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PFE - Pfizer Inc at Cowen Health Care Conference

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MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

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

PRESENTATION

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

Well, good afternoon -- or good morning once again. We're very pleased to have with us, at the Cowen Conference, Pfizer. Unfortunately, because of the weather issues, they were unable to be here in person, but we're very happy to have them on the line. So we'll get underway with the session.

On the line from Pfizer is Chris Boshoff, who's Senior Vice President and Head of Immuno-Oncology, Early Development and Translational Oncology; as well as Andy Schmeltz, who's Global President of Oncology.

At Cowen, we like Pfizer for a number of reasons. One of them is the emerging innovative capability that we think Pfizer is starting to demonstrate. And we think you only need to look as far as drugs like IBRANCE, Eliquis and Prevnar 13 as good examples of that. We think drugs like these will allow this company to deliver growth over the next 3 to 4 years, which can beat the S&P 500 and as well as the drug sector overall. And we don't feel that that's reflected in the PE multiple.

So with that, I'd like to turn it to Andy, who will walk us through just a few slides. And then we're going to jump right to questions. So Andy, why don't you take it away?

Andy Schmeltz - *Pfizer Inc. - Global President, Pfizer Oncology*

Great, Steve. Thank you, and good morning to everyone. I'm pleased to join you on behalf of Pfizer, along with Dr. Chris Boshoff today. We really tried to be with you live via planes, trains and automobiles, but Mother Nature simply wouldn't cooperate, so we'll make do virtually. And before engaging in the dialogue, Steve, with you, I thought it'd be helpful to frame the Pfizer Oncology portfolio and our focus.

So if you can move to the next slide, please. I need to acknowledge that Chris and I will be making forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Additional information regarding these factors can be found in Pfizer's 2017 annual report on Form 10-K filed with the U.S. SEC and available on sec.gov and pfizer.com.

Next slide, please. Over the past decade, Pfizer Oncology has experienced a strong growth trajectory. The business, with just 2 medicines and 3 indications back in 2010, today consists of 10 in-line medicines spanning 17 indications, with potential multiple launches on the horizon. We've transformed from a niche player to a leader, particularly in breast and prostate cancers, with the launch of IBRANCE in 2015 and the acquisition of Medivation in 2016, bringing Xtandi into our portfolio. As we look at near-term opportunities beyond our significant IBRANCE and Xtandi life cycle programs, we're particularly excited by the prospects of launching 4 new molecules over the coming 12 to 18 months: with dacomitinib and lorlatinib in EGFR-positive and ALK-positive non-small cell lung cancer, respectively; glasdegib, our SMO inhibitor for acute myeloid leukemia; and talazoparib, initially for BRCA-positive breast cancer.

To double-click briefly, lorlatinib, our investigational next-generation ALK inhibitor, was specifically designed by Pfizer scientists to inhibit tumor mutations that drive resistance to other ALK inhibitors and to penetrate the blood-brain barrier. Additionally, talazoparib, a potent investigational PARP inhibitor, has a differentiated product profile not only in showing superior efficacy to chemotherapy and prolonging progression-free survival in patients with BRCA-mutated HER2-negative breast cancer, as presented in San Antonio in December of 2017, but it also has a survival trend that



MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

was observed in the interim analysis in this study, although the data is yet to fully mature. We're also really excited about the potential for talazoparib in prostate and ovarian cancers and as a combination medicine for immuno-oncology. We recently initiated a basket trial with avelumab and talazoparib in a number of solid tumor types.

If you could go to the next slide, please. We have a rich and diverse pipeline with some exciting near-term and longer-term opportunities. If you take a look at the near term, you can see some of our earlier investments in TKIs are potentially paying off now. And if you look at our earlier pipeline, you can see the clear shift in focus to have cutting-edge science and investments in immunotherapies. Immuno-oncology, I/O, is transforming outcomes for patients and represents the future of cancer treatment. And as you can see in our early pipeline, I/O is an important component to our overall Pfizer Oncology strategy. We believe the true value of immuno-oncology is expected to be an effective combination, driven by solid preclinical science. And we're in a good position to possibly lead in a number of tumor types given our broad portfolio here.

Next slide, please. Just to bring it together, our vision in Pfizer Oncology is to be a leader by speeding cures and accessible breakthrough medicines in patients, effectively redefining a life with cancer. To realize this goal, we're laser-focused on 3 core areas. First, our anchors, IBRANCE and Xtandi. We continue to generate evidence for broader and optimal use with these medicines, as evidenced by the recent PROSPER data presented at ASCO GU in February for Xtandi in non-metastatic castrate-resistant prostate cancer, which has been submitted to regulatory authorities in collaboration with our partner, Astellas. Our second area of focus is our broad and deep pipeline, which includes talazoparib, as I've mentioned; avelumab, in partnership with Merck Serono; and a number of rational I/O-based combinations. And third, our patients-first mindset, where we're committed to innovative and meaningful patient engagement. We strongly believe that by putting the interest of our patients first, we will ensure we're successful in realizing our potential.

So with these opening comments, Steve, I'd like to turn it back over to you, so we can have a dialogue.

QUESTIONS AND ANSWERS

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

Thanks, Andy. That's a very nice overview. So let's start out with the CDK 4/6 space. Your competitors, both Lilly and Novartis, were here earlier in the week, and they don't dispute the fact that this could be a massive class of agents, as we agree, but they have differences of opinions as to who will be the leader. So far, IBRANCE has obviously been tenacious in maintaining, by far, the dominant market share. To what do you attribute that given the fact that you have 2 new competitors?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Thanks for the question, Steve. Chris and I are going to tag team, and I'll take this one. We attribute IBRANCE's continued leadership to the strength of our data, the compelling benefit-risk profile of the medicine, our significant first-mover advantage and a very positive patient and oncologist experience with the medicine. To date, more than 100,000 patients have been treated. To be honest, we haven't seen any material impact to date in terms of performance from the competition, and there's so much opportunity here. To date, only 60% of newly diagnosed HER2-positive -- or HER2-negative/HR-positive patients are receiving a CDK agent. And across lines of therapy, only 50% of patients are receiving a CDK agent. We've been growing the penetration of the class. And with the availability of multiple agents now, we expect to see the penetration of the class further grow, with IBRANCE continuing to take a disproportionate share. So we're very bullish on continued growth for IBRANCE in the category.

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

One of the points that Novartis raised is that, in Europe, it's more of a neck-to-neck situation between Pfizer and Novartis, where they launched in closer proximity. Is that indeed the case as you see the performances? And to what do you attribute that?



MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

No, I appreciate the question. Certainly, the lead time of IBRANCE's availability is not as significant outside the U.S. But today, IBRANCE is approved in more than 80 countries, with reimbursement secured in more than 25. And I'm happy to say that reimbursement now includes all 5 major European markets, Canada and Japan. So we see strong trajectory in Europe and in the early days in Japan, to be honest with you. And certainly, we're ahead. We don't see the competition there showing up.

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

Okay. I assume that the answer to this question is no, but just to check the box, let me ask. With 3 agents on the market, are you seeing any sort of payer pressure or pushback pitting one drug against another?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Yes. To date, we don't see that. IBRANCE is covered by 98% of commercial health plans in the U.S., 100% of Medicare Part D plans. Certainly, we recognize that oncology, which historically has not been managed at all, is an area that we have to be much more attuned to. But we don't see any issues in terms of access to IBRANCE now.

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

Okay. Should the PALLET study be successful, what would the path forward be for Pfizer?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

I'll start with that and then maybe hand it to Chris. So as part of our life cycle program for IBRANCE, we're -- have ongoing studies in both metastatic breast cancer with the current indication as well as early breast cancer. In early breast cancer, we have 3 ongoing trials: Phase 3 trial PENELOPE in high-risk early breast cancer; Phase 3 trial PALLAS in intermediate-risk early breast cancer; and then PALLET, the study that you were referring to, is the Phase 2 trial in neoadjuvant, newly diagnosed breast cancer. The goal of the PALLET study is to inform translational hypotheses and to further inform our confidence in other adjuvant studies. So we see it, really, as an informative trial. We're looking forward to the results and kind of incorporating the learnings. Chris, anything to add?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

No, just perhaps to add that we know that with a number of antiproliferative agents, new adjuvant studies have often helped us to get confidence in adjuvant studies. So I think a positive PALLET study will provide further confidence in both PENELOPE-B and in PALLAS.

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

Okay. Two more questions on CDK 4/6 before we move to other topics. First, when both Lilly and Novartis were here earlier in the week, we talked about exploring other tumor types beyond breast cancer with this particular mechanism. And Lilly made it sound as though they could be announcing a multitude of additional tumor types being explored, perhaps, later this year. And Novartis was the complete opposite, saying they just don't see promise outside of breast cancer. Where does Pfizer line up in this spectrum?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

Chris here. I'll start. So I think that's a very relevant question because, as you know, the cell cycle and cell proliferation is fundamental to cancer. So most cancer cells use the cell cycle to actually proliferate. We had many studies that were done across solid tumors, including ongoing studies



MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

currently, with over 30 investigative research studies with various combinations. We've seen some signals, for example, potentially with cetuximab in head and neck cancer and also with ibrutinib in mantle cell lymphoma. We have an ongoing study in pancreatic cancer, which is a Phase 1b study, with abraxane plus palbociclib in metastatic pancreatic cancer, and we hope to get a readout for that study later this year. And that can inform us whether we should follow registration study, for example, in pancreatic cancer. We also continue to participate in a number of collaborations. For example, we are part of the NCI collaboration in lung cancer. We've been looking at -- we are testing palbociclib in specific subpopulations with genetic vulnerabilities that may predict responses to palbociclib. But I think in general, overall, it is clear that palbociclib or blocking CDK 4/6 plus blocking hormonal receptors in breast cancer, that's where you really see the significant added effectivity. And we may not see that, that meaningful difference, in other tumor types. And we will continue to explore them.

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

Okay. What can you share with us about your next-generation CDK 4/6 inhibitor? Or maybe it's not a 4/6 inhibitor. It's a CDK inhibitor.

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

Yes. So we haven't declared all the functions of that specific new medicine yet. It is entering the clinic now. It's a very exciting molecule for us, for Pfizer. There's actually 2 of these that we bring to the clinic, 1 this year and potentially 1 next year. Specifically also was just addressing potential resistant mechanisms to palbociclib. So we hope to give an update of that study later, but you should also see something on ClinicalTrials.gov very soon regarding the next-generation drug.

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

Okay. Maybe we can move to Bavencio. How do you see Pfizer positioned in immuno-oncology? And how is immuno-oncology positioned within the overall Oncology business?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Let me start, Steve. So immuno-oncology remains an important component of our overall Pfizer Oncology strategy and pipeline. We remain committed to our partnership with Merck Serono on Bavencio and our broader I/O research efforts. It's a dynamic space with the standard of care evolving with each scientific conference and data readout. Furthest along, of course, we have Bavencio with 2 in-line indications, Merkel cell and bladder cancer. But those are niche spaces. And we recognize that monotherapy in immuno-oncology is quickly moving on to combinations. And while we're not a leading player, to say the least, in this first wave in monotherapy, we believe that we've got some interesting opportunities in this next wave of combinations, particularly pairing Bavencio with a range of other molecules across our pipeline. And we're also, as I mentioned earlier, looking at different I/O combinations beyond our partnership with Merck Serono. Chris, you want to add anything?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

So I think Andy said it nicely. So we believe that immunotherapy will become one of the anchors of cancer medicine but only one of the anchors. And those other anchors, including -- whether it's ADCs or small molecule tyrosine kinase inhibitors, will continue to be very important. And as we see in breast cancer, having a CDK 4/6 or having a prostate cancer in anti-androgen or breast cancer in anti-estrogen or in lung cancer. 25% of lung cancers will be dependent -- are oncogene-addicted and will be dependent on targeted therapies. So what we firmly believe is that the future combination therapies, some of these combinations will be I/O-I/O, but in many cases, it will actually not be. And as we've recently seen with the data that we've shown with Inlyta plus Bavencio as well as with Inlyta plus pembrolizumab, both of those combinations have breakthrough therapy designations, these combinations have ongoing Phase 3 studies, that that may actually become the best combination or the most meaningful combination in first-line renal cancer. So we, as Andy pointed out, has a number of important studies with Bavencio that will read out over the next 12 to 18 months, including first-line renal cancer with Inlyta. First-line ovarian cancer, this is upfront ovarian cancer, with chemotherapy combinations with taxane and cisplatin. We're leading in this space. We've got 2 ongoing Phase 3 studies in ovarian cancer, and others have started studies slightly



MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

behind us. We've got readouts in first-line bladder cancer, a differentiated strategy with a chemotherapy upfront and then sequence with a checkpoint inhibitor. And then a combination study in head and neck cancer. We combine both radiotherapy and chemotherapy. We also -- in terms of, in general, immunotherapy, I think we're now looking forward to our next wave of therapies entering the clinic. We've already started with some of our bispecifics in the clinic, both in solid tumors and hematological malignancies. And as you know, we also have an ongoing program with an allogeneic CAR T-cell approach. So overall, immunotherapy is going to be important, but it's just going to be one of our anchors in cancer medicine.

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

Let me ask one question about lorlatinib. Very exciting agent. Can you look forward and, perhaps, describe what you see as the distinguishing characteristics versus Roche's Alecensa?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Absolutely. Good question, and thanks for asking about lorlatinib. We see lorlatinib as a potentially best-in-class ALK inhibitor. Lorlatinib was developed specifically to address the emergence of ALK resistance in patients treated with first-generation ALK inhibitors. And given the penetration of first-generation ALK inhibitors now, the diagnosis of ALK-positive non-small cell lung cancer is now the standard paradigm. And so there's an emerging population of patients that can really benefit -- who has cycled through a first-generation ALK inhibitor that could benefit. And so lorlatinib really addresses that unmet need. We have filings submitted and accepted for lorlatinib with the FDA, the EMA and Japan. And we've been granted priority review by the FDA for lorlatinib. So we're excited to bring to market this next-generation ALK inhibitor and think that it really fulfills a void in the space.

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

Okay. Let's move to talazoparib. So most physicians with whom we have spoken view PARP inhibitors as undifferentiated. What data points within your studies could you point to that would distinguish this agent from Olaparib's OlympiAD trial data?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

So talazoparib has a unique profile given its high potency and its dual mechanism of action with high PARP trapping and enzyme inhibition activity based on preclinical data. We presented, as I mentioned earlier, the data from our EMBRACA trial at the San Antonio Breast Cancer Conference back in December, where there was a survival trend observed at the interim analysis, although the data are yet not mature. So we believe that, although it's early days, that talazoparib has the opportunity to have a differentiated profile. And beyond breast cancer, I think there's opportunity for this to play out with following indications where we have ongoing trials, particularly in prostate cancer, a Phase 2 trial TALAPRO-1 in castrate-resistant prostate cancer; and our Phase 3 TALAPRO-2 trial, which is in combination with Xtandi. And so it's both the unique attributes of talazoparib combined with the places where we generate data that we think that are going to differentiate it from the other PARP inhibitors. Chris?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

Yes. I think Andy has said it nicely. So preclinically, it is the most potent PARP inhibitor and not only blocking the enzyme but also because of the so-called PARP trapping -- trapping PARP onto DNA, which potentially could be exploited in various combinations. So we can be testing talazoparib with various combinations. In terms of clinical data, as Andy pointed out earlier, a survival trend was seen for talazoparib in the interim analysis for the EMBRACA study, so we'll see how that plays out. And clinically, it's meaningfully different from the others. And in the large program, we started with a combination with talazoparib with immunotherapy in various tumor types, including breast, prostate, bladder and lung cancer. And so that study is ongoing, a Phase 1 study going into Phase 2 study soon. Yes, so we're excited about this medicine.

MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

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

To the best of my recollection, we have seen higher rates of heme tox with talazoparib versus olaparib. Is this a concern? And if it is, then how can this be managed?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

Shall I start, Andy? So yes -- so as you know, anemia is a common side effect for most cancer treatment, and that potentially is managed very effectively. Discontinuation due to adverse event in EMBRACA study was only actually 7% in patients on talazoparib, it was 7.7%, and 9.5% in patients on chemotherapy. And overall, within that study, the quality-of-life data, and that was performed using the EORTC quality score, also showed a significant benefit for talazoparib versus chemotherapy. So I think, overall, the class effect, the class effect of all PARP inhibitors having hematological toxicity is there, but it is manageable. And we do not see that as a specific detriment to talazoparib compared to the other PARP inhibitors.

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

Okay. Perhaps we can move to Xtandi. I think Pfizer, and correct me if I'm wrong, I think Pfizer has previously said that the non-metastatic prostate cancer market would be about twice the size of the current opportunity. So correct me if I'm wrong in my recollection. How quickly can the potential of this market be harnessed and show up in terms of Xtandi sales going forward?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Thanks for the question on Xtandi. And the PROSPER data, which was presented at the GU just last month in February, which we're very excited to see and now in the process, hopefully, to see it published in a peer-reviewed journal shortly, we have submitted our filing for the expansion of our indication. And we expect to get confirmation of acceptance of the filing soon from the FDA. This really extends the opportunity for Xtandi from the metastatic castrate-resistant prostate cancer population into the non-metastatic. And you're generally correct. We see that moving earlier with the life cycle program we have in place for Xtandi, that there's really double the treatment opportunities for our -- beyond our current indication, combined with the prospect for longer treatment duration. So that's the case. The benefit we have here is that Xtandi is used broadly in comfort level both with our oncologists and neurologists, and so the extension of the indication to this broader population will enable clinicians that are already comfortable using Xtandi to use it in a broader range of patients. So we're optimistic that it will be a natural opportunity. And obviously, we're bullish on how quickly we can enable more patients to benefit from Xtandi in this broader population.

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

2017 was a year in which Xtandi was impacted by the dynamics around the patient assistance program. To what extent are we working through that headwind? And will be -- at what point will we be relieved of that headwind?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Yes, that's a good question, Steve. Patient assistance enrollment rates fluctuate, particularly early on in the year, where there's re-enrollment opportunities and people also who can kind of also get coverage, especially in this population from a Medicare perspective. So we're early in the year. But based on early enrollment and re-enrollment trends, we're supportive of the belief that patient assistance, as a percentage of total demand for Xtandi, will decrease in 2018. So I think bottom line, we think that the -- lots of the uncertainty is behind us, but it's premature now because we're still early in the year to see the trends.



MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

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

Okay. Maybe we can chat about UCART19 for a bit. When will we get pivotal data in pediatric ALL and also adult ALL?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

I'll start. So we haven't actually announced yet the completion of the pivotal study. As you know, we've got ongoing studies, including the ALM and the CALM study, which determine maximum tolerated dose, the activity and the safety of the compound. The initial data, to point out again, regarding safety and tolerability with UCART19 showed an 83% complete remission across adult and pediatric population. So we are continuing to develop CAR T to work with our collaborators like Cellectis and Servier, and we hope to present further data on UCART19 later this year.

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

Okay. Many of the ALL patients that have been treated with UCART19 have proceeded to a transplant rather than using UCART19 as a substitute for transplant. Is that how UCART19 will be used commercially? Or is this just an artifact in early data?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

So it's partly to do with the early data in terms of the patients that's eligible for the study. Having said that, it is an opportunity to be curative with a sequencing of UCART19 plus a transplant. And that will be a forward path for some patients. And we hope to also update data later in patients that may not necessarily need a bone marrow or stem cell transplant.

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

Okay. We're down to less than a minute left. What key data readouts can we expect at AACR and/or ASCO this year?

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

So if I'll start with that. So we -- for AACR, we have a number of presentations on some of our earlier compounds, including OX40, a molecule we didn't discuss today. So we have a nice update on the mechanism of action on OX40. Andy, do you want to add anything to that?

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

No. I think that specifically at ASCO, with our in-line portfolio, continued stream of data to reinforce the benefit-risk and the value proposition. And we're looking forward to ASCO to reinforce, particularly with IBRANCE, with Xtandi, the benefit-risk of the medicines.

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

Perhaps, I just should add. At AACR, we also have an update on our HER2 ADC that's currently in the clinic. This is an exciting molecule for us. Again, building on our breast cancer portfolio with talazoparib, IBRANCE and now HER2 ADC.

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

Okay. Great. Well, we are now out of time, so I'd like to thank both Andy and Chris for a very nice discussion. And with that, we'll close the session. Thank you for participating.

MARCH 14, 2018 / 2:40PM, PFE - Pfizer Inc at Cowen Health Care Conference

Chris Boshoff - Pfizer Inc. - Senior VP and Head of Immuno-Oncology, Translational Oncology & Early Development

Thank you.

Andy Schmeltz - Pfizer Inc. - Global President, Pfizer Oncology

Thank you.

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