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# EDITED TRANSCRIPT

BAYN.DE - Bayer AG Meet Management Conference in New York

EVENT DATE/TIME: JUNE 25, 2015 / 12:00PM GMT



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## PRESENTATION

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### **Alexander Rosar - Bayer AG Leverkusen - Head - IR**

So, good morning, everybody. And welcome also on behalf of the entire management team of Bayer to fourth Meet Management conference here in New York. My name is Alexander Rosar and I'm responsible for Bayer's investor relations program.

So what have we prepared for you? Firstly, Marijn Dekkers, our CEO would briefly outline recent developments and our strategic priorities. After him, Joerg Moeller who is heading the development group within Bayer healthcare will briefly outline some of the highlights in our cardiovascular pipeline.

After the presentations, you will have the opportunity to discuss all aspects of Bayer in four breakout sessions. One session focusing on group aspects, one on healthcare, one on CropScience and one on pharma R&D.

And in order to facilitate the discussion, we have split the entire audience into four groups, A, B, C and D, and you will find your group on the nametag. So the format is the following group A, for example, starts with group continues with healthcare, moves on to crop and lastly can focus on R&D. All breakout sessions are located on this floor. After the breakouts, we cordially invite you to join us and the entire management team for a lunch session.

So one last aspect I have to mention - please be aware that during the entire conference we will make forward-looking statements, so we kindly request that you carefully read through the safe harbor statement. (*See "Disclaimer" chart at the end of this transcript*).

And with that, I would like Marijin to take the floor for his presentation. Thank you.

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### **Marijn Dekkers - Bayer AG Leverkusen - CEO**

Yes, thank you Alexander. Good morning, everybody, and thank you so much for your interest in Bayer. We have a fun-filled morning planned for you. And you can basically ask us anything you ever wanted to know about the company and it will hopefully be a lot of useful information for you this morning.

As Alexander said, I will take about 30 minutes to give you an overview of the company, where we are at the moment to both, in terms of performance and our key strategic priorities, and then Joerg will follow up will some details about the pharma pipeline, and then we'll go into the breakouts.

So you, of course, heard that we are transforming into a pure Life Science company and I will show you a little bit about our portfolio and what that means for us. We are transforming into a Life Science company and we're exiting MaterialScience. We are continuing to execute a strategy of organic growth particularly from new products, new innovations, that we've done complement with bolt-on acquisitions. And we have been able and we'll also in the future, in the next years, will be able to generate significant organic growth from those new products.

We have a number, particularly in pharma, of important R&D pipeline projects that are in phase 2, some in phase 3. We'll get a lot of data available in the next 12 to 18 months, and that we've updated our guidance for 2015 at the end of the first quarter. We were thinking to have single-digit organic growth but high-teens improvement in core EPS.

This is the track record since 2010. And you can see here that we have been able to have about 5% organic CAGR on the top line and core EPS of 9%, relatively consistently over the last five years, and we're also confident that we can continue this upper trend. Just to show you in the first quarter where we have 3% organic sales growth and we have 10% EBITDA and 8% core EPS, core EBITDA -- which is adjusted EBITDA before special items as you can see there. And core EPS of 8% growth. So we're happy with the start to the year.



Our current outlook that we communicated at the end of the first quarter is at the time that we get the original guidance for 2015, we were still using foreign exchange rates that were at the end of the fourth quarter, so the end of 2014, and we updated that to the end of the first quarter 2015. And that gave us a quite a boost in our outlook, of course not in organic sales which is low single digit as you can see there. But in EBITDA and core EPS, we got FX effect of plus 8%, plus 7% and that is where we are now guiding in the high-teens improvement for the year.

We have four key elements that our strategy is based on. And the first is delivering growth. I'm just going to give you a little bit more of a look back and a look forward in some of the key businesses. This is the pharma business, the top line development since 2010. You can see that from 2010 to 2011, we have 1% organic growth, then it was 4%, then it was 9%. Last year, it was 11%. In the first quarter, it was 7%. And this is the result most significantly of five new products that we have introduced over the last years, and you see there's acceleration of top-line growth.

The five new products are Xarelto, the biggest one; then Eylea, Stivarga, Xofigo and Adempas. And you can see the development of those five since 2012. In 2011, there were hardly any sales. And then last year, EUR2.9 billion and we are now expecting to be over EUR4 billion in 2015 for these five products. And that is what is boosting the pharma top line very significantly.

Two slides. One on Xarelto, one on Eylea. But again, you have plenty of opportunity in the breakouts to talk about this. But just so you'll see, here on the left, you can see in 2014, we had almost EUR1.7 billion of revenue recognized from Xarelto for Bayer. In the first quarter, it was 482 which was up 38% over the year before.

On the right, you see global market sales. At the end of the first quarter, where of all the anti-coagulants, Xarelto had 33% share and our competitors, Pradaxa and Eliquis, 12% to 13%. So you know, we will be very likely well over 2 billion of sales with the Xarelto this year, and we are reiterating our big sales potential for Xarelto at around 3.5 billion.

Eylea has a similar success story. Actually, the growth rates are even higher there. And you can see in 2014, we were 759 million coming from nothing in 2012 essentially. And then in the first quarter, we were up 55% year-over-year with 253 million. Eylea, we represent outside of the U.S. and you can see in Europe, in five main countries plus Switzerland. You see, the Europeans don't consider Switzerland to be Europe. Obviously, it's seen within there. It's up now 37% share. And in Japan, 55% share. So a significant share for Eylea. And there also we are working on new indications being approved across the world and we're there reiterating our peak sales potential to be over or equal or better than 1.5 billion.

So these are two very significant products for us of the five newly introduced products in the last few years.

Then to change gears a little bit, OTC. A lot is happening in our OTC business, our over-the-counter medicines. You can see here on the left that we had in 2013, 3.9 billion of sales; and pro forma in 2014, 5.6. So we had some organic growth on our own, significant organic growth. And then we did the acquisition of the Merck OTC business where we picked up brands like Claritin, and Coppertone, and Dr. Scholl's. We also did a smaller acquisition of Dihon Pharmaceutical in China.

So we think that critical mass is very important in the OTC business where we want to be one of the top people there in terms of revenue and position globally. And with this acquisition, we are strong number two. The focus there particularly with the Merck OTC business is to get a lot of revenue synergy, 400 million by the third year in 2017 coming from better leveraging our commercial position in general, but also introducing some of the Merck brands outside of the United States. Because Merck has traditionally been a very U.S. focused OTC business, we're taking these strong brands also outside of the U.S.

People sometimes ask me, "But aren't these products off patent? And why is it a good business if products are off patent?" Well, let me show you this chart. Aspirin, we introduced in 1899, OK. Look at this 9% growth. Aleve, you know, it's the best thing if you ever have any muscle problems. And then Bepanthen is not so well known in the U.S., but it's a very well-known brand in Europe. It is a cream that fixes all kinds of rashes on the skin. It started with diaper rash but then developed into other skin problems' treatment. That's the formulation that was developed in 1944. We had 14% organic growth in the first quarter.

So these types of products, if you manage them well, the gift that keeps on giving. And you can see here that, organically, we had 8% growth in the first quarter basically in the traditional Bayer brands. And then the Merck OTC business on top of this so this is becoming a very strong pillar also in our portfolio.

Now this chart is in green for a reason. This is CropScience so there's chlorophyll in this chart. You can see here the development of CropScience which is really something that we are very proud over the last years, where you can see the organic growth rates in revenue, 9%, 12%, 9%, 11%; but then also only 1% quarter-over-quarter in the first quarter of 2105.

So what has been going on here? We have had a very good set of market conditions over the last four years in CropScience. The agriculture commodity prices were relatively high, and that means that farmers have more confidence investing in our products to get the yields up because they know they can get good prices for additional yields. That has gotten softer now, and I'm sure that will be a topic in the CropScience breakout.



So we're seeing, you know, a significant moderation there in terms of the demand this year compared to the last years. But that's not the full story. We also feel that based on our new products and a very strong new market strategy, go-to-market strategy, we've been able to gain share in this industry over the last years. And the organic growth pattern that you see there is a combination of a good market, yes, but also Bayer being stronger than we were before.

Develop new growth opportunities. And this is all about the pipeline, what is coming in the next few years. And as I said, Joerg will talk about this in more detail. But there's sort of three things to think about. On the left, it's the things, what do we do in research in very early development. And our focus there is on three areas, cardiology, hematology, one; oncology, two; and additional capabilities in ophthalmology. Then we have some very specific mid- and late-stage pipeline projects and you see them listed here. I'll show you one more slide of it.

And then we have life cycle management. And life cycle management means we introduced these five products and we're very pleased with the acceptance of the market. So the question then is what kind of other indications we could get approval for that broadens this scope of these products. And we are spending significant amount of our R&D money into life cycle management just to see whether more indications will be available to us for our Xarelto, Eylea, also Xofigo, Stivarga and Adempas.

On the mid section here, mid- and late-stage line products, this is a little bit more detail. And you can see here the list of the products and this will be obviously also a topic of much discussion in the pharma R&D breakout. In green, you see what is now in phase 3; and in blue, you see what is now in phase 2 and you see phase 3 decisions. So in the next 12 to 18 months, there will be a lot of actions in this pipeline on moving things along particularly, you know, blue going into green here, phase 2 to phase 3. And therefore, it's an exciting time for this pipeline over the next months. Good.

CropScience. This is a very busy slide. Sorry for that. But again, this can be a good topic for the breakout. Similarly, as I mentioned CropScience, very good new product introductions in the last years and we intend to continue that both in the crop protection sides, so the chemical and biological side of what you spray on the plants but also on the seeds side. And this is an overview of that. Again, I'm not going to go into the details, but this is a nice overview of what we're planning to do and the details can be discussed in the breakout. So that is the top line growth drivers.

And then what about portfolio? We have the priorities there, of course, to integrate the acquired businesses, to bolt-on businesses, but also to exit MaterialScience. And then we are looking at some reorganizations that once MaterialScience is gone, we are now then the Life Science company, and adjusting some organizational structures as a result of it.

I find this an amazing chart. We know that we have been busy over the last 10 to 12 years at Bayer. But when we put it all on one chart, it was sort of jumping out of page. So here on the left, you'll see our 2003 sales of around 28 billion and you can see that is made out healthcare and crop at the top two, were about half, maybe a little less than half of the total portfolio. MaterialScience, chemicals and some other chemical-oriented businesses, they were the rest of the portfolio.

And if do go to the right, the pro-forma 2014 sales of 31 billion is basically only healthcare and CropScience left. And all these were chemically -- both chemical or specialty chemical oriented businesses that do not have a Life Science orientation, have been divested or brought as a separate public company to the market. And that meant, you know, a total of divestitures of 12 billion. You can see it on the left. But also acquired a set of acquisitions that you see on the right. Merck, of course, the biggest one, but a number of other ones both in healthcare and in CropScience for a total of 36 billion, so a significant shift. While in the end, the revenue gone from 28.6 billion to 31 billion, didn't really change all that much.

So what are we doing right now? We're very focused on the demerger of MaterialScience. We're focused on the Merck consumer care integration of course. And then we also announced last week that we were going to divest our diabetes care business to Panasonic KKR.

On the left, demerger of MaterialScience. We are making good progress there in the disentanglement of MaterialScience from the rest of the company. And we think that we can bring this to the market at the latest by mid 2016 where an IPO is our preferred option.

The Merck consumer care integration is going as planned. At the bottom there, I told you there are quite some synergies as a target, 400 million top line by the third year and 200 million of cost synergies by 2017. So these are in terms of the portfolio changes, strong areas of focus.

Quickly about the balance sheet. Our priority continues to be to fuel organic growth. It's the best type of growth, the most profitable type of growth you can have. And for that, we are actually willing to spend money. So our CapEx budget this year is 2.3 billion and our R&D spending will be a little over 4 billion this year. So we're putting our money where our mouth is. And innovation R&D pipeline is very important for our businesses and we're spending significant amount of money.



We have about 20 billion, 21 billion in debt and we would like to pay that down. We want to maintain our single-A credit ratings. Our proceeds that will come from the diabetes divestiture, potentially also from the MaterialScience IPO will be in principal use to pay down our debt. But of course when M&A opportunities come along, bolt-on, that are right for us, we'll be taking a look at that as well. And then the dividend policy has traditionally been 30% to 40% of core EPS. And in that vein, we had a dividend of EUR2.25 for 2014.

So a quick summary. Bayer is a world-class Life Sciences company. We have one of the fastest global pharma businesses and we have a very strong position in the OTC industry. And we're gaining market share in CropScience. We have shown that when we spend on R&D, we get something in return for it with an ability to commercialize new products in the global world.

And what is also interesting about Bayer I think is that -- and I was surprised by that when I joined six years ago -- how global the company is. We have a long tradition of being in emerging countries that makes it -- that we have a very good position usually commercially in countries like China, Brazil, Russia, India, named BRIC, which is helping us when we introduce new products to have a very quick presence there.

From a value point of view, whatever we're doing for you as shareholders, the innovation pipeline, this is, as I said, organic growth driver, the key value creating capability that we have and changing that sales growth into increased value is really where our focus also for the future will be.

So with that, I think, you know, I've got through it pretty well. Joerg, the floor is yours now. Thank you very much for your attention. I look forward to further discussions in the breakout.

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**Joerg Moeller - Bayer AG Leverkusen - Head - Global Development**

Yeah, thank you Marijin, and good morning. Also, from my side, welcome to New York and our Meet Management meeting.

It is my task to take through some more detail on some of our exciting late-stage development projects. Bayer R&D is really going through very exciting times. We have brought, as you're fully aware, five products in the recent years to the market. And we are at a stage where we've been in the next 12 to 18 months, that's indicated by Marijin, we have the opportunity to bring potentially another set of five assets into phase 3 development.

Our focus in R&D at Bayer is on first in class or best in class mechanisms in areas of very high medical need. And a very good example of that is heart failure. Heart failure is a deadly disease that has a high prevalence and the growing incidence is more than 26 million people diagnosed with heart failure worldwide. More than 600,000 new cases of heart failure are diagnosed in Europe per year. More than 500,000 in the U.S. and more than 6 million Americans suffer from heart failure. And over the course of one year, one in five patients diagnosed with advanced heart failure is going to die.

Now, to put this into perspective, such mortality makes heart failure as deadly as we see in the mortality rates in patients diagnosed with metastatic cancer. And it think that just speaks to the very high medical need of this disease condition.

Now, we define heart failure in basically two general forms. One is heart failure due to reduced ejection fraction or HF<sub>r</sub>EF, formerly known also as systolic heart failure, and it's characterized by the comprised ability of the heart to eject blood during its compression cycle. And different from that is heart failure with preserved ejection fraction or called HF<sub>p</sub>EF, previously known as diastolic heart failure, a condition that is more recently being discovered as having very similar mortality and morbidity.

And the big difference is while in heart failure with reduced ejection fraction, we have a couple of different classes of compounds such as mineralocorticoid receptor antagonist, ARBs, ACE inhibitors, beta-blockers, approved and being used in this setting, there's no approved therapy and no evidence-based therapy that has shown a benefit in heart failure with preserved ejection fraction. Of course, there are other classifications and I think most well known is probably the New York Heart Association characterization of classes of heart failure. But in the recent years, HF<sub>r</sub>EF and HF<sub>p</sub>EF have emerged as the two main categories this year.

Also in recent years are probably driven by a higher attention of the discovery of the importance of heart failure with preserved ejection fraction. Its prevalence has surpassed the heart failure with reduced ejection fraction population if one looks at the number of hospitalizations driven by this setting. You can see here that over the years, the blue line is going up and that is patients that still have an ejection fraction of more than 50%. Whereas, the red line of patients that have heart failure with reduced ejection fraction is going down. But if you look at the right-hand side of the chart, it's very important to see that in terms of mortality and morbidity, both are similarly deadly.



Bayer is active in both fields, in both conditions of heart failure. And we have a pipeline that aims to address both forms, heart failure with reduced ejection fraction as well as heart failure with preserved ejection fraction. And I will give you some more details in the next couple of slides.

This is a slide that you also saw in Marijn's presentation. And as I mentioned, we aim to bring in the next 12 to 18 months up to five additional assets to phase 3 and we are well under way to be able to achieve that goal. And I will focus in my presentation on the cardiovascular assets in our portfolio.

And I want to start with Vericiguat. Vericiguat is a novel soluble guanylate cyclase stimulator. You may recall that Bayer is active in this field for the better part of 20 years and we have brought with Adempas the first approved member of its class to approval in pulmonary arterial hypertension and patients that have increased pulmonary pressure on the basis of repeated thromboemboli into their lungs called CTEPH. Adempas in CTEPH is the only drug that has shown a benefit in the controlled phase 3 trial in the setting.

And we have built on our expertise in research in this field and came up with Vericiguat which is a member of the same class of compounds but has an improved pharmacokinetic profile and we are developing it in both forms of heart failure in the SOCRATES program. The phase 2b program consists of two studies, the SOCRATES-REDUCED trial, where we aim to present first data at the upcoming American Heart meeting in November this year; and then in heart failure with preserved ejection fraction, the SOCRATES-PRESERVED study has also completed its enrollment, but we're going to see data readout shortly, just prior to AHA to be able to meet the deadlines so that data will be presented at an upcoming cardiovascular meeting in the first half of 2016. But both trials are fully recruited here.

Some more words on the mechanism in heart failure. We have a relative insufficiency of soluble guanylate cyclase driven by oxidative stress and inflammation that leads to endothelial dysfunction via the cyclic GMP pathway ultimately to myocardial dysfunction and vascular dysfunction. To address this relative soluble guanylate cyclase into insufficiency, Vericiguat directly stimulates the soluble guanylate cyclase, and thereby again, via cyclic GMP, addresses the cGMP deficiency leading to improved myocardial function and improved vascular function. Again, there are no evidence-based therapies for the treatment of patients with heart failure with preserved ejection fraction.

Now, it's important to point out that we are not just going with Vericiguat in this indication. We hope for the best, we indeed have looked at related conditions on using riociguat, Adempas, where we conducted two studies, the LEPHT study and the DILATE study. LEPHT recruited more than 200 patients that have increased pulmonary pressure and left ventricular dysfunction. And we could show important improvements in hemodynamics over 16 weeks' prevalent period.

And similar improvements in hemodynamics, we could also see in the DILATE study which recruited a population of patients with preserved ejection fraction. So there is evidence that this class of drug does something beneficial in this setting. Based on this evidence, we decided to move Vericiguat in this population of patients with very high medical need.

This gives you some details on our phase 2b program, SOCRATES-REDUCED and PRESERVED, which are two randomized parallel-group, placebo-controlled, double-blind studies, basically looking at dose-findings of Vericiguat in this population and we treat patients over a period of 12 weeks. The important differentiation here is that SOCRATES-REDUCED includes patients that have an ejection fraction of lower than 45% versus an ejection fraction of more than 45% in the SOCRATES-PRESERVED population, which also has an additional inclusion criterion, a left atrial enlargement.

NT-proBNP is the primary endpoint. In addition, we looked at left ventricular size at 12 weeks in the SOCRATES-PRESERVED study.

I want to point out that, of course, over the last 20 years, we have all learned that there isn't really predictive surrogate marker for mortality and morbidity in heart failure that we you can rely on phase 2. So typically, one looks at an array of different endpoints and that is also what we do here. So secondary endpoints include clinical outcomes, cardiovascular death, recurrent hospitalizations for worsening heart failure and so on. Both trials are sizeable and have recruited more than 400 patients each in five arms.

I now switch to Finerenone, our non-steroidal, third-generation mineralocorticoid receptor antagonist. And also here, we have two phase 2b programs under way; one looking at heart failure, the other one looking at diabetic kidney disease. Now MRAs are an established class of compounds but they are underutilized by physicians because of their side effect profile.

Now, Finerenone is different from the two approved members of the class as it is a non-steroidal mineralocorticoid receptor antagonist. In heart failure, we have completed the phase 2b study. And also, we have completed a separate study in Japanese patients. And I think the ESC has published that we are presenting the data at this year meeting of the European Society of Cardiology in London.

In diabetic kidney disease, we also have completed the so-called ARTS diabetic neuropathy trial. That study met its primary endpoint where we look at urinary albumin excretion over glomerular filtration rate because these are two predictive surrogate markers for outcome in kidney disease. And that data was presented in March at the



Nephrology meeting in South Africa and it did show a dose-dependent reduction of albumin excretion here. We are now in discussion with health authorities and are planning to design our phase 3 program in this setting where we expect to have the first patient recruited in the second half of this year.

Now, I mentioned that MRAs so far are underutilized. They are underutilized because of their risk of hyperkalemia, renal dysfunction, but also anti-androgenic effects or progestogenic effects. Now, because of this, neither spironolactone nor finerenone are approved in kidney disease. And you'll see on the left-hand side the three main trials forming the evidence-based for the use of MRAs in heart failure.

In three trials, Spironolactone and Eplerenone have shown a morbidity and mortality benefit. And I also want to point out the size of these trials because heart failure -- and I showed you the mortality and morbidity rates -- is a condition where patients relatively quickly deteriorate and that means the sample size, you need to have, in order to be able to hopefully show a benefit in phase 3 is limited compared to what may be used with oral anti-coagulant. So these are programs that can be done in a couple of thousand patients, but not in trial sizes of 20,000 patients like you have seen in some of the programs with the new oral anti-coagulant.

Finerenone has a differentiated profile compared to both approved mineralocorticoid receptor antagonist. It is a non-steroidal structure. And our aim is to come up with a compound that is at least as potent as Spironolactone, and as selective, or better than Eplerenone. And our data, including the phase 2b data we presented in March in diabetic kidney disease, confirms that we are on the right track. And this is very encouraging data for us because it means that Finerenone in diabetic kidney disease in particular could really make a difference and become the first approved agent of this class in this disease setting.

This is the trial design of the ARTS-heart failure study. We initially started in a parallel group design having an active comparator with Eplerenone and we dose patients up to 10 milligrams once a day after they have been treated for 30 days with 5 milligrams and then they were up titrated. The DMC and safety committee overlooking the trial, after looking at the data, determined that the tolerability of the compound is so good that it allowed to increase the dose. And then we increased the dose and dose-finding study to up to 20 milligrams once a day, again, following an up titration schedule.

The primary endpoint here is again NT-proBNP and we took a baseline measure there. And we'll evaluate, in addition also, all-cause death and cardiovascular death in typical fashion in heart failure. As I mentioned, you look at the number of different endpoints.

Diabetic kidney disease again is a condition of high medical need. There is almost 30 million people diagnosed with diabetes in the U.S. and it's a growing population. Diabetes is the main cause for kidney failure. We have 35% of people that are older than 20 years that develop diabetic kidney disease. And in that condition, after some time, cardiovascular mortality dominates as the main cause of death in patients with kidney disease. So there's a real need for innovative therapies, and in particular, the mineralocorticoid receptor is the link between heart failure, diabetes and chronic kidney disease. And therefore, we believe that addressing this receptor with a very innovative compound can make an important contribution to improve on the therapies that are available in this disease condition.

We presented, as I mentioned, the data in March and I also mentioned that we were able, in a dose-dependent fashion, to show that Finerenone decreased urinary albumin excretion, an important and validated (surrogated) marker for outcome. The drug was very well tolerated. We were seeing side effects, treatment-emergent adverse events and serious adverse events in a frequency comparable to placebo, and importantly, the very low incidence of confirmed hyperkalemia. And that makes it possible to move Finerenone in this disease condition forward into phase 3 where the other MRA antagonists couldn't go.

So we believe we have a differentiated profile with Finerenone compared to Spironolactone and Eplerenone. We saw a balanced renal and cardiac activity and electrolyte modulation compared to also anti-remodelling effects. Therefore, we believe Finerenone could become a first-in-class mineralocorticoid receptor antagonist in diabetic kidney disease where no MRAs are approved. And in heart failure, it has the potential to become the best-in-class mineralocorticoid receptor antagonist and may overcome the restricted usage of this class of agent in this population.

Last but not least, I come to Molidustat, our HIF-PH, hypoxia-inducible factor inhibitor. Molidustat is a potent oral erythropoietin inducer that we currently develop in phase 2b for treatment of renal anemia. Molidustat is a hypoxia mimetic that has a high selectivity of induction of erythropoietin-gene expression. It did show in earlier studies a favorable pharmacokinetic and pharmacodynamic profile, very good tolerability. And we believe its once daily administration may offer advantages to stimulate the erythropoietin system within the physiological range. Importantly, we did not see any signs of hypertension and that may offer an additional benefit in this population which is often characterized by concomitant hypertension.

The trial in the phase 2b program -- and I should rather say because it is a number of trials and I will show you some details later on -- are also fully recruited and we are on track to see clinical completion towards the end of the year. And that would mean that in early 2016, we have the data enabling phase 3 decision making.

Again, this cartoon shows you the mechanism of action in situations of low oxygen levels, so-called hypoxia. Healthy patients release erythropoietin via the kidneys and that stimulates the formation of red blood cells leading to an increase of red blood cells. Patients that have an impaired kidney function lack the ability to stimulate the formation of red blood cells via the release of erythropoietin, and that leads then to anemia.



Again, this is a condition of high medical need. The prevalence in patients of CKD is about 13%, that means there's about seven million renal anemia patients. And erythropoietin stimulating agents including erythropoietin have a share of 70% among the therapies that are used to treat CKD patients. The limitation of erythropoietin is that they have to be given parenterally. We have an oral compound.

And over time, it also has been shown that erythropoietin, if not carefully dose monitored, may lead to very high peak levels of hemoglobin and that led to bad things happening, namely, myocardial infarctions and strokes in patients that have high hemoglobin levels. So our goal here is to modulate hemoglobin levels, physiologically avoid the high peaks that led also to the restriction in usage of erythropoietin.

And this cartoon shows you how our phase 2b program looks like. We have focused on both populations, patients that are already having end-stage renal disease and require dialysis, where we looked at maintaining hemoglobin levels in a dose-finding study that allowed up titration and patients were treated over a time period of four months and we also have here an active control arm of erythropoietin. Patients completing the four-month treatment have the ability to continue in a long-term extension.

Importantly, we also focused on the population of patients with pre-dialysis. And here, we have one study that looked at treatment naive patients, those that have not yet been treated with erythropoietin. Again, they were treated in a fixed-dose setting over four months. Here, we could compare against placebo. But then also we looked at patients that already had been started to receive erythropoietin and now were switched to Molidustat and the aim was to maintain them in the hemoglobin levels. In this study, we compared against Darbepoetin alfa. And also, patients in the pre-dialysis setting had the opportunity to continue into a long-term extension trial.

The primary outcome is change in hemoglobin levels. We looked at the baseline of the average and to compare it to the average of the last four weeks during the treatment period. Other secondary outcome parameters include safety, hemoglobin levels in the target range between 10 gram to 11 gram per deciliter.

So I'm coming to the end of my presentation and I was hopefully able to show you that not only Bayer R&D continues there in our exciting times. And we are well on track to have a portfolio where R&D also allows sustainable growth by bringing new and innovated therapies in very high medical need indications to patients. In my presentation, I tried to show you that our mid-stage cardiovascular pipeline is progressing, well on track.

And in particular, given our long heritage in cardiovascular and our expertise across the whole value chain, we believe Bayer is in a unique position to address areas of high medical need in the cardiovascular arena. Between now and the first half of 2016, you will see a number of data points, and hopefully, we are able to move as many of these exciting assets into late-stage development as we can because they all address very important medical needs.

This chart gives you the to-be-expected news flow from our pharma pipeline. And as I mentioned, you can expect in the next 12 months to see exciting data coming up from our late-stage assets that we aim to move into phase 3 development.

I'm coming to the end of my presentation, I want to thank you for your kind attention, and I'll hand back to Alexander. Thank you.





## Disclaimer

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