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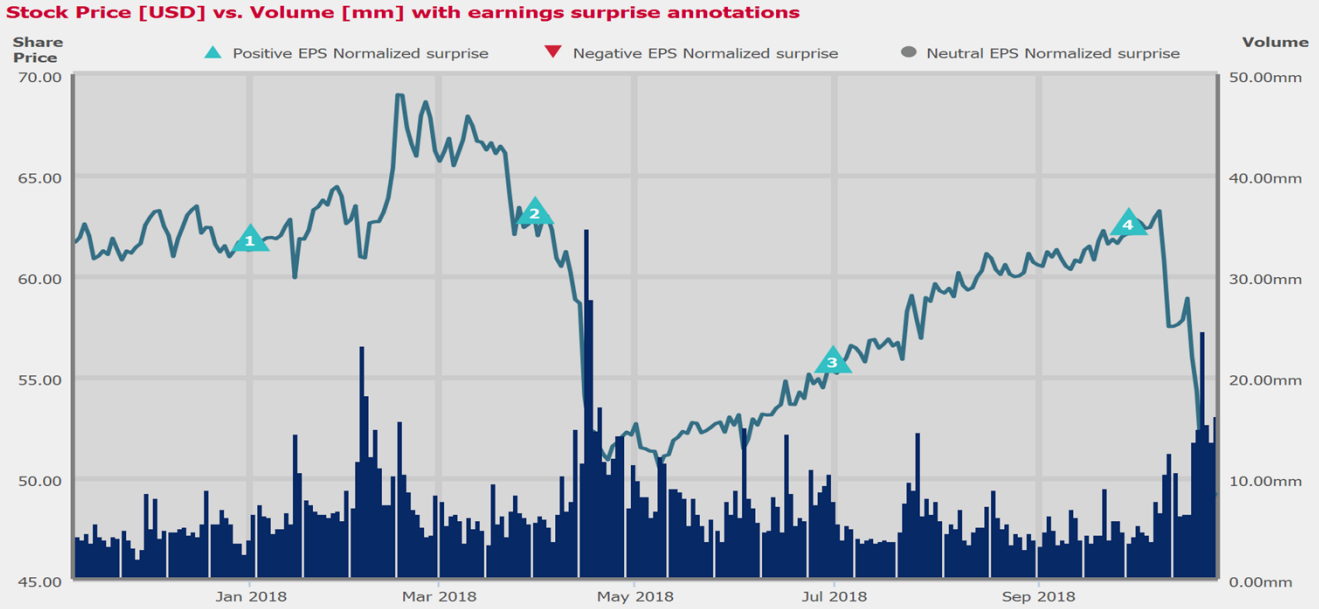
Bristol-Myers Squibb Company NYSE:BMY FQ3 2018 Earnings Call Transcripts

Thursday, October 25, 2018 2:30 PM GMT

S&P Global Market Intelligence Estimates

	-FQ3 2018-			-FQ4 2018-	-FY 2018-	-FY 2019-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	0.91	1.09	▲19.78	0.81	3.68	3.93
Revenue (mm)	5722.11	5691.00	▼(0.54 %)	5835.60	22433.03	23687.17

Currency: USD
Consensus as of Oct-25-2018 2:53 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ4 2017	0.67	0.68	1 1.49 %
FQ1 2018	0.85	0.94	2 10.59 %
FQ2 2018	0.87	1.01	3 16.09 %
FQ3 2018	0.91	1.09	4 19.78 %

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Presentation

Operator

Good day, and welcome to the Bristol-Myers Squibb 2018 Third Quarter Results Conference Call. Today's call is being recorded. At this time, I would like to turn the conference over to Mr. John Elicker, Senior Vice President, Public Affairs and Investor Relations. Please go ahead, sir.

John E. Elicker
Senior Vice President of Corporate Affairs & Investor Relations

Thanks, Vicky, and good morning, everybody. Thanks for joining us for the Q3 call. Giovanni and Charlie will have prepared remarks as usual, and joining us for Q&A are Tom Lynch, our Chief Scientific Officer; and Chris Boerner, our Chief Commercial Officer.

Before we get started, I'll take care of the safe harbor language. During the call, we'll make statements about the company's future plans and prospects that constitute forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the company's SEC filings.

These forward-looking statements represent our estimates as of today and should not be relied upon as representing our estimates as of any future date. We specifically disclaim any obligation to update forward-looking statements, even if our estimates change.

We're also going to focus our comments during the call on our non-GAAP financial measures, which are adjusted to exclude certain specified items. Reconciliations of these measures to the most comparable GAAP measures are available at our website.

Giovanni?

Giovanni Caforio
Chairman of the Board & CEO

Thank you, John. Good morning, everyone. Today, we announced another a very strong quarter, with sales growth of 8% and non-GAAP earnings per share growth of 45%. With that said, I'm aware of some of the frustration that many of you have. I wanted you to know that I acknowledge your concerns and today, I'm going to give you my perspective on some of the things I've heard from you.

Let me start with the news on our TMB filing, then I'll provide my perspective on the quarter. And finally, I'll discuss how I am thinking about the company going into 2019 and beyond. Charlie will provide some color on the financials, and Tom and Chris are here for your questions.

So let me step back and discuss first where we are with TMB. We have always believed in pursuing areas of high unmet need and following the science to bring the best options to patients. TMB is an important example of that. As we described earlier this year, based on the emerging data for TMB, we amended Study -227 to evaluate PFS in high TMB patients and demonstrated a significant improvement in PFS. We did it in a way that had no impact on the statistical plan for OS in Part 1a and Part 2.

With regard to the current regulatory filing for TMB, we have always said this was going to be a complex review, and we recognize that the additional OS data increases that complexity. We remain committed to working with health authorities on the application. We continue to believe that TMB is scientifically important and as you know, several other companies as well as academic institutions are working to advance the understanding of TMB.

Based on everything we've seen, we believe TMB will play a role in the treatment of cancer, and we look forward to advancing our research in this area.

Turning now to our results. We delivered another great quarter with outstanding execution across the company. We saw strong demand growth and meaningful market share trends in our portfolio, with

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OPDIVO and ELIQUIS continuing to be positioned well. Specifically, our I-O franchise performed well in a highly competitive market. Our existing indications contributed strong results, including second-line lung, where we maintain a leading share.

Our new indications also performed well. We continue to see strong update -- uptake for the adjuvant melanoma indication in the U.S. and have begun to launch in the early reimbursement markets in Europe such as Germany.

Let me turn to the other newly-launched indication, first-line renal. I know there has been a lot of news and debate about how this market is going to evolve. So let me give you my perspective. I feel very good about our market position. We were the first I-O approved in renal, and we've been calling on physicians who treat renal cancer for almost 3 years. We've established OPDIVO as the leading agent in the second-line setting in a very competitive market.

With the approval in first-line, OPDIVO plus YERVOY is already the leading treatment for patients with intermediate and poor risk. We've achieved this by executing well in the market and leveraging a competitive profile for the combination, which includes strong overall survival, compelling complete response rates and good tolerability.

We operate in competitive markets around the world, and I have full confidence in the commercial organization to continue to be successful in RCC.

Looking forward for OPDIVO, based on the strong trends through 3 quarters, we continue to believe that OPDIVO will grow in '19 based on the current set of indications today.

Let me now turn to ELIQUIS, the other key growth franchise in our business. We are seeing strong trends and ELIQUIS has now become the #1 oral anticoagulant in the U.S. This is an incredible milestone, reinforcing the clinical value that ELIQUIS offers in stroke prevention in atrial fibrillation. I'm confident that ELIQUIS continues to have an important opportunity for growth going forward.

Now looking ahead into '19, the momentum in our business gives us a solid foundation for growth. Additionally, for 2020 and beyond, I see further potential growth drivers in the future coming from a number of sources. First, in oncology, we have over 20 registrational trials reading out between now and 2023 in more than 10 tumor types. Importantly, this includes 6 ongoing trials across multiple indications in the adjuvant setting. This is an area with great progress, with readouts beginning in 2020.

With respect now to the early pipeline. One of the things we've learned is that for earlier I-O assets, it is helpful where possible to see randomized data before moving to registrational studies, and we've applied this to 4 to 5 programs where we expect data to enable go-to-order decisions in '19.

As you know, one of my key priorities is to further diversify our portfolio and I think we've made good progress in '18. I want to highlight some key areas. First, we've moved TYK2 into Phase III based on the very promising data in psoriasis you saw in September. And I look forward to the opportunity to broaden the TYK2 program based on Phase II readouts in the other potential indications such as Crohn's, UC and lupus.

In addition, earlier this year, we entered into a partnership with Janssen for Factor XIa, which is now beginning Phase II. With respect to the FGF21 program, we started the Phase II needed to enable a Phase III program. And finally, next year, we expect data from our nitroxyl donor agent that will inform a potential registrational start.

Business development has always been a core part of our strategy as we look to source innovation externally to diversify the portfolio and then further support long-term growth. This remains a company priority, one that I am very focused on. Our strong balance sheet gives us flexibility in this regard.

In closing, while acknowledging the intensely competitive markets where we operate, I feel good about our performance in the quarter, the momentum in our business as we head into next year and the breadth of opportunities for longer-term growth.

With that, I'll hand it over to Charlie for more specifics on the quarter.

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Charles A. Bancroft
Executive VP of Global Business Operations & CFO

Thanks, Giovanni. Good morning, everyone. This was another strong quarter for the company, highlighted by continued growth across our key brands, including OPDIVO and ELIQUIS. As Giovanni mentioned, OPDIVO trends remain strong, and we are executing at a high level with our new launches in adjuvant melanoma and first-line renal cell in the U.S.

Looking at our international business. We continue to see growth across core indications, and we are in the early days of launching and securing reimbursement for adjuvant melanoma. The strength of YERVOY in the U.S. continues to be driven by the uptake of the OPDIVO-YERVOY regimen in renal cell and continued leadership of the regimen in metastatic melanoma. With these trends in mind, we feel really good about our competitive position and expect that OPDIVO will deliver growth in 2019.

Also contributing to the strong commercial execution was ELIQUIS, which during the quarter became the #1 OAC in the U.S. in total prescriptions. While ELIQUIS TRx volume was up 36% versus prior year, it's important to remember that the impact of coverage gap is most pronounced in the third quarter, and when compared to our second quarter, net sales were reduced by roughly $100 million.

Also impacting sales was an inventory reduction of approximately $50 million. We believe that ELIQUIS's profile and leading market position will be further strengthened by compelling real-world data such as the ARISTOPHANES study shared at ACC earlier this year. And with warfarin TRx share at roughly 35% in the U.S., we believe ELIQUIS has significant headroom for further growth as the leading agent in the expanding NOAC class.

Now I'd like to highlight a number of items from our non-GAAP P&L. As I mentioned back in July, we are beginning to see a moderating of the impact of product mix on our gross margin. Regarding OpEx, we remain disciplined in order to facilitate differential investment behind R&D. As you know, we tend to see a natural phasing of investment towards the final quarter of the year.

As I previously mentioned, other income and expense has increased mainly due to royalties from our Diabetes Alliance and PD-1 products. And finally, with regard to our tax rate, favorability in the quarter was largely due to the release of a reserve from higher periods and the impact of U.S. tax reform.

With respect to capital allocation and as Giovanni mentioned, we continue to view BD as a top priority. We maintain a very strong balance sheet that provides us significant financial flexibility and we'll evaluate opportunities on the basis of their strategic, scientific and financial fit.

I'll now move onto guidance. Based on strong sales trends and favorable product mix, we expect to deliver revenue growth in the high single-digit range and gross margin as a percentage of revenue of approximately 71%. We now expect our effective tax rate to be roughly 17%. With these revisions, we are increasing our non-GAAP EPS guidance range by $0.25. And as always, our guidance assumes current foreign exchange rates.

Now I'll turn it back to John to start the Q&A.

John E. Elicker
Senior Vice President of Corporate Affairs & Investor Relations
Thanks, Giovanni, and thanks, Charlie. Vicky, I think we're ready to go to questions.

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Question and Answer

Operator

[Operator Instructions] And we will take our first question today from Alex Arfaei with BMO Capital Markets.

Ardalan Arfaei
BMO Capital Markets Equity Research

I appreciate all the color. First on RCC, is it fair to assume that this is going to get an increasingly fragmented market. I fully appreciate your OS data in the high-risk patients. What is your, I guess, confidence about being able to protect that business given your survival data? That's the first question. And then Tom, I'm just wondering if I could get your thoughts from Merck's anti-CTLA-4 data at ESMO. It looks to be active, seems to be better tolerated. I appreciate that the data is relatively small and early, but just wondering how you view that as a competitive risk for YERVOY.

Giovanni Caforio
Chairman of the Board & CEO

Thanks, Alex. Why don't we start with Chris on RCC and then we'll move to Tom?

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Yes, Alex, thanks for the question. I think it's useful to step back and really level set on the dynamics in renal cell even beyond Giovanni's opening comments. And so let me get at your question by sort of giving a little bit of perspective here. We've been in this market for a number of years. We know these physicians, they know us, they know our drugs, and we have a strong base book of business in renal cell. In second-line, we're standard of care in most of our major markets and in many of those, including the United States, market share is at/or north of 50%. So that's the second-line business. As we look at the first-line setting, share is currently in the 30% to 35% range, which you may know, we've achieved in roughly 6 weeks post-approval. And as was pointed out at ESMO, both from the podium as well as with the customers we spoke with, OPDIVO plus low dose YERVOY is and should continue to be standard of care in the U.S. So I think if you step back and ask yourself why have we achieved that level of success, I think there are a couple of things at play. First, we have a very good profile with OPDIVO plus YERVOY. We have OS demonstrated both with a compelling median as well as compelling 2-year landmark data. We've got deep and durable responses, and as I think we've talked about previously, durability is really important not just in this market but also in other tumors. We have a manageable safety profile, and OPDIVO plus YERVOY has demonstrated an improvement in patient quality of life in this setting, so that's important as well. Now with respect to the competitor news that we've seen, I think you're right. In the long term, you will see a much more fragmented market. But a couple of things are true. First, we need to see the data coming from Merck. And we look forward to seeing that at an upcoming conference. But with comparison to the data that we saw at ESMO, we continue to believe that OPDIVO plus YERVOY has a very competitive profile. We're compelling on overall survival, we're compelling on complete response rate, and we are compelling with respect to the safety profile and quality of life. Now how the competitive data evolves, we'll have to see. But based on what we've seen so far, we feel very good about the competitive profile of OPDIVO plus YERVOY in renal cell. The second thing we feel very good about is the ability of our team to compete in this market. I actually ran the U.S. business when we launched in the second-line setting. That was a market that was dominated by TKIs. We not only introduced I-O, but we made it standard of care. That same dynamic has played out in the first-line setting and I feel very good about our team's ability to continue to compete in this space. So net-net, this is a very dynamic environment. There are things that we don't yet know, but if I step back and think about the things we do know, we've been promoting in this space for almost 3 years, we have a very competitive profile, and the teams are executing exceptionally well and I have every expectation they'll continue to do so.

Thomas J. Lynch

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Executive VP & Chief Scientific Officer

Alex, thank you for your comment, your question on CTLA-4. So let me just say a couple things. I'm not going to comment directly on Merck's drug. I think that's probably better for them to do that. What I will tell you is a couple of things about CTLA-4. I think CTLA-4 is a very important target. It's been something that we've been extremely proud of at Bristol-Myers Squibb in terms of how we have pursued this target. Let's just think about what we've learned about CTLA-4. We have shown, as Chris just told you, we've shown that we are able to improve outcomes dramatically in renal and in melanoma. We've made major improvements in the outcome of taking care of patients in those settings. The durability of response that we see with OPDIVO and YERVOY together is something that again we're very proud of and I think it's made a big difference for patients. And not only in renal cell and melanoma, but if you look at MSI colon cancer, if you look at bladder cancer, if you look at small cell lung cancer, if you look at non-small cell lung cancer, those are all areas where we have shown evidence that CTLA-4 plus OPDIVO can make a difference. I think those are all very important to keep in mind. I think also something that Chris said that I think is extremely important to emphasize, is when you look at patient-reported outcomes, and we've looked at patient-reported outcomes in our non-small cell studies, we find that the patient-reported outcomes where a patient's treated with a combination of OPDIVO-YERVOY can be superior to those for patients treated with a chemotherapy backbone. So I think that the CTLA-4 remains a very important target. We also think that when you give CTLA-4 in the doses that we're giving it in renal cell and non-small cell, it is very well tolerated. In addition, we're continuing to develop new ways of targeting CTLA-4. For example, we have a CTLA-4 Probody that we'll be developing with CytomX. This is an agent which we think will preferentially get into tumors and will be able to possibly modulate some of the peripheral immune-related events and accentuate some of the anti-tumor events. We also have a non-fucosylated formulation of CTLA-4. Both of these drugs are in Phase I. Both of these drugs we expect to have some readouts in 2019. So CTLA-4 is a very important target for Bristol-Myers Squibb and one we look forward to presenting additional data for in the next coming year.

Operator

We'll now go to Jami Rubin with Goldman Sachs.

Jamilu E. Rubin
Goldman Sachs Group Inc., Research Division

Giovanni, I very much appreciate your opening comments. They were helpful, but I can't help to think that Bristol-Myers feels like the company is in a similar situation it was in 2 years ago after the failure of CheckMate -026. And clearly, the big bet the company made in exploring ipi/nivo in frontline lung hasn't materialized exactly the way it was expected. And while we still await the outcome of chemo combo, it's looking less and less likely that Bristol will have a meaningful role in the frontline lung market. You might disagree and I'd like to hear that. Then how are you hedging your bets against what clearly was supposed to be one of the most important growth drivers of the company? Is there more of an urgency to explore M&A options or other strategic initiatives that change the company narrative? And can we read into to the fact that you did not announce a share buyback program today like Merck did, even though your stock is at a 52-week low, that you're likely to do something in M&A relatively soon?

Giovanni Caforio
Chairman of the Board & CEO

Thank you, Jami. So let me answer your 2 questions. First of all, on our oncology strategy. If you step back, I believe it is fair to say that from the beginning, a really important core pillar of our strategy has been to focus on I-O/I-O combinations as a way of replacing standard of care where appropriate. And what I would say is that in some areas this strategy has been very successful because when you look at melanoma, when you look at renal cell and potentially other tumors in the future, first of all, we've established new standards of care, and second, we made YERVOY into a really important medicine for patient and a good -- and an important product for the company. I think it's also important to recognize that as data has matured that has shown the value of combining immuno-oncology agents and specifically OPDIVO with existing standards of care like chemotherapy and some targeted agents, we have broadened our scope to include combination strategies, including chemotherapy, which is currently ongoing across

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multiple types of tumors and where appropriate with targeted agents like TKIs, which is for example, the case in the work we are doing in renal cell. So our strategy has broadened and the clinical trials that we designed over the last few years has reflected a broader approach to immuno-oncology. With respect to your question about capital allocation, as I said in my prepared remarks, we continue to think about business development as really an important driver. As I said, it's one I'm really focused on personally. And as part of that, I would say we've demonstrated to also have a fairly balanced capital allocation strategy. We've been committed to the dividend for a long time, and we've increased it year-over-year multiple times. In the past, we've executed meaningful share repurchases programs where we felt it was the right thing to do, maybe more opportunistically. And again, as I said, a core pillar of our strategy is business development, which is really linked to my priority to continue to diversify the business.

Operator

Next is Jason Gerberry with Bank of America.

Jason Matthew Gerberry
BofA Merrill Lynch, Research Division

I wanted to come back to the comment about the importance of TMB. As we think about next year, CheckMate 9LA, in lieu of some of the more recent updates, is that a patient population you plan on selecting for in the primary analysis? Just trying to get a sense of how you're prioritizing TMB. And then my second question just on TYK2. Can you comment, the trials on ct.gov obviously don't list the dose strengths and the dosing regimens. But can you at least confirm that these are the dose strength that got PASI 75 scores that were roughly 2x the active comparator that you're going to be studying against?

Thomas J. Lynch
Executive VP & Chief Scientific Officer

Jason, thank you. So a couple of ways of approaching it. The first one, just to talk about TMB. I think as Giovanni said in the very beginning, TMB is a great example of how we are following the science that helps us understand how drugs work well in immuno-oncology. I think that's a very important pillar to how R&D is done at Bristol-Myers Squibb. I think that, as you've seen, we have introduced the measurement of TMB in a number of our different studies. In 9LA, we have required collection or attempted collection for TMB from patient samples, but we don't stratify based on TMB in study 9LA. I think that's really important to keep that in mind. So I think TMB will continue to play an important role. I think we look forward to seeing the interaction of TMB with a number of different biomarkers as we move forward. And I think that 9LA will be a data set that will hopefully give us that opportunity for looking at that, but of course, that's not till sometime next year. I think your second [Audio Gap] is a very good question, and I think one that is an area that we think is extremely exciting to us. As you know, Jason, TYK2 is very unique as a molecule in that it hits both the IL-12/23 axis as well as a type 1 interferon axis. And it's an oral compound. And what's interesting is that we -- this was done, and again it's a real testament to the discovery chemists at Bristol-Myers Squibb under the leadership of Carl Decicco. What they were able to do was actually target the pseudo-kinase. So we don't end up with the JAK-type side effects that you see with some of the JAK inhibitors. So it's got a unique mechanism of action, which we think is going to lead to a favorable side effect profile. And of course, we only have one large Phase II study and so it's going to take more time before we understand fully how the drug is going to be used. At this point, we have not disclosed the dose that's being used for competitive reasons, but we do think we have 2 very well-designed trials that will unlock the potential for this drug in psoriasis. Now in addition, Jason, I think it's important to remember, TYK2 is a drug we're not developing -- we're developing not just for psoriasis, but we also have active studies in psoriatic arthritis, we're moving into inflammatory bowel disease, and we also think it's important to think that lupus is an area that could be important. I know lupus has been an area very difficult in the area of drug development and drug design, but we do think because of the type 1 interferon interaction of TYK2 that it's an area that we really should be looking at with this drug as well.

Giovanni Caforio
Chairman of the Board & CEO

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Jason, let me just go back to your first question for a second. And I just want to make sure to clarify that as we think about TMB being an important element of many of our studies going forward, you shouldn't be thinking about that as being a primary endpoint in future studies. It's one of the areas we are exploring that's clearly the case for 9LA.

Operator

Next is Tim Anderson with Wolfe Research.

Timothy Minton Anderson
Wolfe Research, LLC

A couple of OPDIVO questions. Investors are starting to question what sort of OS hazard ratio you might show with Part 2 of -227 relative to the big hazard ratio number out of KEYNOTE -189. And I'm really only talking about the nonsquamous segment where you can make an appropriate side-by-side comparison to -189. To me, it seems pretty improbable that most trials are going to show a hazard ratio as good at what was shown in -189. But to me, that also doesn't render your program irrelevant in first-line depending on what that number is. So the question here is really what sort of hazard ratio do you think you need to show in the nonsquamous population such that institutions that are currently using OPDIVO in second-line lung or other tumor type say, "Hey, that's good enough" and continues to support the PD-1s are probably in reality all the same? And then second question is beyond 2019, of course, everyone is asking whether OPDIVO goes to x growth in that period. So you're only confirming 2019. So any sort of comfort you can give us about the beyond 2019 outlook? And if not today, when might we get such guidance?

Giovanni Caforio
Chairman of the Board & CEO

Yes, Tim. Thanks for the questions. Let me start with your second question, about the outlook. As I said in my remarks, we -- we're just coming out of 3 very strong quarters for OPDIVO and for the company in general with good momentum commercially across the board. And I feel pretty good about this year. I've made comments about the fact that we see OPDIVO having -- being a growth brand in 2019 based on the currently approved indications. With respect to more guidance on 2019, we'll do that in January, as we always do. But as I said earlier, I feel pretty good about the momentum in the business. Now let me ask Tom to answer the first part of your first question and then Chris will give you some comments as well.

Thomas J. Lynch
Executive VP & Chief Scientific Officer

So Tim, thank you for your question. I'll say a couple of things. One is we obviously look forward to seeing the results of our chemo combo studies, both Part 2 of -227 and 9LA. As you know, those are event-driven, and we look forward to seeing those when they occur. And we're predicting that's going to be sometime in 2019. I'll tell you one thing about hazard ratios. I practiced oncology for 28 years. Never once, never once did I ever mention the word hazard ratio to a patient. It was never anything I ever spoke to a patient. It's not a factor in patient selection. What patients care about is the regimen or is the given approach, something that's going to give them a chance at being cured or living longer with their disease. So I tend to think what really matters when you've got a profile such as what we see in immuno-oncology, it's really the duration, depth and durability of treatment that's so important. And so I think things like landmark analysis, 2 years, 3 years, 4 years, swell, but one of the things we are most proud of when we were at ESMO this year was presenting our 4-year data in melanoma. We were starting to see landmark analysis at 4 years with OPDIVO-YERVOY, which is really quite impressive in that setting. And so for me, looking at the durability and duration of response is really something that I think that doctors are going to focus on that we're going to be looking at from a research standpoint.

Giovanni Caforio
Chairman of the Board & CEO

Chris?

Christopher S. Boerner

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Executive VP & Chief Commercial Officer

The only thing I would add to that is when we talk to customers, interestingly both in academia as well as in the community setting, we hear a very similar story about landmark and the importance of landmark. Very few physicians talk to patients about hazard ratios and I think that's absolutely going to be critical. The other thing I would say just from a commercial standpoint is lung cancer is a space that we know exceptionally well. It's an area that we've obviously had success competing in and I think we'll be ready from a competitive standpoint to compete, depending upon the opportunities that we have going forward.

Operator

The next question will come from Chris Schott with JPMorgan.

Christopher Thomas Schott
JP Morgan Chase & Co, Research Division

Just 2 here. Maybe first, OPDIVO in second-line lung. Can you just give us an update on the trends you're seeing and the overall size of second-line through PD-1s now that we've had a bit more time to see KEYTRUDA ramp in front line? Basically, how do we see that market evolving? What percent of patients you think are still going to be seen in PD-1 second-line, and then probably more importantly, is there any change from your prior views here? My second question was coming back to TMB. I guess, just how are you interpreting what seems to be very different PFS versus OS trends that we saw for the TMB high versus low populations in -- 227? And I guess, does that update change at all your confidence in TMB and its predictive power as a biomarker? And if not, why not?

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Let me take the first part of that question, Chris. So market dynamics in second-line are pretty much as we have been discussing for the last couple of quarters. Our market share in second-line is stable at roughly 30%. In terms of patient eligibility, these dynamics are very much in line with what we have been forecasting. We have seen a continued gradual decline in second-line eligibility since the approval of PD-1 agents, both as monotherapy and in combination in the frontline setting. That continues to be more gradual outside the U.S. just given the timing of approvals. In the U.S., we think that roughly 50% of patients are eligible for I-O in the second-line, and we still believe that that's going to level out somewhere in the range of 40% to 45%, consistent with what we've said previously.

Thomas J. Lynch
Executive VP & Chief Scientific Officer

Thanks. And Chris, let me just take a second to explain a little bit about TMB and what you saw happen over the past week or 2 since we -- a week since we reported the interactions with the authorities. So let's think back to TMB. So how did we get to TMB? We got to TMB because we were looking for a scientific reason to understand or explain how our I-O drugs work in cancer. And cancer in general and lung cancer specifically. And as you know, TMB can be a surrogate marker for increased number of new antigens or possibly increased specific new antigens that could be driving the immune response. And I think both of those are potential reasons that TMB can identify patient groups that could do better. So we designed prospectively to look at -227 part 1 for patients who had high TMB. And our initial look showed that the high TMB group, in reaction to OPDIVO-YERVOY, had an increased response rate, a clearly improved progression-free survival and then a descriptive statistic, remember because the survival was not in the hierarchy statistically evaluated, a descriptive that showed a survival advantage for those patients treated with OPDIVO-YERVOY in that setting. We were very happy to see that result, and we shared those with the authorities and those resulted in submissions both in the United States and in Europe. At the specific request of the European agency, they specifically asked us to look at survival in the TMB low patients. And of course, I've been asked by many people over the past 3 or 4 days at ESMO, why didn't you look at that initially? And the reason we didn't look at that initially is we wanted to be very careful to protect the integrity of the survival in all parts of the trial. And that's why we did not look at that the first time around. But when we did look at it in response to the European agency, we found that there was this overall survival trend again favoring the group treated with OPDIVO-YERVOY in that setting. So what can

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you conclude from this data? I think the first is that TMB clearly -- high TMB clearly is predictive for a response rate and PFS in an important group of patients, and those are important end points, and that's what the trial was designed prospectively to show. However, we also probably can conclude that TMB at least is in part prognostic as well to a certain degree, and we know that not just from the data we generated but from the data that some of our competitors have generated. And when you look back at some of the academic studies like the LACE meta-analysis of resected lung cancers, you find that higher TMB patients do better. But I think one thing that's important, Chris, to look at is if you look at the overall survival and response rate and progression-free survival magnitude of benefit, it's definitely higher and better in the group that has high TMB, again attesting to this depth, durability and duration of benefit in that patient population. But I also think it's important, Chris, to remind everyone that we're still early in the process. We will continue to follow the science, and we'll continue to work to try to understand how to use TMB, and how to use TMB in relation to other biomarkers as we understand better how to treat lung cancer.

Operator

The next question will come from Umer Raffat from Evercore.

Umer Raffat
Evercore ISI Institutional Equities, Research Division

Maybe first, if we can get a bit more granular on OPDIVO sales breakdown today and if you fast forward 3 years, what indications lose how much, and what indications gain and how much? It would be really helpful given all the investor questions on the topic, first. And secondly, just wanted to get a bit more color on 9LA as it relates to the thought process behind changing the sample size as well as the criteria on when a patient should be discontinuing from therapy or not, depending on the progression. Will that be consistent with how -227 did it? Or are there any changes?

Giovanni Caforio
Chairman of the Board & CEO

Thank you, Umer. So Chris, why don't you start describing sort of the distribution of our business today and some of the growth into next year, and then Tom can answer on 9LA.

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Yes. Umer, thanks for the question. So let me start by just giving you the distribution of the business as it sits today. So in the U.S., lung is about 35% of our business for OPDIVO. Renal is roughly around 20% and that -- and then 30% of that is going to be in melanoma and then the remainder will be spread across other tumors. Ex U.S., you will see a different space mainly on a different set of indications that you have ex U.S. versus in the U.S. So outside of the U.S., lung is a larger percentage, it's about 60%. Outside of the U.S., renal is around 20% and then we've got 20% in melanoma. A couple of things to keep in mind. This is going to be dynamic over time, so for example in the U.S., you have a larger percentage of the business in renal cell that's a result of obviously the frontline indication. Adjuvant melanoma plays an important role in the U.S. That's just launching outside of the U.S. So what you're going to likely see is a continued diversification of the business in the U.S. You'll likely see the percentage of the business in lung cancer outside of the U.S. continue to decrease as we get more business in other markets like adjuvant melanoma.

Thomas J. Lynch
Executive VP & Chief Scientific Officer

And I think Umer, just to address your question on 9LA. I think a couple of things. Let's think about 9LA and why it was designed. It was really designed to bring the very best immuno-oncology along with chemotherapy. And the benefit of chemotherapy is that if there are patients who are early progressors, chemotherapy can help address that. Plus there's theoretically the possibility that could you be generating more new antigens or uncovering new antigens that could help to stimulate and drive an immune response. So we thought we'd design 9LA, which also gave us an opportunity to look at maybe just using

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2 cycles of chemotherapy as opposed to 4 cycles of chemotherapy. And we thought that might also give us an ability to reduce some of the chemotherapy-related side effects in patients while still maintaining the benefits that we see. As you know, this trial accrues very, very quickly, and so when we saw the rate of accrual, we realized that by adding an extra couple hundred patients to 9LA, we were going to be able to increase our optionality of looking at specific biomarkers and that really was what drove the desire. It was accruing very, very fast, and it was really following on -227 where we had engaged a number of great centers throughout the world. And so we thought that 9LA increasing the pool at that point made sense. So that really is the reason that we increased the size of that trial. Thanks.

Operator

We'll go to Matthew Phipps with William Blair.

Matthew Christopher Phipps
William Blair & Company L.L.C., Research Division

Just 2 quick ones. One, you've recently presented data on CheckMate -511 of different doses of OPDIVO in melanoma and saw a decrease in AEs there with similar overalls to there. Do you plan on submitting that to regulators? And then also, I don't know what you can really say on this, but CheckMate -459 has kind of had continued delays in readout there, and I realize it's an event-driven study. Can you also walk us through some of the other changes in the trial and why that is taking so long?

Thomas J. Lynch
Executive VP & Chief Scientific Officer

So let me just make a couple of comments. As you know, we don't comment on the interactions with regulators until we have firm communications from them. I will say that CheckMate -511, I think offers some flexibility and optionality to doctors and give them some guidance, and Chris may want to comment on his view of dosing, particularly in melanoma globally in that setting. But what I'll say about CheckMate -459 is, Matthew, you kind of answered the question yourself there. It is an event-driven process, and we will have to wait until a number of events occur to be able to help us understand the dynamic in hepatoma. We do believe that OPDIVO is an active agent in this area -- in this setting, and we look forward to seeing how it compares to a TKI in this setting, and again, we look forward to sharing that data with you as soon as we have that data. It's just event driven and it takes some time.

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Matt, I'll just make a couple of comments on -511. We're encouraged to see the alternative dosing of OPDIVO plus YERVOY. Overall, we think the data from the safety study is going to be important in providing physicians with some additional information on the benefit risk of the combination dosing. And the implications commercially, we'll have to wait and see how physicians think about adopting this. It's obviously not something that's going to be promotional for us. We see a bit of low dose YERVOY in metastatic melanoma now and you certainly could see that increase over time, but we don't anticipate a wholesale shift in dosing based on what we're seeing so far.

Giovanni Caforio
Chairman of the Board & CEO

Yes, and let me just clarify that this is really a medical study to inform questions from physicians in practice. We do not have a registrational intent with that trial.

Operator

Next is Seamus Fernandez with Guggenheim.

Seamus Christopher Fernandez
Guggenheim Securities, LLC, Research Division

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Just a couple here for Tom. Tom, can you just update us on how you guys have stratified Part B of the -227 study by different PD-L1 levels and how confident you are that this will successfully include PD-L1 high patients, just given the risk of selection bias? And then the second question is just, it's my understanding that the OPDIVO plus cabozantinib study is likely to complete in the first half of 2019. Can you just confirm the timing and how you think this study may distinguish itself from your own OPDIVO plus YERVOY combination?

Thomas J. Lynch
Executive VP & Chief Scientific Officer

So let's just say a couple things. I think what you meant by Part B was actually Part 2 of -227. As you know, that's an event-driven study, and when we enrolled patients into that study, we enrolled patients with a broad histology, and enrolled regardless of histology, regardless of PD-L1 status, and we'll look forward to seeing what that data shows when we have a chance to see that data when it matures. In terms of the renal cell work, as you know, we think that the approach of using OPDIVO along with a TKI can be a very potentially interesting approach with TKIs. And you saw some data presented at ESMO this year with some of our competitors and we've seen press releases from other competitors. TKIs have the advantage of having rapid early on response, and that's one of the reasons that we combined OPDIVO with cabo, and we think cabo is one of the best TKIs in renal cell carcinoma. And again, we look forward to seeing that study 9ER, watching that data mature as well. I think, Seamus, you had suggested it might be early next year. I'm tending to think that it's probably going to be a little bit later than that, but again, as you know, it's event driven and it's very difficult to be able to pin that down.

Operator

Next is Andrew Baum with Citi.

Andrew Simon Baum
Citigroup Inc, Research Division

A couple of questions on ELIQUIS. First, do you see either an opportunity or need to launch a second NDC code version for ELIQUIS under Medicare? And then second, in a world without rebates and without service fees, how much volume and market share risk do you see to ELIQUIS given quite how competitive that segment is? And then finally, just very quickly, can you share any details about planned interim analysis for the ongoing renal trial with cabozantinib?

Giovanni Caforio
Chairman of the Board & CEO

Andrew, just a couple comments from me. So first of all, we currently don't have plans to launch additional ELIQUIS forms. And second, I would say we don't generally comment on interim analysis of ongoing clinical trials, but let me just ask Chris to give you a perspective about ELIQUIS coverage and performance in a competitive access world.

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Yes. So thanks for the question. I mean, I think that what you see in the cardiovascular space is this is a class that has been and will continue to be targeted for increased utilization management. That said, we have a strong advantage, which is that ELIQUIS is a differentiated product. That's important not only for physicians and patients, but it's also been very important for payers. We have historically been able to demonstrate to payers superior performance for ELIQUIS, both in terms of efficacy and with respect to reduction in bleed and the risk of stroke through real world data in patient populations that are relevant to those payers. And so as a result of that, we've actually seen a strengthening of our access position. We've seen, in particular, a strengthening of our access position in Part B plans year-over-year. That carries with it some gross to net exposure, but we've been able to leverage that improved access really across both commercial Medicare and Medicaid channels, and what you've seen is a continued growth in both the brand share as well as revenue.

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Operator

We'll go to Steve Scala with Cowen.

Stephen Michael Scala
Cowen and Company, LLC, Research Division

I have 2 questions. The first-line renal CHMP rejection of CheckMate -214 was now 3 months ago. Bristol had been expecting a quick hearing, which did occur, but also a quick resolution, which has not. And I'm just wondering if anything has changed in the CHMP's eyes. And then secondly, on NKTR-214 in lung cancer, when could we see the data? Will another trial be needed? And how does the deadline to start Phase III trials impact your decision?

Giovanni Caforio
Chairman of the Board & CEO

Thank you, Steve. Let me just [ask] the CHMP question on renal. What I can say is, we are going through the procedure. Every one of those, as you know there aren't many, every one of those has its own timing. There is really no comment at this point and our team are working with the European regulatory authorities on the application.

Thomas J. Lynch
Executive VP & Chief Scientific Officer

And Steve, thanks for your question about the NKTR-214 in lung cancer. So let me just start by saying a couple things. Why did we do NKTR-214 and why are we working so closely with our partners at Nektar. I think what it comes down to is that when you look at immuno-oncology, there are 3 validated mechanisms. You've got the PD-1 access, you've got CTLA-4 and you got IL-2. And we think the opportunity to partner with Nektar to develop this agent, the PEGylated form of IL-2, was a unique opportunity. And we worked very hard with them this year to put together a number of clinical trials to determine how to best use these agents in cancer. So the PIVOT-02 study, which is a study run by Nektar, has shown some very interesting data in terms of activity and certainly, also in terms of safety profile. Because as you remember, the other premise with the PEGylation process is perhaps you may change the immuno-oncology related -- the I-O related side effect profile by stimulating peripheral to your eggs. And, of course, we need more time and more data to be certain of that, but it's certainly an intriguing prospect to how one uses NKTR-214 in that setting. So from PIVOT-02 we saw some data that certainly justified trials in renal cell cancer, in melanoma and in bladder, and you've seen the design of the melanoma study. And we continue to follow the cohorts from PIVOT-02 to determine which tumor types are going to be included next, and we're certainly looking very closely at lung cancer. I think one of the important things from our perspective is to make sure that the trials are done, and the best trials are going to be able to help us most understand how to use this drug, because it's early in the process of drug development and we want to make sure that we optimize its therapeutic potential.

Operator

We'll go to John Boris with SunTrust.

John Thomas Boris
SunTrust Robinson Humphrey, Inc., Research Division

First, on first-line renal, in the intermediate to high, what percent of patients are in the intermediate to high area relative to where PD-1 plus INLYTA might be used. The second question has to do with YERVOY. As an inflection obviously it may have increased the use in YERVOY. Can you give a breakout of use by melanoma, renal, lung MSI-high and other tumor types? And then last question on ELIQUIS, you indicated warfarin still 35% of volume. How low can that number go, especially since it's pretty extensively used in patients with heart valves, but how much lower can you go before you exhaust growth?

Giovanni Caforio
Chairman of the Board & CEO

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Yes. Thank you, John. So Chris, why don't you take the 3 parts of the question?

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Yes. So let's start with the renal question. So the renal question around the percentage of patients who are intermediate and poor prognosis patients is roughly 75% of that population. And by the way, in terms of our performance in frontline renal, we continue to see very good momentum in frontline renal shares, I mentioned is roughly 30% to 35%. We've got opportunities to continue to grow. There are subpopulations within our improved indication where we continue to drive utilization, and that's been the focus in frontline renal. With respect to your question on warfarin, as you mentioned, we continue to see significant use of warfarin, both in the U.S. and ex U.S. U.S. warfarin still garners roughly 22% of new share in the U.S., and in terms of total share, it's roughly 35%. If you look ex U.S., you've got markets where warfarin is still upwards of 40% of utilization. So we believe we can continue to drive utilization of warfarin down. The key constraints on the use of warfarin in the U.S. are going to be things like familiarity with warfarin as well as price. But if you look at the efficacy profile as well as the safety profile of ELIQUIS, we have -- continue to believe that we can continue to take share, not only from other NOACs, but also from warfarin.

Giovanni Caforio
Chairman of the Board & CEO

And the only -- the other thing I would say, John, is I believe one of the reasons for our very, very strong performance with ELIQUIS has been the fact that we've been very disciplined in looking at different business opportunities over time. And our first priority was to be the leading NOAC, then we moved on focusing on expanding against warfarin, and that is ongoing and continues to have good potential. And then the third point that I would say, that there is clear opportunity for the total market to grow in terms of undiagnosed patients and poorly treated patients in many of our countries where we are the most advanced with the warfarin erosion. Strategy are beginning to work on market expansion opportunities which are important. And as you said, YERVOY, melanoma and renal are really the 2 sources. The rest of these, the average are very small.

Operator

We will take the next question from David Risinger with Morgan Stanley.

We'll go ahead and move on to the next question, and that will come from Vamil Divan with Crédit Suisse.

Vamil Kishore Divan
Crédit Suisse AG, Research Division

So just 2, both sort of a higher level, one following up on your other question about business development, and another, Tom, Giovanni says the priority and something you're personally focused on, I'm just trying to get a sense, I think the question was also related to the urgency and sort of how you're feeling the urgency now relative to maybe a few quarters ago, how things have evolved for OPDIVO and YERVOY if -- has there has there been a change in the desire to pursue business development, especially in terms of size, maybe something bigger as opposed to something smaller to diversify the company? And then the second one, I would just love to get some updated thoughts from you on all the debate around drug pricing, and I know we're going to hear more from the President later this afternoon. But just maybe from a Bristol perspective, what are your expectations on what is likely to happen, what may be likely not to happen and what should we focus in as investors?

Giovanni Caforio
Chairman of the Board & CEO

Thank you, Vamil. A couple things, stepping back and going back to my comments at the beginning. When I think about where we are today as a company, there is very strong momentum in the business. We obviously operate in very competitive markets, which I acknowledge, and there is good momentum going into next year with a significant number of potential growth opportunities looking at the medium and long term. In that context, business development has always been a priority for us, and it is an important

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priority today. And many of the lenses that we put on the types of business development opportunities that we look at remain valid, scientific, from the perspective of areas we know well where we can develop truly transformational science. They need to be strategically aligned with areas where we already have presence and expertise and obviously needs to make sense financially. So there is a clear focus on BD, but I think the elements of that focus must be put in the context of a significant set of internal opportunities that have not really changed qualitatively in the past, as I said. From a pricing perspective, my point of view is that we're very early, and it's difficult to predict how many of the policies being discussed by the administration will evolve, both in terms of the policies themselves and the way they're implemented. From our perspective, what's important is a couple of things. It's important that patients continue to have access to medicines they need for very serious diseases. I think it is important to focus on policies that address the issue of patient out-of-pocket costs and affordability, which is really important to us. And the third very important thing is that as a company and as an industry, we are very open to dialogue with the administration in order to progress new policies forward in a way that really benefits patients. But it's difficult for me to comment on specifics because it's very early.

Operator

Our last question today will come from Geoff Meacham with Barclays.

Geoffrey Christopher Meacham
Barclays Bank PLC, Research Division

Tom, on your strategy on I-O/I-O, you guys have optimized nivo/ipi combos and you've added many other doublets, including IL-2, to the mix. But it takes some time to optimize these before Phase III. So my question is, has your urgency or the hurdle rate to advancing these doublets changed over time? You look at targets like STING or OX40, and it may take a few years to figure out if they're even viable. And then the last question, Tom or Giovanni, I want to get more color on the -- more context on TMB and the regulatory review. Is it your sense that regulatory -- regulators need more validation or experience in the clinic for TMB? It doesn't appear to be a worry from KOLs, but is the science in your view mature enough for widespread use in the community?

Giovanni Caforio
Chairman of the Board & CEO

Geoff, thank you. Let me just answer the second question first. I think we've made quite a few comments on TMB, and Chris can give you some perspective on what we hear from the market. We and prescribers and thought leaders, we're not going to comment on the ongoing interaction with regulators. Chris and then Tom can answer your question on next-generation combos.

Christopher S. Boerner
Executive VP & Chief Commercial Officer

Yes, let me just give you a sense of what's happening with respect to the use of TMB and the interest in TMB, at least based on what we're hearing. So right now, TMB testing is around 15% if you look in frontline lung cancer. And that's -- there's been a slight uptick on that in the U.S., but that's a rough percentage of the patients who have been tested and have an evaluable TMB status. As you think about the dynamics in the marketplace right now, what you're seeing is lung cancer is becoming a bit more of a segmented market, the interest in that being driven in part by the interest in being able to have specific drugs targeted to specific patients. That's why, for example, you've seen such a rapid increase in PD-L1 testing in the frontline setting. It's also why you are seeing continued interest in TMB as a biomarker. We've seen that increase going back to AACR and certainly, at ASCO. It's also, I think, going to continue to be an important consideration for physicians because TMB is clearly telling us something about the prognosis for patients in this setting. And when you do TMB testing, you not only get the TMB results, but you also get a number of other biomarker-related data that could be informative of physician choice. So I think there is an organic uptick that you will continue to see in interest in testing of TMB. But obviously, we'll have to wait and see how that plays out as more data becomes available and as potentially you have products like OPDIVO plus YERVOY which could be an option for patients with high TMB.

Giovanni Caforio

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Chairman of the Board & CEO

Tom?

Thomas J. Lynch
Executive VP & Chief Scientific Officer

Chris, thank you, and Geoff, thanks for your questions. It's obviously something that we think a lot about and, gosh, we talk a lot about in terms of how do we identify doublets and triplets and quadruplets even that can make a difference. I'd say a couple of things. The first is, our field needs to continue to remain grounded in the science, and what we're doing in Cambridge, we just recruited MLEs to join Saurabh Saha up in Cambridge to help look at our -- at why patients become resistant. I think the concept of studying resistance is going to be extremely important in understanding which doublets make the most sense, which combinations beyond CTLA-4 and PD-1 make the most sense. And I think that the other thing we've learned is the importance of doing good randomized Phase I and Phase II studies where you got a control arm so you can isolate the effect of the new drug. I think some good examples of that are what we're doing with CSF1R in our relationship, to be able to look at CSF1R in pancreatic cancer. This is an area where we've got randomized Phase IIs that are going to be able to tell us and isolate the impact of the new agent that's being added, CCR25 being a great example of that as well. I think, Geoff, your concept of urgency is extremely important. I think patients need options. When you look at -- we were looking at CCR25 and CSF1R, it's in pancreas, it's in colorectal cancer that's not MSI-high, these are areas that are screaming for innovation and where the market and patients are demanding new options. So I think your question about urgency is very well taken. But at the end, it's going to be fundamentally grounded in the science.

Giovanni Caforio
Chairman of the Board & CEO

Thank you. So in closing, we had a good quarter with strong commercial performance. There's good momentum in the business. We discussed some of the opportunities for growth in '19 and longer term opportunities for growth. I want to thank everybody for being on the call, and obviously, John and his team are available to continue to answer your questions. Thank you.

Operator
And thank you very much. That does conclude our conference for today. I'd like to thank everyone for your participation, and you may now disconnect.

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