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EDITED TRANSCRIPT

PFE - Pfizer Immuno-Oncology Strategic Alliance Announcement

EVENT DATE/TIME: NOVEMBER 17, 2014 / 3:00PM GMT

OVERVIEW:

PFE announced that it has formed a global strategic alliance with Merck KGaA to jointly develop and commercialize anti-PD-L1 to accelerate presence in immuno-oncology.



CORPORATE PARTICIPANTS

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Mikael Dolsten *Pfizer Inc. - President Worldwide R&D*

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Immuno-Oncology Strategic Alliance Announcement. Today's call is being recorded.

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

Chuck Triano - *Pfizer Inc. - SVP IR*

Thank you, Operator. Good morning, everyone. Thanks for joining us today to discuss today's announcement regarding our global strategic alliance with Merck KGaA of Darmstadt, Germany.

Here with me today are Albert Bourla, Group President of Pfizer Vaccines, Oncology, and Consumer Healthcare; Mikael Dolsten, President of Pfizer Worldwide Research & Development; and Mace Rothenberg, Head of Clinical Development and Medical Affairs for Pfizer Oncology.

Before we begin, let me remind you that our discussions during this call will include forward-looking statements. Actual results could differ materially from those projected in the forward-looking statements. Factors that could cause actual results to differ are discussed in Pfizer's 2013 annual report on Form 10-K and in our subsequent reports on Forms 10-Q and Form 8-K and in our press release issued today, November 17, 2014.

Also, the discussion during this call may include certain financial measures that were not prepared in accordance with US generally accepted accounting principles. Reconciliations of those non-GAAP financial measures to the most directly comparable US GAAP financial measures can be found in Pfizer's current report on Form 8-K dated October 28, 2014, and Pfizer's quarterly report on Form 10-Q for the fiscal quarter ended September 28, 2014. These reports are available on our website, pfizer.com, in the investors' SEC filing section.

With that, I will turn the call over to Albert Bourla. Albert?



Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Thank you, Chuck, and good day, everyone.

I am pleased to be here today to provide greater context on our recently announced global alliance with Merck KGaA in immuno-oncology. We believe this alliance will significantly accelerate our position in this key area of cancer research and position our growing immunotherapy program into the first wave of potential therapies.

This collaboration is a tremendous opportunity for both Pfizer and Merck KGaA. It allows us to combine the strengths of our companies with a goal of meeting the needs of the millions of cancer patients who are looking for new and innovative therapies.

Pfizer Oncology is a fast-growing business with leaders who possess deep scientific expertise; a proven track record in commercial success, including three launches in the last two years in different cancers; and strong relationships with regulatory authorities and the oncology community.

Merck KGaA has a strong legacy and commitment to oncology shared by Pfizer. They are emerging as a leader in immuno-oncology with their near-term PD-L1, which we look forward to continuing to develop together. We have been very impressed with their leadership, talent, and passion, which they have demonstrated in progressing this drug.

Combining this promising anti-PD-L1 antibody with Pfizer's and Merck KGaA's extensive portfolio of approved and investigational oncology therapies provides an exciting opportunity to potentially broaden the use of immunotherapy for patients with cancer and rapidly expand our oncology business.

With this alliance, we will work together with aligned interest in rapidly developing immunotherapy programs in areas of high unmet medical need. This has been and will remain a key priority for us.

The opportunity to work in this truly joint collaboration, the first of its kind, is an exciting element of this deal. Both companies will jointly fund all development and commercialization costs, and all revenues earned from selling anti-PD-L1 or anti-PD-1 products generated from this collaboration will be served equally.

Under the terms of the agreement, Merck KGaA will receive an upfront payment of \$850 million and is eligible to receive regulatory and commercial milestone payments up to approximately \$2 billion.

We have also agreed to jointly co-promote XALKORI in the United States and several major markets. The co-promotion will allow both companies to combine commercial resources and expertise so that we can lay the groundwork for a strong integrated organization in advance of potential PD-L1 monotherapy and combination launches in the future.

Importantly, we believe we will be able to expand the commercial footprint and increase our commitment to identifying ALK-positive patients who may benefit from XALKORI treatment.

Both companies will jointly make decisions expeditiously in the best interest of patients and the alliance.

We have previously established immuno-oncology as a key priority area, investing significantly in several immuno-oncology programs and giving these programs the highest levels of management's attention.

Because we believe PD-L1/PD-1 agents have the potential to transform cancer treatment, we also have been eager to accelerate our progress in this area of immuno-oncology. With this agreement, Pfizer will have access to a promising PD-L1 already in clinical development, with the ability to move quickly to initiate other PD-L1 single-agent studies and, more importantly, combination studies with our oncology assets, expanding the depth and breadth of our portfolio.



Building on the ongoing Phase 1 program that has treated more than 550 patients, both companies will collaborate on up to 20 high-priority immuno-oncology clinical development programs expected to commence in 2015. The clinical development programs include up to six trials, Phase 2 or 3, that could be pivotal for potential product registrations.

We will quickly move into the first wave of potential immuno-oncology-based monotherapy treatment regimens. We will potentially accelerate entry for both companies into the second wave of immuno-oncology combination approaches, and specifically combine PD-L1/PD-1 in clinical development programs with Pfizer's other oncology assets, including our existing early-stage portfolio, as well as our marketed products.

Shared development costs will enable a much broader development program for both companies and a greater range of potential new therapies for patients.

With that, I will turn it over to Mikael to speak about the clinical data.

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Thank you, Albert.

We are very optimistic about the potential for this PD-L1. Early results for this compound in patient trials are encouraging, with objective response rates consistent with the results seen with other agents in this class.

We based our decision to move forward with this transaction on the full data set of more than 550 patients who have been treated with this anti-PD-L1 antibody in a Phase 1 trial across multiple tumor types.

Pfizer conducted a thorough assessment as part of the due diligence process, including conversations with internal and external experts in the field and a review of data beyond what are currently in the public domain. So far, as part of the analyst and investor day hosted by Merck KGaA in September, interim data were presented from an ongoing Phase 1 study demonstrating a complete and many partial responses in patients with non-small cell lung cancer and ovarian cancer. We have been encouraged by the lengths of the duration of response and tumor shrinkage observed in these trials.

It is also worth mentioning that a Phase 2 trial is ongoing in Merkel cell carcinoma, a rare form of aggressive skin cancer.

You can see here the Phase 1 efficacy data in non-small cell lung cancer presented by Merck KGaA. Based upon these interim results in 90 patients, the PD-L1 objective response rate and duration of therapy was similar to other agents in this promising category. The use of this drug as either a monotherapy or in combination with a Pfizer oncology asset has the potential to fulfill the high unmet need for patients with lung cancer and other cancers and expand our franchise leadership in the future.

Similarly, in ovarian cancer, Merck KGaA presented positive interim data, which once again demonstrates the potential of this therapy in a small segment of patients in an area where there is an incredible need for new therapies. The data demonstrated partial responses with encouraging durability in this population.

This, along with more expansive clinical data we reviewed as part of our due diligence process, has given us the confidence to move forward with this collaboration and invest in its potential as the foundation of our first wave program in immuno-oncology and advance our goal of greater participation in the next generation of therapies.

Overall, the safety profile of the PD-L1 appears acceptable. The adverse events were comparable to other compounds in this class and includes expected immune-related events. Using the expanded patient cohort, only 13% of the patients experienced adverse events grade 3 or higher. As we progress the program, we will continue to monitor these events.

Additional clinical data is expected to be presented next year at major medical conferences.



It's worth mentioning that Pfizer has a broad and deep immuno-oncology, short IO, and non-IO portfolio available for potential combinations. Over the past several years, we have been investing in the infrastructure, technical expertise, and capabilities and programs to drive success in the development of novel immunotherapy agents.

For example, one of our most promising assets is our 4-1BB agonist. It's currently in Phase 1 with a potential use in combination with other immunotherapeutic agents and with marketed agents.

We also have an OX-40 and PD-1 targeted agents that are both expected to enter the clinic in 2015, and we have our Bifunctional T cell redirected anti-tumor mAb, mAbs that may be combined with various drugs, including potentially drugs within the PD-L1/PD-1 class.

Further, we are developing cancer vaccines that are preclinical and based on a unique set of antigen delivery platforms that can be combined with a variety of immune-modulators, among others, and set to enter the clinic next year.

And we have established partnerships, such as with Cellectis to develop Chimeric Antigen Receptor T-cell therapies, short CAR-T, with Merck US to combine their anti-PD-1 antibody with four Pfizer assets, and with Kyowa Hakko Kirin to combine our 4-1BB with their anti-CCR4 antibody.

Overall, these different mechanisms have the potential to harness the immune system to attack cancer cells to provide new options to patients.

Given this broad pipeline, there are many opportunities to combine the PD-L1 and the PD-1 in this alliance with many Pfizer assets. Identifying the winning combination is a key element of our immune-oncology strategy.

Potential registration and combination studies in lung cancer, renal cancer, and ovarian cancer will start in 2015. We will consider combinations with our small molecules, including XALKORI and Inlyta, and also with our antibodies, such as 4-1BB, OX-40 and Antibody Drug Conjugates currently in or soon entering early-phase clinical studies.

We believe these and other compelling combinations have the potential to meet the needs of patients with multiple types of cancer. As the science continues to emerge, we believe we are very well positioned to be a leader in this space.

In summary, this is an exciting opportunity for both companies to collaborate at the forefront of these new potential cancer treatments. This alliance will allow us to significantly accelerate the timeframe of our development immuno-oncology programs and move into the first wave of potential treatment regimens. We look forward to working with Merck KGaA to co-promote XALKORI and bring these novel potential therapies to market for many cancer patients.

With that, I will turn it over to Chuck to begin the Q&A portion of the call.

Chuck Triano - Pfizer Inc. - SVP IR

Thank you, Mikael and Albert. Operator, at this point, if we could please poll for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum - *Evercore ISI - Analyst*

Number one, if I may, can you describe the intrinsic properties of this antibody and how it differs with the others? My understanding is the antibody from Merck KGaA does induce ADCC. I was wondering if you think that -- first of all, am I right? And two, does that matter?

Number two, the lung data that you have put up in the slide, which is very helpful, thank you, in 90 patients, would it be possible to give us slightly more information about those patients, such as what line of therapy they were and, if possible, the PD-L1 status and how biomarker-positive patients did?

Then if you will tolerate this question, and if you don't want to answer it, I certainly understand. But since Mikael is on the phone, Mikael, beyond this, what are the four or five late-stage pipeline drugs that you are most excited about right now that investors should focus on as we move into the new year? Thanks so much.

Albert Bourla - *Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare*

Thank you, Mark, and, in fact, I will pass immediately the question to Mikael, and then if Mace needs to also join us. Mikael?

Mikael Dolsten - *Pfizer Inc. - President Worldwide R&D*

Thank you for the question. This is an IgG1 antibody. It has very high affinity, sub nanomolar for the PD-L1, and interacts with the binding side of both PD-1 and B7.1, thus completely inhibit the function of PD-L1 as is desirable.

It does have some ADCC activity, which was shown in animal model to have a potential positive impact, although we think it's more of moderate importance, and it's clearly the strong binding activity of this antibody, and the clinical activity that we have seen that is very encouraging seems to be comparable to the other PD-1 and PD-L1 antibodies that has been shown.

The data on non-small lung cancer patients shared in the slide represent very advanced patients, and you can see an objective response rate above 13%, and with quite a number of durable responses and studies ongoing as we continue to monitor those responses.

I will ask Mace to comment if there is anything further that has excited him as we have reviewed this great opportunity to partner with Merck KGaA.

Mace Rothenberg - *Pfizer Inc. - SVP Clinical Development & Medical Affairs, Pfizer Oncology*

Thanks, Mikael. To finish up the question regarding non-small cell lung cancer data, indeed these are patients in greater lines of therapy where responses would be expected to be short and of low frequency with the standard therapy, so any activity we see in this setting is exciting.

The PD-L1 status is being checked on in these patients using a Ventana IHC method, and those data are going to be reported at future meetings.

In terms of drugs in our late-stage portfolio that we are excited about, certainly palbociclib would have to lead that group of drugs. As you know, we have an NDA that's pending at the FDA with a breakthrough therapy designation in advanced ER-positive breast cancer, but we also have a number of other late-stage compounds that continue to excite us, some of which are very likely going to be evaluated in combination with the anti-PD-L1, drugs like XALKORI for ALK-positive lung cancer patients; Inlyta, our anti-VEGFR inhibitor in renal cell carcinoma.

But also, we have ADCs -- inotuzumab ozogamicin is an anti-CD22 antibody drug conjugate that is in Phase 3 testing in patients with acute lymphocytic leukemia.

So we have a number of compounds that are exciting in their own right, but also compounds that we think can make very good partners for this anti-PD-L1 molecule.

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Thank you very much, Mace, here.

Obviously, we're excited about pembiciclib in breast cancer, both advanced and as we move it also into early breast cancer, and we have a number of studies now ongoing in non-breast cancer segments that we think are very encouraging.

Of course, our pipeline goes far beyond oncology, although that's the focus for this conversation, and we have made good progress with bococizumab, our PCSK9 inhibitor. We have multiple salient indications (inaudible) moving very well forward.

We have a staph aureus vaccine moving into Phase 2b where we have Fast Track and very good conversations with agencies about the importance of this therapy and how to advance it swiftly through the development pipeline.

We actually have growing biosimilar pipeline also in oncology and immunology.

In summary, we hope next year to have up to five immuno-oncology drugs in the clinic and up to five ADC. You will hear about an increasing vibrant and exciting pipeline in oncology and outside oncology, and we look forward, Mark, to many discussions together.

Chuck Triano - Pfizer Inc. - SVP IR

Thank you, all, very much.

Operator

Tim Anderson, Sanford Bernstein.

Tim Anderson - Sanford C. Bernstein & Company, Inc. - Analyst

If I could just clarify on your biomarker program, so all future work as it stands today will be through Ventana for an off-the-shelf solution?

A separate question, does every IO program by each company get thrown into the partnership here or can we assume that Pfizer can do as it wishes with its own IO programs if those are not being combined with a PD-L1? Thank you.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

I will take the second part and then I will give Mikael a chance to comment on the first one.

This is a partnership that involves PD-L1 and our PD-1. Other assets, immuno-oncology or not, are not part of this alliance and collaboration.

Mikael, you want to take the first one about Ventana?

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Tim, I don't want to go into details on the diagnostic strategy that Merck KGaA has been embarked in, although we have reviewed it with them and the regulatory dialogues that are in the planning, and we think that it is well in place and we will work with them to continue to optimize it.



As you know, on one hand these agents can be quite effectively used in patients independent of PD-L1, plus or minus, but there are reports that this type of drugs have an even better effect on PD-L1 positives, and all data we have seen with the Merck Serono drug is very consistent and show comparable similar activities as been reported with other drugs in this class.

Chuck Triano - Pfizer Inc. - SVP IR

Thank you, Mikael.

Operator

Jami Rubin, Goldman Sachs.

Jay Olson - Goldman Sachs - Analyst

It's Jay Olson on behalf of Jami Rubin. Can you please talk about just the pros and cons of PD-1 versus PD-L1 antibodies, and since you already have your own PD-1 antibody about to go into the clinic, how you decided to pursue this partnership for PD-L1?

Can you also comment on your previous agreement with US Merck to do combination studies with some of your oncology compounds with Keytruda and how that may or may not be impacted by today's agreement?

Then, lastly, can you please just describe some of the events that would trigger the \$2 billion in milestones? Thank you.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Let me take the last two ones and then I will pass it to Mikael to comment on the first one.

This transaction will not have any impact on our current collaborations in the immuno-oncology space and beyond, so that includes the Merck collaboration.

Also, on the up to \$2 billion milestone payments, I can tell you that these are regulatory and commercial milestones, but we do not disclose the exact structure of these milestone payments.

With that, I will pass it to Mikael and then to Mace to comment.

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Thank you. Concerning the difference between PD-L1 and PD-1, I should say up to now there are no clinical data that show any particular differences.

Theoretically, we know that PD-1 may bind PD-L1 and/or PD-L2. PD-L1 may bind PD-1 or CDAC B71. The implication of this different receptor system in the clinic, however, so far that when you break the PD-1/PD-L1 interaction, whether with this Merck Serono antibody or with other antibodies, you get impressive response data and durable responses and an acceptable safety profile throughout this class of drugs. We haven't really seen large differences.

As we learn more in this space, there may, of course, be unique niches, particular when you consider combination of drugs. So I want to underline what's really unique about this partnership, I think, is we're leaders in having PD-L1 in the clinic with more than 550 patients and, as you heard in my introductory remark, ready to go next year into up to 20 clinical development studies and up to six registration intent studies, but we also have

the PD-1 that will go into clinical studies next year, and that gives us a tremendous opportunity for flexibility, whether you study immuno-oncology agents, OX-40, 4-1BB, cancer vaccines, bifunctional antibodies, or, as Mace alluded to, like XALKORI.

We think the partnership with Merck KGaA will allow us to accelerate this foundation that we have built with strong strategic intent over many years, which makes us very excited about this.

I will also ask Mace if there is anything you want to add here.

Mace Rothenberg - Pfizer Inc. - SVP Clinical Development & Medical Affairs, Pfizer Oncology

I think you have covered it very well.

I think just to reinforce one of the points that you made, this relationship allows us to leverage our experience and our resources with an outstanding partner. Their expertise, their PD-L1, our experience in terms of being able to drive molecules forward in development quickly to identify areas of unmet medical need, and our complementary immuno-oncology assets, including antibody drug conjugates, makes this a very strong partnership.

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Thank you.

Operator

Alex Arfaei, BMO.

Alex Arfaei - BMO Capital Markets - Analyst

Good morning and thank you for taking the question. The upfront payment on milestones are obviously significant. They suggest you have very high expectations for this market. Could you comment on that? And basically from your perspective, how large do you see this in terms of potential for the immuno-oncology market? Thank you.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Thank you very much. Immuno-oncology is a high priority for Pfizer, and this deal is a significant step forward for our immuno-oncology program.

As Mikael alluded, let's not forget that next year Pfizer will have five immuno-oncology agents in the clinic -- PD-L1, which we just [protect us]; our PD-1; our OX-40; our 4-1BB; and the cancer vaccines. To that, we need to add the five antibody drug conjugates that we have already in the clinic.

Now for this particular deal, this is a molecule that we did extensive due diligence. We saw data of 550 patients, data that are not publicly available, and we used internal and external experts. We came to the conclusion that this molecule is comparable with the other agents of the class.

That will give us an opportunity to be in the first wave of immunotherapy, and we will be in the forefront of the second wave that will include combinations. All in all, this is almost transformational for our immuno-oncology program.

Operator

Andrew Baum, Citi.



Andrew Baum - Citigroup - Analyst

Three questions, please. Firstly, could you just outline the financial obligation to Merck in the event of a future acquisition of an alternative PD-L1 or PD-1 sponsor?

Number two, with ovarian cancer, there has obviously been some data showcased. Could you help me understand how much ovarian data there is in the ongoing Phase 1, and could it potentially support a filing as it stands currently?

Number three, on the call you mentioned a couple of other oncology products. The line wasn't great, so I didn't quite hear them. I think you might have mentioned p-selectin with adrenal cancer, and then T-cell selective antitumor monoclonals. Again, I didn't quite hear that, so if you could clarify, that would be great. Thank you.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Let me take the first one about the financial obligations in terms of other acquisitions. As you can expect, we are not disclosing other terms than the ones that we have disclosed so far.

For ovarian data, I will ask Mikael to comment, and then I am not sure which part you didn't listen well. Let's see if we can answer that. Mikael?

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Yes, so I could refer to the ovarian cancer data presented by Merck KGaA at their investor day, September, this year, which contained 21 patients and showed more than 17 percent -- 17% partial response and a large number of stable disease and also durability.

It looks like very promising data in an advanced patient population. We will continue to review those data set and see how we can bring it forward as fast as possible, and ovarian cancer was part of the Phase 3 [renstatinal] intent studies we are planning next year -- lung, ovarian, renal cell cancer.

Concerning combinations, I think we have mentioned among the marketed drug XALKORI for lung cancer, Inlyta for renal cell cancer, I do think my colleague Mace also alluded to that we have interesting mid-stage compounds, such as [snow] for hematological malignancies, [desigh] for various solid cancers, and then you heard about the antibody-drug conjugates, five different, across many different solid and hematological tumors, and also our five immuno-oncology products that will be in the clinic next year.

Altogether, that is a very broad portfolio that will allow us to have an ambitious plan to bring forward combination therapies across the most impactful areas to address high unmet medical need in many different human cancers.

Operator

Colin Bristow, Bank of America Merrill Lynch.

Colin Bristow - BofA Merrill Lynch - Analyst

Thanks for taking the questions. Just on timing and opportunity, given you will be one of the later entrants to the immuno-oncology markets, how do you view your offering as differentiated versus the competition? Or do you just see the market as large enough to remain attractive even under the assumption of late entry?



Then number two, you mentioned IO as high priority for Pfizer. How should we view appetite for further deals in this space? Are you now happy with your IO portfolio or will this become an area of ever-increasing focus? Thanks.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Thank you very much. Look, in terms of the entrants into the market, we do think that we will be in the first wave, and that means there will be some cancer indications that will be third or fourth, and some cancer indications that will be first or second. That's in monotherapy.

To believe that we will be in the forefront of the next wave, which is combinations, because we will initiate a significant program. As we said, up to 20 studies, programs will start next year, but many of them will be combination trials, so that we can position ourselves very strongly in this next wave. That will be extremely important.

As regards our immuno-oncology, our appetite for further, let's say, developments, we think that right now, as I said, we are among the strongest players in terms of how broad our portfolio could be with five different agents in the clinic, but, of course, as I said, immuno-oncology is a very high priority for Pfizer with a lot of management attention and we will be looking for everything that is available.

Mikael, would you like to add anything on that?

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

Excellent comment, Albert. I just wanted to punctuate that we have an ambitious agenda to be a leader here and we aspire every year to bring one or more novel immuno-oncology programs into the clinic.

We have an internal pipeline that can deliver on that target, but we will continue to do partnership and licensing opportunity in this space. You'll see really one of the leading portfolios created today by the alliance to continue to evolve strongly across many different tumor types.

Operator

John Boris, SunTrust Robinson Humphrey.

John Boris - SunTrust Robinson Humphrey - Analyst

Congratulations on the deal and thanks for taking the questions.

If you are using the PD-1 that you have your agreement with Merck KGaA with, and you have 4-1BB that would potentially be competitive with your earlier mAb from Bristol-Myers, just help us understand, along with OX-40 plus PD-1, T cell, and those combinations, how that works with using it with PD-1, and does Merck have any rights to those?

Then second question just has to do with any standstill agreement built into your agreement with Merck KGaA in the event that there is an overture for takeover of Merck KGaA or future takeover by you of Merck KGaA? Thanks.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

John, thank you very much for the question. I think I can handle it. Any revenue that will come from PD-L1 and PD-1 will be shared equally.

Also, all development and commercialization costs for our PD-1 or our alliance now, our -- for our PD-L1, of Merck's PD-L1, also will be shared equally. The two companies will jointly move the PD-1 right now, in addition to the studies -- up to 20 studies of PD-L1 will also advance the PD-1 into the clinic Phase 1 next year jointly.

As regards the standstill question, we do not make any comments. We do not disclose any terms about this deal, other than the ones that we have already disclosed in our press release.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

A few questions here. First off, can you guys talk a little bit about the additional tumors that you would hope to open up in the near term, whether it be with monotherapy or combination therapy, and where you think Pfizer may be -- Pfizer with Merck KGaA may be particularly well positioned?

In addition, could you also provide a little bit more color and clarification on the potential registrational studies? My understanding is it says that there could be as many as -- I think it was five registrational studies to start in 2015. Can you just clarify that for me and, if possible, give us a sense of the potential tumors, where we might see that? Does that include the Merkel cell carcinoma study as well?

Then last question, Mikael, a little bit of a curveball. I assume that most people are wondering what you are thinking about the successful outcome of the IMPROVE-IT study, which we saw hit this morning. Just wondering if you might be able to provide us a little bit of your thoughts on the implications of that outcome for the PCSK9 inhibitors. Thanks a mil.

Albert Bourla - *Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare*

Thank you very much. Just to remind, we spoke about up to six pivotal studies that will be registration enabled, and with that, I think Mikael will be more appropriate to comment on additional tumors and also on the question on PCSK9.

Mikael Dolsten - *Pfizer Inc. - President Worldwide R&D*

Thank you, Albert. Right now, we have agreed to disclose that we are moving swiftly forward together with Merck KGaA with a plan next year to start pivotal studies in lung cancer, ovarian cancer, and renal cancer.

The alliance are discussing additional tumor types and multiple combinations. Many of these tumor types are significant when it comes to the number of patients and the unmet medical need, but we will continue to share the plans of the alliance as they are detailed during the period to come.

Concerning the curveball, it is obviously good for patients when positive news are delivered, and I just noted the IMPROVE-IT study stated that they have reached a primary endpoint, so we'll have to see as data is shared more publicly the strengths of those data and how that can contribute to -- in the regulatory discussion around registration on LDL versus [feed] outcome.

So it is still, I would say, early days, but obviously positive news for patients that are using this type of drugs.

Chuck Triano - *Pfizer Inc. - SVP IR*

Thank you, Mikael. Operator, if we can take our last question, please.



Operator

Steve Scala, Cowen.

Steve Scala - Cowen and Company - Analyst

I have two questions. Mikael, you mentioned that the PD-1 offers overall response rate and safety consistent with others in the class. That being said, it's not clear to me why you did this deal.

With PD-1 available commercially for at least one tumor type and other tumor types on the way, it seems like Pfizer has access to PD-1 for combo studies with Pfizer agents. Or do you believe that having PD-1, despite sharing revenue on PD-L1, is additive to Pfizer? So by doing the deal, it would appear that Pfizer is saying that PD-1 is more attractive than PD-L1 and that you had to have access to a PD-1.

Second -- from the commercial standpoint. Second, there is some debate among companies as to approach. Some companies believe it's important to fully characterize the PD-1 as monotherapy before aggressively pursuing combos, while other companies are aggressively pursuing combos immediately. I am wondering which side of the fence Pfizer is on. Thank you.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Let me maybe comment on the reasons why we did the deal.

There is a dominant belief among the scientific community and the investment community that basically PD-1s and PD-L1s are the different face of the same coin, different side of the same coin, and the clinical benefits from both are comparable and equal.

What this deal is allowing us to do, it is to jump immediately into monotherapy combinations that, as I said, will come in the first wave. Some will be third, fourth. Some will be first or second, some tumor types. But also, more importantly, to start immediately our combination studies, and we do think that it is important to be able to have both monotherapies and combinations and to have your own PD-L1 doing these combination studies.

Mikael, anything to add to that?

Mikael Dolsten - Pfizer Inc. - President Worldwide R&D

I think you said it very well. It allows the alliance to plan and put together very comprehensive program around PD-L1, the Merck compound, together with our broad portfolio, and it also has success to the PD-1 from Pfizer, but as you said, Albert, the PD-L1 allows already next year to go into Phase 3 studies.

I will also invite Mace to comment here.

Mace Rothenberg - Pfizer Inc. - SVP Clinical Development & Medical Affairs, Pfizer Oncology

Steve, if we were having this call 20 years ago, we wouldn't be talking about these compounds; we would be talking about EGFR inhibitors.

Many people, myself included, felt that whether you inhibit as with a monoclonal antibody or with a small molecule tyrosine kinase inhibitor, you were inhibiting the same molecule, same pathway, and you get the same results. We were wrong.

I think we are at the same point right now in PD-L1 and PD-1 inhibitors. They seem to affect the same pathway, the same receptors. Early responses look fairly similar, but I think we should recognize the fact that we are just beginning to explore the impact of these molecules as single agents, and as Mikael alluded to earlier, as combinations we may see an evolution where it might be preferable to combine a PD-1 or a PD-L1 with one of the other molecules that we've mentioned.

With regard to the monotherapy versus combination therapy question, I think we have to look at this collaboration with Merck KGaA and Pfizer as allowing us to combine our resources, or combine our expertise, and pursue a dual strategy to be committed to being within that first wave of approvals for monotherapy, but in parallel being able to explore the most promising combinations, which experts in the field all agree is really where the next major improvement will occur.

Because, remember, with inhibiting the PD-1/PD-L1 pathway, we are removing the inhibitory effects on the immune system, so you are releasing the brake on the immune system. The molecules we have talked about are ways of actually putting the foot on the accelerator and creating a steering wheel to direct that immune effect against the tumors.

So I think we're really at the very beginning of this field, and what we are saying by this announcement today is that we want to be leaders of immuno-oncology going forward.

Albert Bourla - Pfizer Inc. - Group President Vaccines, Oncology & Consumer Healthcare

Thank you very much.

Chuck Triano - Pfizer Inc. - SVP IR

Thank you, and thank you, everybody, on the call for your time and attention this morning.

Operator

Ladies and gentlemen, this does conclude today's conference. You may now disconnect.

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