THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

PFE - Pfizer Inc Conference Call to provide Update on Oncology Business and to Review ASCO Data Presentations

EVENT DATE/TIME: JUNE 09, 2017 / 3:00PM GMT

OVERVIEW:

Co. provided an update on Oncology business and a review ASCO data presentations.

THOMSON REUTERS

CORPORATE PARTICIPANTS

Charles E. Triano *Pfizer Inc. - SVP of IR*

Chris Boshoff *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Elizabeth Barrett *Pfizer Inc. - Global President of Pfizer Oncology*

Mace L. Rothenberg *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

CONFERENCE CALL PARTICIPANTS

Ami Fadia *UBS Investment Bank, Research Division - Director and Equity Research Analyst*

Ardalan Alex Arfaei *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Charles Anthony Butler *Guggenheim Securities, LLC, Research Division - MD and Senior Equity Analyst*

David Reed Risinger *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Gregory B. Gilbert *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Jamilu E. Rubin *Goldman Sachs Group Inc., Research Division - Equity Analyst*

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

Timothy Minton Anderson *Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst*

Vamil Kishore Divan *Credit Suisse AG, Research Division - Senior Analyst*

PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's analyst and investor call to review oncology business and ASCO data presentations. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Thank you, operator. Good morning, and thanks for joining us today to review Pfizer's oncology business and data presentations from the just-completed ASCO conference in Chicago. I'm joined today by Liz Barrett, Global President of Pfizer Oncology. From our Global Product Development Group, we have Mace Rothenberg, Chief Development Officer for Oncology; and Chris Boshoff, Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology. Liz, Mace and Chris will each make some prepared remarks, and then we'll move to a question-and-answer session. The slides that are being presented with the call can be viewed on our website, pfizer.com/investors.

Our discussions during this conference call will include forward-looking statements about, among other things, our oncology strategy, our in-line and pipeline oncology portfolio that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition, the forward-looking statements in this presentation speak only as of the original date of this presentation, and we undertake no obligation to update or revise any of these statements.

With that, I will now turn the call over to Liz Barrett. Liz?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Thank you, Chuck, and good morning, everyone. Today, I'm pleased to provide an update on our oncology portfolio, where we continue to provide new treatment options and hope for patients. I'll start by providing an overview of the momentum that we are building as an oncology business. And then I'll turn it over to Mace Rothenberg and Chris Boshoff to discuss our pipeline in more detail and provide some important updates from ASCO.

After last year's ASCO, we were proud that we had the best showing ever. But this year reflects even greater momentum, as we presented more than 50 abstracts for more than 15 clinical-stage assets and 12 mechanisms of action. We were excited to share these data with the oncology community over this past weekend in Chicago and look forward to sharing them with you this morning.

With a growing pipeline of cancer therapies, we continue to break boundaries in cancer care with cutting-edge treatment options. Let me highlight a few points that illustrate our significant progress. We now have 9 approved cancer medicines, 6 of which have been launched over the past 6 years. We have received 5 Breakthrough Therapy designations since 2013. We received our latest with lorlatinib, our investigational next-generation ALK inhibitor for non-small cell lung cancer in late April. Lorlatinib was specifically developed in our labs to overcome the resistant mechanisms of ALK inhibitors and covers against most known clinically acquired ALK mutations. We have 11 immunotherapy agents in the clinic as of November 2016.

We now have 2 antibody-drug conjugates currently under FDA review for acute leukemia. And more importantly, more than 580,000 patients have been prescribed our medicines since 2006. We have a multi-faceted strategy in place that focuses on our anchors: Ibrance, Xtandi and immuno-oncology, as well as continued focus to advance our pipeline. Now when we talk about our anchors, we're referencing those areas in oncology where we have a strong commitment, supported by leading assets, which we believe have strong market potential across many indications or patient populations, and where we also are anchored in leading science.

By taking a patients-first approach to cancer treatment, we are also focusing on outcomes and real world data, integrating that with strong patient engagement. Of note, our extensive pipeline has ushered many firsts in cancer care and includes therapies for a range of advanced diseases such as breast, lung, kidney, prostate and blood cancers. Ibrance, a breakthrough therapy, was the first FDA-approved CDK 4/6 inhibitor, representing a significant treatment advance for metastatic breast cancer patients. Since its introduction in February 2015, more than 60,000 patients have been prescribed Ibrance worldwide. Ibrance is currently approved in 65 countries, including the U.S. and Europe. In our initial accelerated approval for post-menopausal women with HR+/HER2- metastatic breast cancer in the first-line setting in the U.S. was recently converted to regular approval. And the range of anti-hormonal therapies that can be administered with Ibrance for this indication was expanded to include all aromatase inhibitors. Ibrance is also approved for HR+/HER2- MBC in combination with fulvestrant in women with disease progression following endocrine therapy.

In March of this year, our anti-PD-L1 antibody, BAVENCIO, became the first product approved for metastatic Merkel cell carcinoma, a rare and aggressive skin cancer. And this was quickly followed by a second approval in advanced bladder cancer in May. Pfizer developed Xalkori, which was the first treatment ever for ALK-positive non-small cell lung cancer and is now the first and only treatment option for ROS1-positive non-small cell lung cancer. In addition, approximately 400,000 patients have been treated with Sutent in advanced renal cell carcinoma, gastrointestinal stromal tumors or pancreatic cancer in 119 countries around the world.

With Pfizer's acquisition of Medivation, our product portfolio now includes Xtandi for metastatic castration-resistant prostate cancer. We continue to be very confident in Xtandi's potential and expect to see significant upside for the brand going forward. Today, Xtandi is the standard of care for advanced prostate cancer and has been prescribed to more than 75,000 patients in the U.S. alone. We continue to believe the greatest potential future growth opportunity for Xtandi, and have been evaluating its use and obtaining a broader indication, in earlier non-metastatic stages of prostate cancer therapy.

And with that, we are pleased to share that the readout of Xtandi PROSPER trial in non-metastatic, castration-resistant prostate cancer has been accelerated by 2 years. Our team identified a protocol amendment that we anticipate will allow us to obtain top line results for the primary endpoint later this year. The main purpose of the amendment is to revise the plan for the analysis of the primary and several secondary endpoints, which allows for a reduction in the target sample size to approximately 1,440 patients from 1,560 patients. When the trial was first designed, we didn't have the results of our currently published trials, demonstrating such a positive magnitude of benefit for patients treated with Xtandi. Upon the

acquisition of Medivation, our Pfizer team worked with the Astellas team to identify the potential to amend the protocol and accelerate the timeline. We reviewed our proposal with the FDA, and we anticipate top line results for our primary endpoint of metastatic-free survival later this year -- metastasis-free survival later this year. This amendment was -- will not impact the strength of the data for the primary endpoint or the potential indication. And we look forward to potentially bringing forward a new treatment option for patients with earlier-stage disease based on this trial.

The acquisition of Medivation also brought us talazoparib, an investigational PARP inhibitor that we will study across multiple tumors and populations. As presented at ASCO, talazoparib is the most potent of the PARP inhibitors, and we are excited to execute a broad clinical development program.

To talk more about our program, let me turn it over to Mace Rothenberg. Mace?

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Thanks very much, Liz. Now looking ahead, we have a strong and diversified pipeline that spans multiple tumor types, platforms and mechanisms of action. Let me give you a few numbers.

Our late-stage portfolio now has 20 Phase 3 trials involving 11 assets, and we currently have 6 oncology assets either in regulatory review or planned for submission later this year. Importantly, we're making significant investments in immunotherapy that span several targets, complementary pathways and novel technologies and positions us well to be a key player and leader in the I/O space. We continue to build our I/O footprint through collaborations with strategic partners, including Merck KGaA with BAVENCIO. And we believe that doublets and triplets are the areas of greatest potential for patients and are pursuing research in this area aggressively.

We're also proud to be one of the few companies with a PD-L1, 4-1BB and OX40 agents all within our own portfolio. In addition to I/O-I/O combinations, we've initiated avelumab combination studies with chemotherapy and targeted agents. Earlier this week, ASCO provided a great opportunity for us to share emerging data that reflect on our strategy and the diversity within our portfolio.

As Liz said, this is our biggest ASCO ever, with more than 50 abstracts presented on Pfizer oncology conference. Presentations covered a broad range of drug development from Phase 1 to Phase 3, from immunotherapy to targeted agents to antibody-drug conjugates, from disease areas in which we have extensive experience to disease areas where we're just entering the field for the first time.

Another highlight is that we had a record 9 oral presentations of Pfizer-sponsored clinical and translational research. I'd like to highlight some of these for you now.

With regard to Ibrance and the randomized Phase 2 PALOMA-1 trial, we presented the final overall survival results from this study. These data demonstrated a numerically longer survival in patients treated with Ibrance plus letrozole versus those patients who received letrozole alone, although this difference did not reach statistical significance. Median overall survival at this final analysis was 37.5 months with Ibrance plus letrozole versus 34.5 months in the letrozole alone arm. Keep in mind, overall survival was a secondary endpoint of PALOMA-1 and that this study was comprised of 165 patients and was therefore limited in its ability to detect differences in overall survival because of the relatively small sample size.

These data are in line with our expectations for this study. As Dr. Finn noted at ASCO, based on previous analyses and given the longer median post-progression survival in patients with hormone receptor-positive breast cancer, a larger sample size would be needed to detect a significant difference in overall survival in the front-line setting. In this population, patients often receive multiple lines of -- and various types of therapies after they progress, and this makes it difficult to isolate the impact of first-line therapy on overall survival. And in fact, this is why progression-free survival is the generally accepted endpoint in this setting and population for regulatory authorities.

The clinical development program for Ibrance is very robust, and this slide summarizes this. In the hormone receptor-positive, HER2- patient population, we have an extensive life cycle management plan with pivotal studies that include 2 in early-stage hormone receptor-positive breast cancer in PALLAS and PENELOPE-B studies; and 2 in advanced or recurrent breast cancer, PALOMA-4 and PEARL studies. Note that PENELOPE-B was initiated in 2013 and PALLAS in 2015. As far as I know, these remain the only 2 large randomized studies currently underway evaluating any

CDK inhibitor in the adjuvant setting. We're exploring the role of Ibrance beyond breast cancer as well and have ongoing Pfizer-sponsored studies in head and neck and pancreatic cancers. There are many more investigator-initiated studies underway in other tumor types.

Now let me turn your attention to talazoparib. With the acquisition of Medivation, we're able to build on our commitments to breast cancer with this agent, our highly potent PARP inhibitor. In preclinical models, talazoparib is not only a PARP inhibitor but also a PARP trapper, a mechanism demonstrated preclinically to induce cell death by trapping a PARP enzyme on DNA, where it prevents single strand repair and can potentially augment damage induced by cytotoxic chemotherapy or radiation. At ASCO, an oral presentation by Professor Nick Turner summarized the results of the Phase 2 ABRAZO study of talazoparib following platinum or multiple cytotoxic regimens in women with advanced breast cancer carrying germline BRCA1 or 2 mutations. And more on that in this slide.

As you know, about 5% to 10% of all metastatic breast cancer carries a BRCA mutation. ABRAZO is an open-label, 2-cohort Phase 2 study that investigated single-agent talazoparib in 83 heavily pretreated germline BRCA-positive advanced breast cancer patients. Primary endpoint was objective response rate by an independent radiologic review. Cohort 1 consisted of 48 patients who previously responded to platinum-based chemotherapy and subsequently developed progressive disease. A 21% response rate was observed in this group of patients. Cohort 2 consisted of 35 patients who developed disease progression following at least 3 lines -- up to 3 lines of non-platinum-based therapy. This group had a response rate of 37%. The main adverse event was myelosuppression, a side effect that is also seen with other agents in the class.

The ABRAZO trial was closed early to make way for the Phase 3 EMBRACA study in women with germline BRCA-positive breast cancer. This trial completed enrollment in April of this year, and we expect top line results by January of 2018. In addition to breast cancer, we're evaluating the potential to develop talazoparib in DNA damage repair-deficient prostate cancer and in combination with avelumab in various tumor types. We know the space is crowded, but we believe we have a PARP inhibitor with many potential opportunities in large segments of various tumors.

Now let me turn your attention to our program in lung cancer. As the leading cause of cancer-related death worldwide, we are working to develop new medicines that meaningfully improve outcomes for patients suffering from this disease. Pfizer Oncology pioneered the treatment of patients with ALK-positive non-small cell lung cancer with the development of Xalkori. Today, we're building on our heritage in biomarker-driven therapies by investigating multiple novel targeted agents. We have a robust pipeline of next-generation therapies that include lorlatinib, dacomitinib, PF-7775 and avelumab that aim to improve outcomes for these patients.

Now I'd like to focus on one lung cancer study that was presented at ASCO, and that was the ARCHER 1050 study. This is the first global randomized Phase 3 trial to perform a head-to-head comparison of a second-generation EGFR tyrosine kinase inhibitor to a first-generation EGFR TKI, dacomitinib, against gefitinib in the first-line treatment of patients with EGFR-activating, mutation-positive non-small cell lung cancer. As you know, these mutations occur in 10% to 20% of non-squamous non-small cell lung cancer tumors overall and about 45% in non-squamous non-small cell lung cancers in Asian populations. Results demonstrated a statistically significant and clinically meaningful improvement in progression-free survival for dacomitinib over gefitinib in this setting. The study findings will serve as the basis for conversations of regulatory authorities and potential regulatory filings.

Now let's turn our attention to another member of our lung cancer portfolio, and that's lorlatinib. This is our next-generation ALK ROS1 tyrosine kinase inhibitor. As Liz mentioned, lorlatinib penetrates the blood brain barrier exquisitely well and has shown potent in-vitro activity against most of the known clinically acquired ALK mutations, including the highly resistant G1202R mutation. Dr. Ignatius Ou had an oral presentation at ASCO that reported the results of the Phase 1/2 study of lorlatinib in patients previously treated with up to 3 different ALK TKIs. We were very encouraged by these results, and we'll work with regulatory agencies with the goal of submitting a New Drug Application based on these data in the second half of this year.

Meanwhile, the Phase 3 trial, known as the CROWN study, recently began enrolling patients. CROWN is an open-label randomized study comparing lorlatinib to crizotinib in the first-line treatment of patients with metastatic ALK-positive non-small cell lung cancer. We're also studying lorlatinib in combination with avelumab and expect to have early data later on this year, early next year.

And with that, I'd now like to ask Chris Boshoff to provide an update on our immuno-oncology program. Chris?

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you, Mace. As Liz mentioned, we were very pleased to have our first accelerated approval for avelumab in metastatic Merkel cell carcinoma in March of this year followed rapidly by second-line bladder cancer. At ASCO, we presented new data from the ongoing JAVELIN Merkel trial in first-line MCC. These results showed an encouraging overall response rate of 68%, one of the highest ever seen in the solid tumor with a checkpoint inhibitor. These data also provides further confidence in the efficacy and the safety profile of avelumab as a comparable checkpoint inhibitor to all the other medicines currently on the market.

We currently have 11 immunotherapeutics in the clinic, and we anticipate another 2 to 3 to enter the clinic during the next several months. By building unique doublet and triplet combinations, pairing immunotherapeutics with each other, or with targeted or conventional therapies like chemotherapy, we believe there are opportunities to address difficult-to-treat cancers that do not respond to currently approved immunotherapies or cancers that progress on current single-agent checkpoint inhibitors. If you look at the right of the slide, for these hot tumors, in addition to avelumab, we also have an anti-PD-1 that was developed at Pfizer, and that's currently in development and could be a potential backbone in the future.

Moving to the left, or cold tumors. We're exploring a number of platforms, including CAR T-cells, oncolytic viruses, vaccines and bio-specific antibiotics. However, with over 200 combination studies currently ongoing, it can be very confusing and difficult to decipher the most promising approaches. In particular, many of these studies are single-arm experiences. We're taking a rational approach to immunotherapy combination studies that can be placed into 5 buckets, and I'll expand on each of these. Eliciting immunogenic cell death, meaning creating an environment where T-cells infiltrates the tumor. Bucket 2, combining checkpoint inhibitors with anti-angiogenic medicines or medicines that inhibit the growth of new blood vessels such as tyrosine kinase inhibitors. There are significant preclinical data supporting this approach. Thirdly, sustaining the immune system. We know that most tumors that respond to checkpoint inhibitors will develop resistance, and one reason for such resistance is T-cell exhaustion. The approach here provides additional stimuli for T-cells to be active and to proliferate. And here, I will include our OX40 and 4-1BB.

Fourth, we also know that in many cancers, there are immune cells, but they may be the wrong type of immune cells, such as myeloid-derived suppressor cells, suppressing the function of T-cells. So in this approach, we are combining checkpoint inhibitors with other medicines that can inhibit an immunosuppressant microenvironment.

Lastly, tumors that have defects in DNA repair pathways are often also the tumors that have a higher mutational burden and higher PD-L1 expression. This provides a rationale to combine medicines like PARP inhibitors with checkpoint inhibitors.

This slide summarizes our current combinations for each of these buckets. As you can see, there are a number of studies with registrational intent ongoing in buckets 1 and 2. If we look at the first bucket, we have ongoing Phase 3 studies combining with chemotherapy and/or with radiotherapy. We also have a number of ongoing Phase 1 studies combining avelumab with targeted therapies like lorlatinib. In the second bucket, we have the ongoing Phase 3 study of avelumab plus axitinib in RCC. And in sustaining immune responses, this is where we have our triplet studies ongoing, including one combining avelumab, OX40 and 4-1BB as well as a number of other doublets and triplets that could be promising. For 4, we are starting very soon our combination of avelumab and our IDO1 inhibitor, and we have an ongoing program with our anti-MCSF antibody to block myeloid-derived suppressor cells. Lastly, coming over to 5, we are exploring starting a basket study with avelumab and a PARP inhibitor that will test the hypothesis with tumors with DNA defects in repaired pathways that could be more susceptible to this combination.

This slide summarizes our 11 ongoing registration programs with avelumab. Just to highlight a few areas where we believe we could be or where we are leaders, including, first, upfront or first-line ovarian cancer. We were one of the first to initiate a registration intent study. This is a 3-arm study with chemotherapy or with sequencing with chemotherapy. We also have an avelumab and DOXIL combination study in platinum-resistant ovarian cancer, and this study has now completed enrollment.

I also want to point out our head and neck cancer program. Although there's a lot of competition and activity in the first-line and second-line metastatic head and neck cancer space, we were the first to initiate a study in locally advanced head and neck cancer, which is the largest opportunity within head and neck cancer.

Lastly, we are continuing to advance our renal program, and I will now share with you some of the updated data that we presented at ASCO. These are the results from the first Phase 1 JAVELIN Renal 100 study combining avelumab with axitinib in first-line RCC. This is a dose-finding study in 55 patients, where we saw very encouraging response rates. Confirmed overall responses was 58.2%, and disease control was achieved in nearly 80% of patients. Two patients showed complete tumor responses, and a further 28 patients showed partial tumor responses. Grade 3 or 4 adverse events related to avelumab were seen in 11 patients. As you can see on the right, the majority of responses occurred early at 6 weeks, and one patient actually converted to a complete response late at week 48. These data in first-line advanced renal cell cancer are amongst the highest ever reported or observed in this setting. This supports our ongoing Phase 3 first-line study of avelumab plus axitinib, which is recruiting on track. During the next 12 months, we'll have a number of additional readouts from Phase 3 studies as well as Phase 1 combination studies that we look forward to discussing with you in the near future.

And with that, I'll turn it over to Liz to close.

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Thanks, Chris, and thanks, Mace. In summary, our oncology business remains a significant growth engine for Pfizer while delivering medical advances for patients. This is a competitive space. ASCO demonstrated that, but it also gave us an opportunity to share data across the portfolio that we are excited about, including pivotal Phase 3 data for dacomitinib in lung cancer; significant Phase 2 data for talazoparib in breast cancer, an area where we are committed to building on the success of Ibrance; and key data combining BAVENCIO plus Inlyta that underscores our I/O combination strategy. We continue to believe that with this portfolio and a multi-tumor strategy designed to allow us to bring accessible and breakthrough medicines to patients more quickly, we're in a position to lead in oncology and ultimately redefine life with cancer.

Now we look forward to answering your questions in the Q&A.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Thanks, Liz. And operator, if we could please poll for questions? Thank you.

QUESTIONS AND ANSWERS

Operator

Your first question comes from the line of Gregg Gilbert from DB.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Can you talk about the implications from positive ZYTIGA data readouts on LATITUDE and STAMPEDE? Secondly, any update you can provide on the sort of foundations issue that impacted results in the last quarter or 2? And lastly, you touched on the PARP space being competitive. Can you talk in any more detail about how you see yourselves as differentiated within the PARP space?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Sure. I'll make a couple of comments about the ZYTIGA data that we saw, and then I'll turn it over to Mace to answer some of your other questions. So I think that -- I was a bit surprised at the conclusions that were really drawn in the reports following the data readout. I think it's important to put this study in context and its impact on our Xtandi. First, the LATITUDE study was conducted among high-risk hormone-na?ve metastatic breast cancer versus placebo and in a setting where the patients had not received current subsequent standard-of-care treatments. So Xtandi is currently in treatment for castration-resistant metastatic prostate cancer, a completely different patient population. So having said that, we agreed this is a

positive study for patients. And we also have 3 Xtandi studies ongoing in a hormone-sensitive population. And these results actually support the use of novel hormonal therapies in this setting. When we look at the future of Xtandi, and as I mentioned earlier, we remain confident in the growth potential in our current metastatic castration-resistant patient population, but then also importantly, the potential to move into the non-metastatic castration-resistant prostate cancer population with PROSPER.

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Gregg, I'll take the part about the talazoparib and its differentiation. I think that there are a couple of different ways that we differentiate. Certainly, preclinically, it's the most potent PARP inhibitor of all. But we know that sometimes those preclinical data don't necessarily translate into clinical benefits. But what we feel is that we have the right dose and we're entering into some spaces where we can make a meaningful difference, including germline mutant BRCA breast cancers, where we showed very promising results in the ABRAZO study and have completed accrual to the EMBRACA study, which is where we think we may also show benefit. We're also looking at this in DDR-deficient, DNA damage repair-deficient, tumors of other types, and we'll be soon initiating a study of this type in prostate cancer. And lastly, the potential for combinations. Again, preclinically, in laboratories of Yves Pommier and others, they've shown real potentiation of the effectiveness of chemotherapy -- low dose of chemotherapy with the addition of talazoparib, presumably based on its PARP-trapping capabilities. And we'll be pursuing this in a basket study with different chemotherapy regimens in several different tumor types. And that's slated to begin later this year. And we'll also be evaluating talazoparib in combination with our PD-L1 inhibitor, BAVENCIO, because of evidence that talazoparib can actually upregulate PD-L1 expression and make that a better target for our PD-L1 inhibitors. So we think we have several points of differentiation in the field.

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

And let me -- I just want to go back and answer the foundation question. When you said foundation, I wasn't exactly sure what you were talking about. So Chuck helped me to understand. So I think our position is that we continue to fund these foundations. We think it's important for patients to be able to afford their medicines. And we believe, as Pfizer has always done, that it's important for us to continue to provide funding in the foundations. Having said that, and I think you know from our earnings call earlier this year, that we have seen -- we saw a significant change this year in the Patient Assistance Program. But we do believe that it will start to level off and then mitigate toward the end of the year. So we're confident about that. We think it's important. We have a commitment at Pfizer to make sure that patients who deserve to be on these treatments are able to be on these treatments. And I'm very proud of the fact that Pfizer puts such a significant amount of resources against that for patients. So thank you for the question.

Operator

Your next question comes from the line of Jami Rubin with Goldman Sachs.

Jamilu E. Rubin - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

So just a couple. I want to go back on your decision today to accelerate the Xtandi trial, PROSPER, by 2 years. Just curious -- I'm still kind of curious why you're doing this. Are you concerned at all about generic abiraterone, and what that might do to the CRPC market and your need to accelerate that before that happens? Also, I was wondering if, in your betting that you can accelerate by 2 years, will you have enough data to hit the primary endpoint anyway?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

So it's a great question, and I think that we are very confident in it. We were not doing it because in response to competition, but we're really doing it because it was a key driver of Xtandi, and we believe it will continue to be a key driver. So we don't believe that ending it earlier will have any impact on the endpoint. And if Mace wants to add something, he's welcome to add something. But we obviously would want to get this out and have an opportunity for patients to have access to this medicine in the non-metastatic setting as soon as possible. So when you look at the data

and so much has changed, if you think about the time in which this trial was designed, we didn't have the results that we have today. So after we've seen such a significant hazard ratio in the clinical studies, if this had been developed, designed at this time, it would have been designed with fewer patients. So I don't think -- I think we're very comfortable with it. We're doing it, and we -- this has been in the planning, as you can imagine, for several months. It's not something that happens overnight. We spent a lot of time working with Astellas. We had a meeting with the FDA to ensure that they were on board with that. So we feel very good about it and don't believe that we're compromising the study at all. I don't know, Mace, if you want to add anything?

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

I think you covered all the points very well, Liz.

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Okay. Thank you.

Operator

Your next question comes from the line of Vamil Divan with Credit Suisse.

Vamil Kishore Divan - *Credit Suisse AG, Research Division - Senior Analyst*

So first one, just on the ALK space and you touched on some of your data. Just curious if you can provide us with some perspective on the ALEX data and how you see that impacting Xalkori. And then also for lorlatinib trying to launch into that market, kind of for the franchise as a whole, what do you see as the -- as the overall sales potential there? And then one on Ibrance. You mentioned that going beyond breast cancer is important. I think in your slide, you showed us sort of 2020-plus opportunity. Can you just give us a little bit better sense of when we'll start seeing some data outside of breast cancer, I think, for the -- for Ibrance and for the class as a whole? I think a lot of people are looking to see, is this potential -- something that can expand beyond breast cancer?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Yes, I'll make a couple of comments and turn it over to Mace and Chris both to comment on lorlatinib and the ongoing non-breast for Ibrance. I think it's a great day for patients, to be honest with you, and we've anticipated the alectinib data. We were not surprised at the data. And I think if you take a look back at what -- at 8 years ago, when -- and Mace and I often talk about the meeting that Mace and I had where we actually -- they found the ALK inhibition and the potential for Xalkori, and we pioneered this area. And then -- and at that point in time, we knew that patients would need multiple treatments after that. So I think at the end of the day, we look at it and say, "This is a great day for patients." Having said that, we also know that sequencing these patients appropriately and making sure that patients are able to get multiple lines of therapy, because they still need it. I think the perspective that we have is unfortunately, we have not found a cure for cancer, and most patients are living longer because of the therapies that have been developed and continue to be developed. But unfortunately, most patients will progress and they need more therapies, which was the reason that our labs started looking at the resistant mechanisms and developed lorlatinib. And so again, as you heard earlier about lorlatinib. So I'll turn it over to Mace and then to Chris to make any additional comments on lorlatinib or Ibrance.

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Yes, Liz, you touched on many of the most important points. And again, I can't emphasize enough how good this is for patients because earlier in my career, when I was involved in clinical investigation and translational research, I saw patients who were young and had widespread metastatic adenocarcinoma. Never smokers. And looking back now, I wish I had lorlatinib, I had Xalkori or even alectinib, for that matter. So we've really come

a tremendous way in a very short period of time, and this is good for patients. Having said that, I think the development of lorlatinib is a shining example of the strength of collaborations between industry and academia, because it was only through the ability of patients who were receiving drugs like Xalkori to then have biopsies that then informed us why they were no longer responding to a drug that helped them so much, allowed us to identify resistant mutations, take that information back to our research scientists and our medicinal chemists and for them to do an astounding job designing a drug in lorlatinib that covers virtually all of the known, clinically-relevant mutations in the ALK space. So we're very proud of this. And I think that this has now shown itself in the Phase 2 results that were presented by Dr. Ou at ASCO last week. And I think that it was really across the board. And I also want to point out that this was even in patients who'd received multiple ALK tyrosine kinase inhibitors, including alectinib. Their response is seen with lorlatinib in patients with [the presence] of alectinib. Now we're not satisfied being relegated to third-line therapy. So that's why we've initiated the CROWN study going head-to-head against crizotinib, so Xalkori, to show what lorlatinib can do in that first-line space and again, try and raise the bar even further in this disease. Then lastly, looking to see, based on preclinical data, if we can take those very deep responses and prolong them by activating the immune system with avelumab, and we have plans for starting a trial of that combination by the end of the year. To address your question about Ibrance beyond breast cancer, it's been a very interesting process because initially, our tendency was just to say, "Well, any tumor that has cyclin D1 amplification or p16 loss, we should just go right into those." And it was actually through collaboration with Bob Abraham, Todd VanArsdale and others in our oncology research unit that really helped us see that it may be more complex than this. And this is, indeed, what we're seeing, that CDK 4/6 inhibitors, while active as single agents, and this data was shown in breast cancer at ASCO this year. Although you can get responses, they're not as deep as when you give it in a combination with a targeted agent. And so we actually stepped back and we evaluated several combinations preclinically. And actually, what emerged wasn't really intuitively obvious when we began. But we felt confident that moving into company-sponsored studies in squamous cell carcinoma to head and neck with cetuximab was a promising area; and with pancreatic cancer, which was a bit of a surprise, with nab-paclitaxel, Abraxane. So we've done those, but those are not the totality of our research. We have a number of investigator-initiated studies, a number of solid tumor and even some liquid tumors that are showing some promise as well. So I think it's going to be -- it's going to take a little bit more time. But I think that in the next year or so, we should begin seeing some of these data emerge.

Operator

Your next question comes from the line of Tony Butler with Guggenheim Partners.

Charles Anthony Butler - *Guggenheim Securities, LLC, Research Division - MD and Senior Equity Analyst*

Chris, one question for you. In the combinations with avelumab and either OX40 or 4-1BB, is the notion that both are absent of the 2 combination agents, are they totally orthogonal to one another? I wanted to ask that, then I have just 2 other questions. And again, Mace, on the new ALK inhibitor, lorlatinib. The question really is around the 48% that you saw that actually crossed the blood brain barrier, which is interesting relative to the other TKIs. So can you actually provide some information around those -- the degree to which those lesions actually were able to shrink? And then lastly on PALOMA-1, was the OS outcome simply a matter of -- and I apologize if you said it, I just didn't hear it -- simply a matter of the size of the trial? Is there a need to actually redo a similar sense of a trial in order to get an OS label? Is that important?

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you. So I'll start with the first question regarding OX40 and 4-1BB. Most of the preclinical data actually are used to indicate that OX40 is mainly for CD4 cells -- CD4-positive T-cells and 4-1BB for CD8-positive T-cells, suggesting that a combination is rational. However, that has become more blurred during the last couple of years. The preclinical data that we generated in-house as well as with our collaborators at Yale and with -- at MD Anderson, does indicate that the triplet of an OX40 plus a 4-1BB plus avelumab could be the most rational combination. We therefore have that triplet now in the clinic as well as the doublets with OX40 as well as with 4-1BB.

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Tony, so regarding lorlatinib, there indeed was a transfer across the blood brain barrier, which was very important to us. We did see responses, including some complete responses in the brain, and these were long-lasting as well. So we think that given the fact that this is an area that seems to be a sanctuary site for a drug like Xalkori and also understanding some of the devastating consequences of a patient developing brain metastasis that it truly is clinically meaningful and beneficial to try and prevent that from happening. And therefore, we think that lorlatinib could well move into first-line setting if the CROWN study is positive. Regarding PALOMA-1 and whether the failure to see an overall survival advantage was just due to size. I think that, that was certainly a factor. It is reassuring to see that the hazard ratio for overall survival is in the same direction as for progression-free survival. It was less than 1. So we're not seeing any contradictory or conflicting information here. You may remember that we actually had not only initiated, but had completed accrual to PALOMA-2, a Phase 3 trial, at the time that Ibrance was first approved back in 2015. That will provide a larger dataset on overall survival. But let me keep -- let me point out that historically, overall survival has not been the basis for regulatory action or approval in hormone receptor-positive breast cancer. It has been progression-free survival, because remember, now more than ever, this group of patients has access to multiple lines of therapy: ER degraders, PI3-kinase inhibitors, chemotherapy. So I think that this is very important. And talking about chemotherapy, something that hasn't been emphasized, maybe should, is one of the goals in the treatment of hormone receptor-positive breast cancer is to delay the time until you need to resort to chemotherapy. It's a therapy that no one likes to get, associated with many more side effects than endocrine therapy. And in that study, it actually showed that the use of Ibrance as part of first-line therapy significantly delayed the need to resort to chemotherapy compared to aromatase inhibitor therapy alone.

Operator

Your next question comes from the line of Steve Scala with Cowen.

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

A few questions. First, you cited the solid dacomitinib data. But can you speak to how you think the competitive landscape will play out post-approval within the EGFR class? So that's the first question. Second, given that you have a CTLA-4 in development but also a multitude of other novel I/O targets, can you speak to your relative enthusiasm for CTLA-4? It's clearly a target that's very controversial in the industry. And I'm wondering how Pfizer -- what side of the debate Pfizer comes out on? And then the last question is, if I heard you correctly in the opening remarks, you said there were 11 I/O agents in the clinic as of November 2016. Presumably, all the other comments on the call were up to the current point or current time. Just wondering why the I/O comment was cited as a different point in time.

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

I'll start with the -- thanks, Steve, for your question. We're going to dacomitinib, and then I'll turn it over to Chris for the I/O questions. It is an increasingly competitive landscape, but we think that there are certain characteristics of the ARCHER 1050 study with dacomitinib that really stand out. Keep in mind that differentiating from the first-generation dacomitinib is an irreversible inhibitor compared to the reversible inhibitors of either Tarceva or Iressa. Dacomitinib inhibits not only EGFR, which is HER1, but HER2 and HER4. And so it does really raise the bar in terms of mechanism, and as we've seen, raises the bar in terms of PFS efficacy. There is another second-generation EGFR inhibitor that is on the market, Gilotrif or afatinib. And they did a randomized study, but it's only a Phase 2b study, a smaller one. And interestingly there, there was no difference in progression-free survival, whereas what we saw was a significant 5.5 months improvement in progression-free survival. So we think that we have some differentiation from that competitor. And I think you were probably also referring to TAGRISSO, which is the generation of EGFR inhibitors that not only hit activating mutations but also resistance mutation in T790M. And right now, we don't have any data from the AURA study in first-line. So I think that there actually is a very clear role and place for dacomitinib in the first-line treatment of EGFR mutant lung cancer. Chris?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Yes, before Chris says, I think we just -- just to clarify your question around the I/O portfolio. We do have 11 of the immunotherapy agents in there since November of '16. So as of November of '16, we have 11 immunotherapies in the clinic. So with that, Chris, I'll just turn it over to add anything and talk about CTLA-4.

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you, Liz, and thank you for the question. So overall, we still believe that anti-CTLA-4 is an important medicine, but we're also all aware of the adverse event penalty with the current combinations and with the current scheduling. And to remind you that although we outlicensed tremelimumab, we maintained the rights to use tremelimumab as part of a cancer vaccine. And in fact, our current cancer vaccine for prostate cancer in the clinic does include tremelimumab as well as our anti-PD-1. And we recently announced the opportunities with BioAtla and with OncoImmune. So 2 additional CTLA-4s in the -- in our preclinical portfolio. We've not announced yet when those will enter the clinic. But we believe that they could potentially be differentiated. The BioAtla compound is a so-called conditionally active biologic that may work specifically more within the tumor microenvironment. And that will hopefully overcome some of the current issues with the immuno-related adverse events associated with anti-CTLA-4. And your follow-up to the 11 immunotherapies in the clinic, I don't know if that was a question.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Yes, Liz covered that. That is in the clinic since November of last year.

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

As of November, right?

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Right.

Operator

Your next question comes from the line of Alex Arfaei with BMO Capital Markets.

Ardalan Alex Arfaei - *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Sorry if I missed this. But can you comment on your thoughts about the abemaciclib MONARCH 2 trial and its implications for Ibrance and your plan to defend Ibrance? And a couple follow-up questions on I/O. Obviously, the field is moving quite rapidly. The standards of care is changing in a number of tumor types. Which I/O markets specifically do you think that Pfizer will be more competitively be positioned? And then finally, you mentioned you have an anti-PD-1 in development. Wondering what the time frame is for that to get into clinic. And are you seeing any differentiated profile for that drug versus avelumab or other anti-PD-1s, for that matter?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

So thanks for the question. I'll start on the Ibrance and turn it over to Mace to add some commentary about the clinical differences. But I want to first just start by saying that we remain very confident in the future and future growth of Ibrance as well as our continued leadership in this area. I mean, as you know, Ibrance has established the standard of care in this patient population, it's been prescribed in over 60,000 patients. And it's not only a testament to the efficacy with over 2 years of median progression-free survival, but also in the manageable safety and tolerability profile.

While the positive results from other CDK inhibitors like MONARCH, they add to the body of evidence, confirming the importance of this CDK inhibition in this class of agents. I think the other thing we have to keep in mind is that currently, only about 50% of the patients in the metastatic breast cancer area actually are getting a CDK and mostly Ibrance. And so we still see a significant opportunity for patients to have access to these medicines. And so because of that, as you know, there's no head-to-head data. But I think what I really wanted to say is that we remain confident in Ibrance and our leadership, and we believe that the patient experience and the positive patient experience and positive feedback that we're getting from the physician community and the patient community gives us all the -- gives us that confidence. So with that, I'll turn it over to Mace talk about any differences in the clinical study, and then Chris can answer the questions on immunotherapy.

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Thanks for that question, Alex, and thanks, Liz. I think that while there is a desire to try and do cross-study comparisons, it's particularly difficult with these 2 studies because they really are in different patient populations. Before getting to any of those details, when you actually look at the control arm of MONARCH 2 and PALOMA-3, both with fulvestrant in the control arm, there's actually a twofold difference in how well the control arm did. It did twice as well in the MONARCH 2 than it did PALOMA-3. So we're clearly looking at different patient populations. Chemotherapy was allowed in PALOMA-3, not in MONARCH 2. There was -- these were really different populations of patients. And I would invite you to look at that just to make sure that you can appreciate those differences. There was -- differences in toxicity is something that's very important. And I think that diarrhea is a more prevalent issue for abemaciclib than it is for Ibrance. Ibrance, we did not see really any Grade 3, 4 diarrhea. It was seen in more than 15% of the patients treated with abemaciclib. And also, there has been a lot said about the different rates of neutropenia and lower rates of neutropenia, of higher grade with abemaciclib. But again, I'd invite you to look not just at those numbers, but -- which really mean nothing to a patient, but the clinical manifestations of that. The number of patients who've had febrile neutropenia or neutropenic fevers, and there, you will not see a difference. So I think that again, as Liz said, we have now 2.5 years of experience in the market, more than 60,000 patients treated with Ibrance. Physicians know it well. Patients have experience with it and are staying on the drug and not falling off due to toxicity at any significant rate. So I think that the -- we have a very strong position, and we have a very active clinical development plan to really expand our knowledge and the groups of patients who can benefit from adding Ibrance to standard of care, including in early breast cancer.

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you very much, Mace. Regarding the immunotherapy, I think we all agree that checkpoint inhibitors are transforming cancer medicine and cancer care, but we also know that immuno-oncology will only be one pillar of cancer medicine. And other therapies, including targeted therapies like TKIs, ADCs, anti-hormonals as well as chemotherapy and other modalities, will continue to be important pillars for the future of cancer medicine. We're really only at the beginning of this whole immuno-oncology era. And we believe that in the long term, a backbone with a checkpoint with the right combination will really be transformative. In our late-phase program with avelumab, I think our programs in locally advanced head and neck cancer, in ovarian cancer, in renal cell carcinoma first-line as well as our differentiated program in first-line bladder cancer could potentially be amongst the leaders in the field. Regarding our anti-PD-1 that we're developing, we hope to share with you data next year and regarding this clinical development program. This medicine is already in Phase 1 currently being tested. We are developing it in a differentiated way, and we believe that it could become also an important backbone in the future, with all the other combinations I mentioned. Thank you.

Operator

Your next question comes from the line of David Risinger with Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Dave Risinger from Morgan Stanley. So I have a couple of questions. First, with respect to abemaciclib, the Lilly product. Lilly is positioning it as best-in-class based upon the fact that the drug can be used continuously, and also, they're emphasizing that it crosses the blood brain barrier in a manner that palbociclib does not. So I was hoping that you could comment on Lilly's positioning of abemaciclib. And then second, with respect

to key immuno-oncology readouts over the next year, could you just focus us on the top few trials that you're looking to see readouts on over the next year or so in immuno-oncology?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

First, Mace?

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Thanks, David. As you may recall from my comments during the prepared period -- comment period regarding talazoparib, I talked about how that was considered the most potent PARP inhibitor based on preclinical data but how sometimes that preclinical data doesn't necessarily translate into clinical data. So I really shied away from saying it was the best-in-class because we just don't have that. And I think the same rule applies to abemaciclib in CDK-4. There's absolutely no head-to-head clinical data to show that there's any advantage of one over the other. It's, again, very dangerous to compare across trials to look at some individual isolated numbers because patient populations can differ. The issue about continuous dosing is also preclinical and based on surrogate tissue when it was obtained from patients. There's really no data about whether the break that's used in -- with Ibrance of one week is in any way undermining the clinical efficacy. And I think the clinical efficacy of Ibrance stands on its own. We've seen that it doubles progression-free survival in both the first- and the second-line setting. It is very well-tolerated. And in fact, its tolerability profile has allowed us to move into 2 large randomized early-phase breast cancer studies. And keep this in mind, if these -- these are early-stage patients where we're trying to prevent disease recurrence. They're not dealing with metastatic disease. A patient's willingness to accept certain toxicities may be different in the early-stage settings than in the later-stage settings. And both of our early-stage settings -- studies, PALLAS and PENELOPE-B, are accruing very well and on track. Then the last issue is about the blood brain barrier. What isn't often said is the -- how big a clinical problem are brain metastases in patients with hormone receptor-positive breast cancer. It turns out that only about 1% to 8% of women with this disease get brain metastases. It's not to trivialize it; it does occur. But it's not a very prevalent issue, and having systemic control is really what we're driving for here. Chris?

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you. For the readouts for our Phase 3 studies during the next 12 months, these include: Gastric cancer; and platinum-resistant refractory ovarian cancer; second-line lung cancer, which will be the basis of our further combinations within the lung cancer space; as well as first-line renal cell cancer. For our Phase 1 studies, we hope to share data with you with the combinations with OX40, with 4-1BB and lorlatinib, amongst others.

Operator

Your next question comes from the line of Marc Goodman with UBS.

Ami Fadia - *UBS Investment Bank, Research Division - Director and Equity Research Analyst*

This is Ami Fadia on behalf of Marc. Two questions. Firstly, at ASCO, there were some concerns about the use of CDK 4/6 without yet having the overall survival benefit. What is your level of confidence with respect to being able to demonstrate that in PALOMA-2? And then separately, I may be mistaken, but this is the first time we've seen the PATINA trial in first-line HER2+ patients. Could you elaborate a little bit about what got you in that direction?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Mace?

Mace L. Rothenberg - *Pfizer Inc. - Chief Development Officer of Oncology - Pfizer Global Product Development*

Thanks, Ami. So in terms of the use without overall survival, again, because of the chronic nature of hormone receptor-positive breast cancer, regulatory statutes have really applied progression-free survival as their expectation for approval. And in fact, when we've spoken to breast cancer experts from around the world, they have echoed this opinion, that having a significant improvement, like we see with Ibrance, in progression-free survival, is the basis for them to accept and utilize Ibrance in this setting. And again, the substantial delay in the need to resort to chemotherapy is very meaningful for patients and physicians as well. Now it's -- you asked about whether PALOMA-2 can detect this. PALOMA-2 had 666 patients enrolled compared to the 165 patients in PALOMA-1. So being of larger size, it is more likely to be able to detect an overall survival advantage. However, this was conducted at a time as Ibrance was becoming commercially available. So it's perfectly possible that there may have been some patients who were treated on the control arm who may have gotten Ibrance in subsequent lines of therapy. So as with so many cancers, we may see the benefit that's seen in progression-free survival somewhat muted in the overall survival difference. Is it going to be in the same direction as the benefit that we see in progression-free survival? I'm very confident that it will, but I can't guarantee that, that will reach statistical significance. And then it will be up to patients and in consultation with their physician to decide whether the evidence is sufficient for them to utilize this as a treatment option. The PATINA trial is one we're very excited about. It's a collaboration between Pfizer and the Alliance, and it's considered a clinical research collaboration. This was an idea that was generated by experts in breast cancer who work with this disease. We were able to interact with them in the design of this trial. It was -- it took a little while for us to figure out where the right place might be for Ibrance in what is an increasingly crowded field. But working together, we found one that really hit that right note. We're very excited about this. And the background for this is interesting because, in fact, the very earliest studies preclinically that were able to tie CDK 4/6 into some cancer was actually in a HER2+ breast cancer model. So we have a very large body of evidence and some small investigator-initiated trials in the space that show a very promising degree of activity that we hope the PATINA trial will be able to confirm.

Operator

Our last question comes from the line of Tim Anderson with Bernstein.

Timothy Minton Anderson - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst*

Two Xtandi questions, one avelumab question. On Xtandi, can you quantify what the early prostate cancer indication would mean if positive, either in terms of patients or sales or however you want to describe it? And the second question on this -- on the same topic. What was built into your expectations for this indication when you bought Medivation? And then on avelumab, it's a question I've asked in a few different venues to different members of Pfizer management. So my apologies for being redundant. It relates to your level of commitment to avelumab. Are you completely happy with the clinical profile of the product and with its likely future commercial positioning in a competitive PD-1 or PD-L1 field, where it is a late entrant?

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Yes, I'll -- it's Liz, and I'll take the questions on Xtandi. And I think that from a patient population, if you think about the non-metastatic patient population for PROSPER, it's about the same size as the metastatic castrate-resistant patient population. So in the U.S. alone, it's about 30,000 to 35,000 patients. And then -- and so we feel very confident about that, and it was a big driver in our acquisition of Medivation. So to answer -- to answer that question. So we feel really good about it. We think that the -- as we talked about earlier in our ability to accelerate the PROSPER trial and then get that out to patients as quickly as possible will be very important. And is there -- was that it?

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Yes.

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Exactly. And then I'll turn it over to Chris to talk about -- but before he does, I will actually just like to make a comment about BAVENCIO in that we do believe that it will continue to be competitive in this space. I think some of the data that we're generating is differentiated, as Chris showed earlier. And so we have confidence in the profile of the drug and that we can be competitive in the marketplace. So with that, Chris.

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you very much, and thank you for the question. So we are pleased with what we've achieved with Merck KGaA or EMD Serono in the last 24 months. We now have 2 approvals, 30 ongoing programs, 11 registration programs. Nearly 5,000 patients have now been treated in clinical trials. So we believe that this will be a meaningful checkpoint inhibitor in combinations in the future.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

Great, thank you, and thanks to everyone here on our oncology team and thanks, everybody, on the call for your attention.

Elizabeth Barrett - *Pfizer Inc. - Global President of Pfizer Oncology*

Thank you.

Chris Boshoff - *Pfizer Inc. - Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology*

Thank you.

Operator

This concludes today's conference call. You may now disconnect.
