Merck's investor call highlighting the announced acquisition of Terns Pharmaceuticals. 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. 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 in the 2025 10-K as well as Terns' SEC filings identify certain risk factors and

cautionary statements that could cause ours or Tern's actual results to differ materially from those projected in any of our forward-looking statements made this morning.

Merck & Company Inc., Rahway, New Jersey USA undertakes no obligation to publicly update any forward-looking statements. During today's call, a 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 speakers this morning include Rob Davis, Merck's Chairman and Chief Executive Officer; Dr. Dean Li, President of Merck Research Laboratories, Jannie Oosthuizen, Executive Vice President and President, Oncology and MSD International; and Caroline Litchfield, Chief Financial Officer.

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

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

Great. Thanks, Peter. Good morning, everyone. The ongoing successful execution of our science-led strategy is enabling us to positively impact patients and drive sustainable growth over the long term. We are transforming our company with launches underway for more than 20 anticipated new growth drivers, almost all of which have blockbuster potential and together represent a combined non-risk-adjusted potential commercial opportunity of over $70 billion by the mid-2030s.

Innovation-driven value-enhancing business development is an important element of our strategy to expand and diversify our pipeline across a broad set of therapeutic areas, including oncology.

Today, we're excited to announce our proposed acquisition of Terns Pharmaceuticals. Its lead candidate, TERN-701, is a potent, orally available next-generation allosteric tyrosine kinase inhibitor being studied in certain patients with chronic myeloid leukemia or CML.

We believe TERN-701 has the potential to be a best-in-class therapy, driven by high selectivity and an improved therapeutic index that could lead to efficacy advantages versus currently approved TKI agents. Patients with CML often remain on therapy for many years. And while significant advances have been made, there remains opportunity to further improve disease control and treatment outcomes.

In addition, challenges with today's treatments related to durability and tolerability lead to frequent switching. TERN-701 is designed to address these unmet needs and provide an important potential new option for patients. Given the size of the addressable population and the remaining unmet medical need, we believe TERN-701 has multibillion-dollar commercial potential and will be a significant driver of growth in the next decade.

This acquisition builds upon our deep expertise in oncology and strengthens and complements our growing hematology pipeline, which has significant future commercial potential as part of the oncology business unit under Jannie's leadership.

More broadly, this transaction reflects our commitment to acting decisively when compelling science and value align and our confidence in the benefits TERN-701 will bring to patients while generating value for our shareholders over time. We're eager to welcome the talented Terns team to Merck and look forward to the contributions they will make as part of our organization.

With that, I'll turn the call over to Dean.

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

Thank you, Rob. Good morning, everyone. Our company has made remarkable progress in treating cancer, most notably solid tumors, but there is more work to be done. As we have advanced our oncology strategy and diversified our clinical pipeline, hematology has become

a particular area of opportunity and interest. The acquisition of Terns provides our company with an opportunity to further investigate the potential of TERN-701 for certain patients with CML.

CML is a slow-growing cancer derived from the bone marrow's blood forming stem cells and is characterized by a distinct translocation between chromosomes 9 and 22 known as the Philadelphia chromosome. Historically, due to limited treatment options, the diagnosis of CML was almost universally fatal. The advent of tyrosine kinase inhibitors fundamentally transformed the treatment landscape and significantly improved outcomes for patients.

Today, CML is generally managed as a chronic condition with many patients remaining on therapy for extended periods of time, often for many years. However, long-term exposure to existing therapies is associated with increased risk of relapse due to the emergence of resistant driver mutations, primarily in the kinase domain or active site of the BCR::ABL protein.

Similarly, while adverse events tend to appear in the first few months, the cumulative risk of developing intolerance to one or more TKI therapies increases with the duration of treatment and the number of lines of therapy.

As many as 40% of patients treated with active site TKIs switch therapies within five years. In the second line and later settings, the majority of people with CML do not achieve a deep molecular response. So despite multiple available treatments, there remains significant need for further options.

The focus of development has therefore evolved with enhanced emphasis on increasing the depth of response and overall disease control while improving long-term efficacy, safety, tolerability and overall quality of life.

TERN-701 is a potent, selective, oral next-generation allosteric BCR::ABL tyrosine kinase inhibitor. Unlike traditional active site competitive TKIs, TERN-701 is designed to specifically target a distinct site on the ABL protein that controls kinase activity, thereby overcoming mutations that occur in the kinase active site.

This differentiated mechanism is designed to inhibit the oncogenic driver while minimizing off-target effects. The high degree of target selectivity observed with TERN-701 supports the potential for higher dosing with more complete inhibition and an improved therapeutic index. TERN-701 has demonstrated preclinical activity against multiple resistance mutations, further supporting its continued evaluation across different lines of therapy.

In the ongoing Phase 1/2 CARDINAL study, TERN-701 has demonstrated promising activity in patients with Philadelphia chromosome-positive CML previously treated with at least 1 TKI with encouraging rates of major molecular responses and deep molecular responses observed by week 24, key measures of the reduction of BCR::ABL cancer cells.

Importantly, these responses were achieved in a previously treated patient population with high disease burden, including those previously treated with multiple TKIs and even those who had previously relapsed while receiving Asciminib, the only allosteric TKI approved for treatment of CML.

We reviewed the totality of data for TERN-701 and estimate that the final MMR achievement using a more conservative intent-to-treat population would be approximately double the MMR and double to triple the DMR achievement of approved TKIs, including Asciminib.

Based on this analysis, TERN-701 has the potential to be a best-in-class therapy for certain patients with CML. Furthermore, TERN-701 has also shown a faster kinetic response to achieving MMR and DMR than approved treatments, providing additional support for its potential best-in-class profile.

Safety is a critical consideration in CML given the long-term nature of treatment. To date, no dose-limiting toxicities have been observed for TERN-701 and the majority of treatment-emergent adverse events reported have been low grade. Furthermore, the overall safety and

tolerability profile appears favorable with a low incidence of serious adverse events based on data available to date. Dose expansion is ongoing to further characterize the safety profile and inform optimal Phase 3 dose selection.

Looking ahead, we see an opportunity to apply our global clinical development capabilities to evaluate the potential of TERN-701. We intend to design a rigorous and appropriately powered clinical program that addresses both frontline and later-line treatment settings in CML. As with all of our programs, our focus will be on generating high-quality data that clearly characterizes TERN-701's benefit risk profile and supports its potential role in the treatment landscape. TERN-701 further augments and complements our growing and innovative hematology pipeline, spanning multiple modalities and disease areas.

In addition to our existing approval for KEYTRUDA, we have a series of pivotal readouts from a pipeline of innovative hematology candidates within the next couple of years, including Nemtabrutinib, our non-covalent BTK inhibitor, Bomedemstat, our LSD1 inhibitor and Zilovertamab vedotin, our ROR1 targeting ADC. As well as MK-1045, our CD19xCD3 T-cell engager, which is being evaluated in a Phase 1/2 study.

We believe TERN-701 provides a strong strategic fit within our broader hematology ambitions and reinforces our commitment to science-driven innovation with the goal of making a meaningful difference for patients over the long term.

Finally, I'd like to reiterate Rob's comments and convey my admiration and respect to the Terns team for their remarkable achievements in discovering TERN-701 and advancing the science in this important disease area.

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

Jannie Oosthuizen - *Merck & Co Inc - Executive Vice President and President, Oncology & MSD International*

Thank you, Dean. As both Rob and Dean highlighted, we are committed to advancing the science in hematology and an area of significant clinical need and opportunity to positively impact patients. Given our expanding pipeline, we are well positioned to launch several innovative therapies in the coming years. And so I am excited to add TERN-701 to our portfolio, and I'm confident in its potential to deliver meaningful benefit for patients. CML is a chronic disease that often requires long term and in many cases, lifelong treatment. As outcomes have improved, patients are living longer, which has contributed to the increasing prevalence of the disease over time.

Across the US, key European markets and Japan, there are estimated to be 18,000 new patients diagnosed with CML each year. As the treated population grows, factors such as tolerability and adherence have become increasingly important.

Despite multiple approved treatment options, unmet need remains, particularly in the context of long-term duration. TERN-701 has the potential to be the best-in-class treatment for certain patients with CML. And as Dean noted, it will be complementary to our current hematology portfolio where we expect a cadence of launches over the next several years.

Given the substantial unmet need for additional options for certain patients with CML and the significant potential benefits of TERN-701, we believe it has multibillion-dollar revenue potential and can be a meaningful driver of growth beginning in the early 2030s and continuing through the next decade.

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

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

Thank you, Jannie. Turning to the financial details of the transaction. We are confident that TERN-701 can be a meaningful driver of growth in the next decade, and this transaction has the potential to create significant value for shareholders.

Merck has agreed to acquire all outstanding shares of Terns Pharmaceuticals for $53 per share, representing a total equity value of approximately $6.7 billion or approximately $5.7 billion net of acquired cash, cash equivalents and marketable securities.

We intend to finance the transaction primarily through new debt, and we do not expect an impact to our credit rating. The transaction is expected to close in the second quarter of 2026, subject to the tender of a majority of Tern's outstanding shares as well as regulatory approvals. We expect the transaction to be accounted for as an asset acquisition.

As a result, we expect a charge to research and development expense in 2026 of approximately $5.8 billion or approximately $2.35 per share. In addition, we expect a negative impact to EPS of approximately $0.17 in the first 12 months, which represents investment to advance the development of TERN-701 and 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. Business development continues to be an important priority. We remain committed to a strong investment-grade credit rating while preserving capacity within it to pursue additional value-enhancing transactions.

In summary, the success we are having in advancing and augmenting our pipeline, including through science-led business development, such as the planned acquisition of Tern, increases our confidence in our ability to deliver important innovation to patients and sustain our long-term growth while providing value to shareholders.

I will now turn the call back to Peter.

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

Thank you, Caroline. Amanda, we're now ready to begin Q&A. I just want to let everyone know that in the room with us is Dr. Marjorie Green, Senior Vice President and Head of Oncology Global Clinical Development.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Evan Seigerman, BMO Capital Markets.

Evan Seigerman - *Bank of Montreal - Analyst*

Congrats on the deal. I really want to kind of get into the nitty gritty. In your diligence, can you explain why TERN-701's allosteric inhibition may be more optimal than other active site TKIs in CML?

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

So this is Dean. I'll just make some really quick comments, and I'll hand it back to Marjorie. So you're asking whether or not inhibitors of an allosteric why they are potentially superior than those who are orthosteric, which is the active site? I think the data from Asciminib suggests that there are advantages of an allosteric site over an active site or an orthosteric tyrosine kinase. That sort of had been played out.

In relationship to Terns, we believe that this allosteric inhibitor could even have more superior efficacy in relationship to the TKIs at our active site and also potentially in a basket in relationship to those who are also on allosteric. But Marjorie, is there anything you wanted to add?

Marjorie Green - *Merck & Co - Head of Oncology Clinical Development*

Yeah. No, thanks, Dean. Part of the interest, I think, has to do with mechanisms of resistance that occur over time. And it does appear that for the different classes of TKIs, there are different mechanisms of resistance. And it is potentially possible that by using different allosteric, you're able to overcome resistance that could exist with some of the first and second-generation TKIs.

Operator

Alex Hammond, Wolfe Research.

Alexandria Hammond - *Wolfe Research LLC - Equity Analyst*

On safety, Terns noted that there was no symptomatic lipase elevation. Should we interpret this as there were asymptomatic elevation? And if so, is there any concern in larger clinical trials that you could see symptomatic elevations? And I guess as a follow-up, what's your appetite for continued BD and any additional therapeutic areas of interest?

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

So why don't -- I'll have Marjorie take the first question, and then I'll answer the second question about continued interest in business development.

Marjorie Green - *Merck & Co - Head of Oncology Clinical Development*

Yeah. Thanks for the question. Regarding the lipase elevations, Terns has publicly disclosed and data that we have confirmed that rates of lipase elevation are present, but they are low grade and in their nature, the majority of adverse effects that occur with these kind of TKIs, you will see signals within the first 6 months of exposure for majority of AEs. And so I think, again, what they are showing are consistent with the class low-grade lipase elevations.

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

Thank you, Marjorie. And then as it relates to business development, to be clear, hopefully, what you see here is a transaction that very much fits into what has been our ongoing business development strategy, which, as you know, and we've communicated pretty consistently always starts with the question, do we see a significant unmet need where there is innovative science that can address it? And then we ask, how does it fit within the strategic portfolio that we have? And then finally, do we see an opportunity for compelling value creation. And in this case, we hit all of those factors.

As we look forward, our interest continues to be to add more to the portfolio while we are very excited about what we have, and I give all the credit in the world to Dean and our scientific team for what we've been able already to achieve as represented in the potential $70 billion-plus. And remember, that's only from a select set of assets, not from our entire portfolio. We feel very good about where we are, but I always believe you can do more.

And in that spirit, we will in a disciplined way, continue to look for opportunities. I'm excited that we can add to our position in oncology here, both in terms of putting ourselves in a position to continue to be a leader in oncology, but also to diversify within the oncology space and add to our hematology portfolio. Beyond that, we continue to be interested in other therapeutic areas. and it should not be a surprise. Immunology continues to be an area we often look and are excited about cardiometabolic vaccines, ophthalmology based on some of the recent deals we've done.

And then we're always opportunistic, again, starting always with the first question, where is the science pointing us and what do we see as the need? And that is always the driver.

Operator

James Shin, Deutsche Bank.

James Shin - *Deutsche Bank AG - Research Analyst*

First question is for either Dean or Marjorie. Appreciate 701's frontline CML trial as against investigator's choice for MMR. Any chance this frontline trial includes testing for noninferiority and possibly superiority to Asciminib? And one for Rob and team. It seems you have line of sight to late line and frontline CML for 701. So how much does this terms deal change the $70 billion peak pipeline figure presented earlier this year?

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

So this is Dean. One of the things I just want to be a little bit cautious about talking about a potential Phase 3 development program is number one, we don't have ownership of this company or the control of the study design. And our intention always is to pursue a robust and appropriately powered program that demonstrates the unambiguous promotable advantage of whatever medicine or vaccines we're advancing.

But I would just ask Marjorie is there anything else that you want to add?

Marjorie Green - *Merck & Co - Head of Oncology Clinical Development*

No, I agree. We're very excited about the potential of TERN-701 to make a clinically meaningful difference for people with CML, and we will execute a robust, well-developed program should the transaction go through.

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

And as it relates to the $70 billion-plus, you should assume, as we said, with multibillion-dollar plus opportunity, commercial opportunity from this asset, we are growing it. I'll let you determine how much multibillion is.

Operator

Louise Chen, Scotiabank.

Louise Chen - *Scotiabank GBM - Analyst*

Congratulations on the deal. So I wanted to ask you if you could elucidate a little bit more how TERN-701 would fit into the treatment paradigm if it's approved? And then how do you expect it to take share? Would it be new patients or from existing therapies?

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

So I'll just give a highlight, which is what we've said in the prepared remarks is our calculation based on early data suggests that there's a possibility that this drug, TERN-701 may have around 2 times MMR versus approved TKIs and 2 to 3 times DMR in approved TKIs and a faster kinetic response than that was treated before and also a very favorable safety and tolerability so that someone could stay on it.

So I just think that, that's the scope of how we view the positioning of this scientifically, but I'll hand it over to Jannie for a commercial view of that potential ambition.

Jannie Oosthuizen - *Merck & Co Inc - Executive Vice President and President, Oncology & MSD International*

Yeah. So thank you, Dean. So as we said, we see this to be a multibillion-dollar commercial opportunity. I'm not going to so much talk about the assumption on share. I think the first order of business would be to stand up the development program to really generate the data that is needed to define the differentiation that we're going to have against other options, both from a clinical option point of view, depth of response, durability and tolerability.

And we will share more as the Phase 3 program shapes up, but we think that this could be a meaningful choice in the CML setting.

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

I might just add, I think the other part of the question, primarily, we see this as new patients coming on therapy and being able to move into that space. That's the way we valued it. Obviously, over time, we will look to see for the opportunities for switch as well. But given the number of new patients that unfortunately continue to become inflicted with CML every year, there's a meaningful opportunity there. Having them stay on therapy chronically allows you to effectively multiply that over time. And then to the extent we drive switch over time, it even goes higher. So all of that is why we're so confident in the multibillion-dollar opportunity.

Operator

Jason Gerberry, Bank of America.

Jason Gerberry - *Bank of America - Analyst*

Maybe just a follow-up question just on the commercial point. I guess from your standpoint, which of the, I guess, data variables in future data really is key to having success driving a switch in a market like this? Is it really the safety? Is it the lack of food effect or efficacy differentiation in the head-to-head comparisons? And then just as a follow-up, did you guys describe any value to assets beyond 701 in this deal?

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

Yeah. So let me just take a first stab at things. In relationship to the basic question, at least my simple sort of view is especially in oncology, especially oncology, but in all therapeutic areas. Efficacy and showing improved efficacy is a critical component of how we look at our own internal programs and how we look at every other program when we do business development. So it's a common sort of thing. Efficacy is critically important.

But with that, I'll hand it over to Jannie.

Jannie Oosthuizen - *Merck & Co Inc - Executive Vice President and President, Oncology & MSD International*

Yeah, absolutely. I will tell you what makes us excited as a commercial organization is if you can have a treatment with double the MMR, 2 to 3 times DMR and that faster kinetic response to achieve both MMR and DMR on top of a very tolerable product, I think this will be a significant choice in that first-line setting.

So again, as Rob said, there's about 80,000 patients annually across the US, Japan and key European markets that is newly diagnosed with CML -- so we see a product with a profile like that capturing a significant number of patients in that first-line setting and could motivate some physicians to switch other patients on to a therapy like this.

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

And Jason, in terms of the valuation, our valuation is based on TERN-701.

Operator

Michael Yee, UBS.

Dina Elmonshed - *UBS - Analyst*

This is Dina on for Mike. Thinking about time lines for the pivotal study, I know that Terns had previously said that the second-line study would start first and then the first line or frontline study would be running in parallel, but about 6 to 12 months behind. Is there any way that that time line can be accelerated, especially for the front line? And how are you thinking about just the path forward from there?

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

So I'll just take it really quickly. I want to be a little bit thoughtful and careful as to how to answer any questions directly related to clinical trial design and timelines until we are fully in control of Terns. And also, this will also require discussions clearly, whether it's Terns or us with the regulatory agencies. So I don't want to get ahead of that.

But there is nothing that Terns has said that we would sit there and we are going with the assumptions of what they have said publicly.

Operator

Geoff Meacham, Citi.

Mary Kate - *Citi - Analyst*

This is Mary Kate on for Geoff. So Terns has mentioned additional data from the CARDINAL trial is to be expected in the second half of this year. I guess just should we expect a similar readout in terms of time lines? And could you maybe walk us through how you're looking at the ongoing clinical trial and what you'd like to see to further bolster your confidence in this program?

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

I mean I would just emphasize the way that we look at this program is we conduct a comprehensive and rigorous evaluation of all available data. And at that level, we're looking at patient level data and always thinking consistent with regulatory standards for registration.

So we're comfortable as we get more data and as people -- more people are treated with this drug and also those who are treated with the drug get more experience, that will inform how we think about future development and the timelines related to that.

But Marjorie, is there anything else that you would like to add?

Marjorie Green - *Merck & Co - Head of Oncology Clinical Development*

Yeah. No, thanks. Terns has done a fantastic job with their development of 701. And I think they've talked about publicly and shown that they've already completed dose escalation are in randomized dose finding. And so we would work with ensuring that that data is well described and understood and presented in a timely fashion.

Operator

Daina Graybosch, Leerink Partners.

Daina Graybosch - *Leerink Partners LLC - Analyst*

Rob, you talked about the four pillars of Merck's BD strategy and one is an opportunity for compelling value creation. And I wonder if you could talk more specifically in this case, why Merck owning this asset is going to create more value for your shareholders.

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

Well, obviously, one of the strengths we've had over the last several years is the position we've been able to enjoy in oncology. And we've been working hard to expand that. As Dean highlighted, we have multiple assets that we'll be launching in the hematology space over the coming years. This adds to that. We've already been building the commercial capabilities and leveraging, frankly, what we already know from the solid tumor side to leverage over to that.

And given the scale we have, both from our clinical programs, which I continue to be proud of what we've done. I think we have the best clinical team in the industry in oncology. And so the confidence that when we give them an asset that they can bring it through and deliver it clinically, we've shown we can do that consistently.

And so that gives me great confidence in our ability to drive this program to success. And then given the scale we have commercially in the marketplace, we will leverage that full network to drive this product. So this is something that builds on where we want to be. As Dean has always said, we started, we were a leader in IO. We are committed to being a leader across broader oncology with a very diversified portfolio of assets, and this adds nicely to that. So I'm very confident in the compelling value this is going to bring for shareholders.

Operator

Mohit Bansal, Wells Fargo Securities.

William Zhang - *Wells Fargo Securities LLC - Analyst*

This is Will Zhang on for Mohit Bansal. Congrats on the deal. So I guess moving over to the first-line setting. So Gleevec and its generics still have meaningful share in the first line despite Scemblix being approved and available there. How are you thinking about overcoming this first-mover advantage with TERN-701?

And just where do you see opportunity for TERN-701 to take share here?

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

Yeah. So I'll let Jannie talk about the shares and the commercial aspect, but I think it will be important to hear from Marjorie as the person who leads late-stage oncology, why she and her teams are excited about bringing this opportunity to patients with CML.

Marjorie Green - *Merck & Co - Head of Oncology Clinical Development*

Yeah. Thanks, Dean. There -- you're correct. There are still physicians who are using the first-generation Gleevec. They've gotten used to the management of the side effects and have seen consistent efficacy over a long period of time. However, there remains significant unmet need in CML. And I think that's what drives a change in therapy showing that value.

If you look at some of the data sets that people still present, you'll see a reference to MR2, which is what Gleevec was founded for, was the ability to get a cytogenetic negative test result with the drug.

However, what's becoming more and more apparent is that while the risk of accelerated phase of CML and blast phase has gone down significantly with drugs, it still exists. And so time to getting to that molecular response and depth of molecular response are important prognostic factors and prediction of how people with CML will do for the long term.

So having a drug that is tolerable that people who are on for a long period of time can get an individual CML to a very rapid and deep response is very prognostic for their long-term outcomes. And we think that is what will drive the clinical uptake.

There is a move to considering for some people treatment-free intervals. And to do that, you need to have very, very prolonged deep molecular responses and people wait for several years before they even consider that. And so I think that's the value proposition that people see. It's that depth of response and the tolerability that will change therapy.

Jannie Oosthuizen - *Merck & Co Inc - Executive Vice President and President, Oncology & MSD International*

Yeah, I fully agree, it's Jannie. I think as we've seen again and again in oncology, it's the data that really makes the difference. And if we can deliver that improved MMR, but as Marjorie said, the deep molecular response at 2 to 3x plus the tolerability versus current options, we are confident that we will take significant share.

Operator

Umer Raffat, Evercore ISI.

Umer Raffat - *Evercore Inc - Equity Analyst*

I have two here, if I may. First of all, congrats to you guys on the deal. Two, if I may. First, just the fact that we're going into a myristoyl binding pocket. I guess my first question would be, have we seen any MMRs in T315i patients because I feel like there's been no conversation on that so far. Secondly, on MMR itself, I feel like any headline number is just -- there's just a lot more to it than the headline itself.

So my question instead is there's a 64% MMR in 28 patients. Separately, we know 18 patients at baseline were enrolled because they discontinued because of lack of tolerability. So how much of this 28-patient denominator is driven by lack of tolerability patients rather than lack of efficacy or truly resistant patients?

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

So I'll turn it over to Marjorie, but I just sort of really want to emphasize that there's probably like maybe 20% to 30% of patients that demonstrate resistance and 70% of those estimated to develop a point mutation in the ABL gene.

In relationship to the data that we've had, we've seen patient level data and also remember that there is continuing to be a dose escalation in relationship to the doses with which the patients are being exposed. But I was just going to turn it over to Marjorie, if there's any other considerations that she wanted to bring.

Marjorie Green - *Merck & Co - Head of Oncology Clinical Development*

Yeah. No, thanks. The Terns are doing a great job at analyzing and evaluating the potential for people with and without different kind of mutations of BCR::ABL. That data has not been publicly presented to my knowledge. And -- but these people are being enrolled into the study to understand the characteristics of TERN-701 further. I think in their public presentation that they did in December, they go through the details of how they calculated the different levels of response.

And so what we did, as Dean said, is we had patient-level data -- and we looked at it through multiple different lenses because the nature of Phase 1/2 studies is that you get a very heterogeneous population. And so we were able to look at people based upon prior therapies.

And as Dean said, a significant number of people enrolled in these studies that had prior assay and lack of efficacy was present in a high number of them rather than intolerance. And so there's a lot of very rich data there. I can't share the full details of the work that we've done, but the study has been open for a long time, and the data that was presented at ASH had a data cut of September. And so what we were able to do is confirm this profound efficacy you hear us all talking about and that it's held up over time.

Operator

Luisa Hector, Berenberg.

Luisa Hector - *Joh Berenberg Gossler & Co KG - Analyst*

Just in terms of the deal valuation, so Caroline said based on TERN-701, could you add any color on how you may have changed your thought process? Is this largely based on US value? Any thoughts around MFN, IRA, channel mix? And then just any comments on IP, just your levels of confidence in the IP.

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

Thank you, Luisa. So the valuation that we do considers a whole number of scenarios. What I would say is TERN-701 is a really impactful product. It's a product that has orphan drug designation. As such, as a product given the current rules, we would expect to not be included in IRA nor in MFN.

Our valuation, however, is predominantly driven by the United States. So we are very confident in the valuation that we have given for the product and very excited for its launch. As we look at IP, we expect that IP will go out into the 2040s.

Operator

Emily Field, Barclays.

Emily Field - *Barclays Services Corp - Equity Analyst*

I guess sort of a follow-up question to the earlier one on Gleevec, but asking a different way. I was just thinking back to ASCO a couple of years ago when Novartis presented the ASC4FIRST data. Most of the questions from the analysts then were really about the genericization of the earlier generation TKIs and how they expected commercial development from a payer and reimbursement perspective.

So I was just wondering how you guys have thought about that and how the sort of generic and payer landscape may have evolved by the time this product could launch and how you'd be able to get coverage.

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

I'll just say from a scientific standpoint, then I'll hand it over to Jannie. My understanding from the physicians that we've talked to is that the desire or the attractiveness of that first allosteric TKI is such that people do want to prescribe it because of what they are perceived as improved ability to get MMR.

And so I just want to sort of emphasize that what we believe is really important in this field is the improved MMR that we may achieve with TERN-701, but also the very much improved deep molecular response that when we look at it, we have not seen data that's similar to that outside of TERN-701.

But with that, I'll turn it over to Jannie.

Jannie Oosthuizen - *Merck & Co Inc - Executive Vice President and President, Oncology & MSD International*

Yeah. I mean, as we looked at it, we couldn't see any utilization management in terms of current treatment options. So we do believe that Asciminib will continue to take share. As we look at TERN-701, we do believe that differentiated data will continue to give the ability to use, and we will have time to really establish this as a treatment choice.

So we do not foresee in terms of how the market currently operates that utilization management, genericization of any of these first or second-generation TKIs will affect the utilization, reimbursement and access to TERN-701, for instance.

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

Great. Thanks, Emily, and thanks, everyone, for your time and attention this morning. Please reach out to the Investor Relations team if you have any follow-up questions. Have a great day.

Operator

Thank you. That concludes today's conference. Thank you for participating. You may disconnect at this time.
