MorphoSys AG – Investor and Analyst Conference Call After the 2017 ASH Meeting

December 12th, 2017

The spoken word shall prevail.

**Speaker: Anke Linnartz, Head of Corporate Communications & IR, MorphoSys AG**

Good afternoon and good morning and welcome to our Investor and Analyst conference call and webcast. My name is Anke Linnartz, Head of Corporate Communications & Investor Relations at MorphoSys. While we speak, the 59th Annual Meeting of the American Society of Hematology is still ongoing. Today we would like to share the data of our L-MIND trial that we presented yesterday at ASH.

**Slide 2: Today on the Call**

With me on the call are Simon Moroney, our Chief Executive Officer, Malte Peters, our Chief Development Officer, and Jens Holstein, our Chief Financial Officer.

**Slide 3: Safe Harbor**

Before we start, I would like to remind you that during this conference call, we will present and discuss certain forward-looking statements concerning the development of MorphoSys’s core technologies, the progress of its current research and development programs and the initiation of additional programs. Should actual conditions differ from the Company’s assumptions, actual results and actions may differ from those anticipated. You are therefore cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof.

**Slide 4: Agenda**

During today’s call, Simon will start with a short introduction before Malte walks you through the preliminary clinical data from our L-MIND trial. We will then open the call up for questions. You will find the slide deck for this presentation on our corporate website.

I would now like to hand over to Simon Moroney.

**Slide 5: Introduction: Speaker: Dr. Simon Moroney, CEO, MorphoSys AG**

Thank you Anke, and also from me, a warm welcome to our conference call and thank you all for joining us today.
The purpose of this call is to take a close look at our most recent clinical data on MOR208. Malte will explain what we published yesterday at ASH and I will keep my comments to a minimum to allow enough time for his presentation.

Before I hand over to Malte, let me say that we’re very excited about MOR208. The data that Malte will talk about formed the basis of the Breakthrough Therapy designation from the FDA for the treatment of relapsed/refractory DLBCL in combination with lenalidomide. This is the first time the FDA has given breakthrough therapy designation to a single-arm, phase 2 combination therapy trial. Armed with this designation, we’re now focused on how to bring MOR208 to the market as fast as possible. We believe that we may have an attractive new therapy for a major unmet medical need, and aim to offer this as a new treatment option for oncologists and their patients.

With that, I will hand over to Malte who will present the clinical data from our L-MIND trial with MOR208.

**Slide 6 / Speaker: Dr. Malte Peters, CDO, MorphoSys AG**

Thank you Simon and also a warm welcome from my side. We are indeed excited about our MOR208 program and I will now explain why.

**Slide 7: MOR208 – The Drug Candidate**

MOR208 is an anti-CD19 antibody. We in-licensed this IgG1 kappa antibody from Xencor, who humanized and affinity optimized the antibody and also Fc-engineered the molecule. The antibody mediates both ADCC and phagocytosis. We have observed preclinical activity as single agent in vitro and also in vivo.

CD19 is expressed very early during B cell development, earlier than CD20, and the expression is maintained during maturation. CD19 is involved in B cell receptor signaling and triggers cell development and proliferation. This function becomes particularly evident for malignancies arising from B cells since CD19 then promotes tumor cell proliferation and survival. CD19 is not downregulated, as has been reported for CD20 after treatment with anti-CD20 antibodies. Therefore, CD19 is considered an excellent target for B cell lymphomas and it is accessible to antibodies.

**Slide 8 – MOR208 Development Plan**

As a reminder, we are currently investigating MOR208 in two types of B cell malignancies, namely relapsed/refractory DLBCL and BTK-inhibitor-refractory or intolerant CLL and SLL. The focus of the development program for MOR208 is clearly on R/R DLBCL, where we are seeing very encouraging results. DLBCL is the most frequently known malignant lymphoma worldwide and is a very aggressive tumor. Approximately 40% of all patients with DLBCL either fail to respond or have a relapse to initial therapy. These patients have a very poor prognosis and the disease is extremely difficult to treat.

Two combination studies are being conducted with MOR208 in DLBCL, namely the L-MIND and B-MIND trials. Both are focusing on relapsed or refractory DLBCL patients who are not
eligible for high-dose chemotherapy with subsequent autologous stem cell transplantation. For this group of patients, the available therapy options are currently very limited.

For the phase 2 L-MIND trial of MOR208 plus lenalidomide we presented preliminary results from 51 enrolled patients yesterday at the ASH conference and I will present the data shortly. B-MIND, the other clinical trial of MOR208 in R/R DLBCL is currently recruiting patients. The study is comparing MOR208 in combination with the chemotherapeutic agent bendamustine with rituximab plus bendamustine, and progressed into its phase 3 part in June of this year. We currently expect primary completion in Q4 2019.

In addition to the two combination trials in R/R DLBCL, we are evaluating MOR208 in the phase 2 COSMOS trial. This trial is investigating MOR208 in combination with idelalisib or venetoclax in relapsed/refractory CLL or SLL patients after discontinuation of a BTK inhibitor therapy. The study is progressing well and is mainly investigating the clinical safety of the treatment combinations. We plan to submit data for presentation at one or more major medical conference in 2018. Other indications are currently under evaluation.

**Slide 9/10: L-MIND trial design**

L-MIND is a single arm, uncontrolled study in which we combine MOR208 with lenalidomide. On slide 10 you can see the design of this trial. Patients were eligible if they had received one to three prior therapies, with at least one CD20 regimen and were not eligible for either high dose chemotherapy or autologous stem cell transplantation. During the first three cycles, MOR208 was given at a dose of 12mg per kg intravenously once a week and during cycles 4-12 treatment moved to every second week. Lenalidomide was given at a full dose of 25mg orally during the first 21 days of each cycle. If patients experience disease control after the end of cycle 12, they have the option of continuing the treatment with MOR208 until disease progression.

**Slide 11: Baseline characteristics**

Enrollment of all 80 patients required by the study protocol is now complete. As of today, we actually have 81 patients enrolled in the trial.

In June 2017, at the time of data cut-off for both the abstract and the poster presentation for ASH, 51 patients had been enrolled in the study, of whom 44 were evaluable for efficacy assessments.

The characteristics of patients enrolled in the study are shown on slide 11. The median age of patients was 74 years. Many of them were staged Ann Arbor grade III-IV, meaning they had advanced disease with spreading to multiple lymph nodes. Further, 47% of patients had a high risk score according to the International Prognostic Index and 51% of patients were diagnosed with elevated LDH levels – a marker associated with progression of disease. Further, 27% of patients were refractory to Rituximab and 39% of patients were refractory to the last previous line of therapy. Summing up, within the enrolled patients, the majority had a bad prognosis.

**Slide 12: Response Rates**

Here is a key data point collected in this study. The objective response rate is currently at 52%. The complete response rate is 32%, partial responses are seen in 20% of patients. These data
are very encouraging, especially when viewed in line with the duration of response. Please move on with me to slide 13.

**Slide 13: Long duration of Response**
This is a so-called swimmer plot. Each line represents one patient. The arrow heads at the end indicate that the patient's response at the time of reporting was still ongoing and the patient was receiving treatment. You can see that a lot of patients at the time of data cut-off were still on treatment: this is true for 19 out of 23 patients with a response, and 13 out of 14 patients experiencing a complete response. The mean time to response was very short, at less than two months, and the mean time to experience a complete response was also short, at 2.3 months. But really what’s most important looking at the slide is that you can assume that patients stay on treatment for a very long time, meaning they either respond and stay in remission or show at least a stable disease.

**Slide 14: Median Progression-Free Survival of 11.3 Months**
Another important data point is the median progression-free survival (PFS), which is defined as the time between start of therapy and disease progression or death. The preliminary median PFS evaluated for 44 patients, is 11.3 months. This means that after nearly one year, 50% of the patients are presumed to be progression-free. This is a very long-time for R/R DLBCL.

**Slide 15: Comparison of Previous Lenalidomide Approaches in R/R DLBCL**
So how do the data that I have just described to you compare to standard treatments, which patients are currently receiving in cancer hospitals around the world? Lenalidomide has been investigated very thoroughly in various clinical trials in R/R DLBCL so far – either alone or in combinations. On slide 15 you see the various lenalidomide based treatments that have been investigated in the past and the data from our ongoing L-MIND trial, all in patients with relapsed or refractory DLBCL. Please remember that there are limitations when one compares data across different clinical trials. The two columns to the right of our L-MIND data refer to studies in which patients received treatment with lenalidomide alone. The objective response rate of 28% is significantly lower than seen in L-MIND. The complete response rate is even lower and what’s particularly striking is that the medium PFS, is only 2.7 and 3.2 months. Combinations with antibodies directed against CD20, rituximab and lenalidomide or obinutuzumab and lenalidomide, do not change the picture significantly: response rates are in the same range and the median progression-free survival is only 3.7 or 4.1 months. This is why we are excited about our L-MIND data: an objective response rate of 52% and a preliminary median PFS of 11.3 months, are better than standard treatments, which are currently available.

**Slide 16: Existing and Upcoming Approaches in R/R DLBCL**
This table puts our data into perspective with new investigational treatments, which are currently in development, or recently approved therapies such as the CAR-T treatments directed against CD19. Again, as a reminder, we need to exercise caution in comparing data from different trials.
Many of you have followed the CD19 CAR-T approaches closely and will know that Novartis and Kite (now Gilead) have received regulatory approvals for their therapies in ALL and DLBCL respectively. Updates from several studies were presented yesterday at ASH and two studies had accompanying papers published in the New England Journal of Medicine on the same day.

It is clear that these are modern and novel treatments using new genetic approaches and the companies, researchers, and FDA have to be congratulated on bringing these therapies to patients. Let’s look a bit closer now at some of the data that were presented.

For Novartis’ Tisagenlecleucel (CTL019) in DLBCL, the best overall response rate was 53%, however, responses dropped to 37% at 6 months. If the intent to treat method was applied, the ORR was 25% at 6 months. Median progression-free survival was 3.2 months. For Kite/Gilead’s Axicel, a best overall response rate of 82% was reported and dropped to 48% at 6 months. The best complete response rate was 54% and dropped to 46% after 6 months. The mPFS was 5.8 months. It becomes clear if you look at the PFS and overall survival curves, that the initial high rate of responses drop quickly to a plateau of 40-50%, and that this is the percentage of patients who may gain a long-term benefit from this treatment. The reasons for these findings are not completely understood and are currently being investigated.

Toxicity remains a challenge for these treatments. 3% of patients died due to side effects in both studies, and 13-18% of patients report Grade 3/4 cytokine release syndrome. 11-28% of patients have Grade 3/4 neurological toxicity, mainly consisting of confusion, encephalopathy, and tremor. Lastly, these recent approvals are associated with substantial economic challenges because of the high cost of care. These costs will likely increase in the future as more patients are treated.

Another study that has evoked much interest is the combination of Roche’s antibody-drug conjugate Polatuzumab-Vedotin with Rituximab and Bendamustine. Reported response rates are high – 70% ORR and 58% CR. The median PFS, however, is reported to be 6.7 months. Further, patients within the study have strong adverse effects, like diarrhea and neurotoxicities - both of which we do not see in our L-MIND trial.

So in summary, the preliminary PFS observed in our L-MIND trial is substantially longer than all established or new and investigational treatments. Therefore, we feel confident that MOR208 could become an attractive treatment option, which may be associated with less toxicity and less economic burden for the health systems.

**Slide 17: Safety Evaluation**

Looking at the safety data, the combination of MOR208 and lenalidomide is well tolerated and the safety profile is favorable. Most frequently observed hematological toxicity of grade 3 or higher was neutropenia which occurred in 36% of patients, followed by thrombocytopenia and leukopenia in 10% and 8% of patients, respectively. The addition of MOR208 did not result in increased lenalidomide toxicity which was very important because the full dose of lenalidomide was used. Lenalidomide dose reductions were seen in 45% of patients which is in line with single agent lenalidomide trials. In summary, the combination of lenalidomide and MOR208 might be a suitable therapy for patients with DLBCL, especially for elderly or frail patients who would not be eligible for a very toxic high dose chemotherapy regimen or a very aggressive alternative therapy.
Slide 18: Upcoming Events and Potential Newsflow MOR208

Based on the clinical data presented today, we received Breakthrough Therapy Designation for MOR208 from the FDA in October. With enrollment in the trial complete, the next steps will be discussions with the FDA to support the clinical development of MOR208. A meeting with the FDA will take place in the first quarter of 2018 and we will provide an update on those talks as soon as we can. We will have the complete analysis of the L-MIND trial based on all 81 patients next year. In addition, we expect data from the COSMOS trial in CLL in 2018.

With this I would now like to hand back to Anke.

Slide 19: Q&A

Speaker: Anke Linnartz, Head of Corporate Communications & IR, MorphoSys AG

Thank you Malte for your presentation. We will now open the call up for your questions.

Q&A Session

James Gordon – JP Morgan:

So the MOR208 PFS data looks very strong, but my question is just that if we contrast it with data for the other agents like the polatuzumab data, can we be sure how much of it to do with the properties of the product versus baseline characteristics. The one pushback has been that the differences might relate to the number of prior lines of therapy, and I think that there are half of the patients that only had 1 prior line of therapy versus patients from the other drugs having being more heavily pretreated. So could that be part of the explanation? And is it dangerous for over-extrapolating PFS from a single-arm study, where baseline characteristics might explain some of it?

Malte Peters, Chief Development Officer, MorphoSys AG:

Thank you for the question. Particularly, the polatuzumab data is based on the patient population that appears to be fairly comparable with our patient population. So for example if you look at the percentage of patients with 1, 2 and more than 3 prior lines of therapies, we are, I think, with 2 studies in a similar ballpark. Similarly, if you look at the IPI risk score of patients having a score of 3 to 5, both studies look fairly similar. And I think you are correct in stating that it's always a challenge looking at a single-arm uncontrolled trial, that's certainly true. But we are very encouraged by the fact that FDA has invited us to submit Breakthrough Therapy application and has granted us this designation based on our single-arm uncontrolled study. So we interpret this as the willingness of the authorities to consider our study for discussions regarding potential regulatory approval.

Anastasia Karpova – Kempen & Co.:

Congrats on the results. Three questions, if I may. 25% of the patients have titration in lenalidomide dose, do you see the difference in the efficacy and the response between those who titrated and who didn't? May second question is, I know that you haven't presented general subtype data yet, but can you give some light on the distribution of the patient population
across the subtypes? Are we talking close to 50? Or is there a significant disbalance in favor of one of the subtypes? And finally, you mentioned in the past, you would consider - or you might need to recruit further patients or additional patients to support potential priority filing, and you announced yesterday that you’ve completed the recruitment. So what was the consideration to not pre-emptively recruit more patients while the recruitment is still ongoing?

Malte Peters, Chief Development Officer, MorphoSys AG:

Thanks, Anastasia. Great questions. So first of all with respect to the lenalidomide patients who have seen dose reduction versus those who have not, we are in the process of looking at these 2 cohorts of patients. And I can't comment yet on the outcome of that analysis, but that's a planned analysis, and we are -- we will do it in the near future. With respect to the cell of origin, the distribution is -- as published, it’s around 50-50. We are waiting for the gold standards -- the results from a Gold Standard Assessment, namely the NanoString Technology, which will be performed in a bulk effort, after all patients have been recruited. So that has happened just very recently, a couple of weeks ago, and we are in the process of running all patients with the same technology. And we are hopeful to have the final outcome on the cell of origin at the beginning of next year. That's obviously a very important point. And we are happy that we have been able to apply really high standards, technologies to answer these questions. With respect to additional patients, you are very correct. We have decided to, at this moment, halt enrollments, the study is still open. So in case regulatory authorities could demand enrollment of additional patients, we could do it. But we did not actively pursue this at the moment because putting additional patients on at this moment would also potentially have challenges, because you might have to look at the 2-patient populations separately. You might introduce a statistical bias between the 2-patient populations after positive results have been published. So investigators could be pressed to put better or not so good patients on the study after very positive results have been published. So at this moment, we are in a sort of holding pattern here. We will obviously discuss this question with authorities. And should the authorities demand additional patients, we can do it.

Slide 20:

Speaker: Simon Moroney, CEO MorphoSys AG

Slide 21: Take-away Messages

Thanks you and to conclude the call, I would like to remind you of the main points to take away. Our L-MIND clinical data suggests that MOR208 plus lenalidomide may offer an attractive treatment option for the treatment of R/R DLBCL. We believe that the data show that MOR208 is clearly differentiated from competing approaches either available today or in development. Supported by the FDA’s breakthrough therapy designation for this indication, we will work closely with the agency to identify how to bring it to the market as quickly as possible. We hope to have more news on this in the first quarter of next year, and will of course update you as soon as we can.

Slide 22: Thank You

Anke Linnartz, Head of Corporate Communications & IR, MorphoSys AG

That concludes the call. Thanks for your support and for joining us today. Goodbye.