MorphoSys and Incyte Sign Global Collaboration and License Agreement for Tafasitamab

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- MorphoSys and Incyte to co-commercialize tafasitamab in the U.S.
- Incyte has exclusive commercialization rights outside of the U.S.
- MorphoSys and Incyte to host joint conference call on January 13, 2020 at 7:00am PST / 4:00pm CET

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ: MOR) and Incyte Corporation (NASDAQ: INCY) announced today that the companies have entered into a collaboration and license agreement to further develop and commercialize MorphoSys' proprietary anti-CD19 antibody tafasitamab (MOR208) globally. Tafasitamab is an Fc-engineered antibody against CD19 currently in clinical development for the treatment of B cell malignancies. MorphoSys and Incyte will co-commercialize tafasitamab in the U.S., while Incyte has exclusive commercialization rights outside of the U.S.

"The global partnership with Incyte is an important step towards unlocking the full potential of tafasitamab and achieving our goal of rapidly bringing tafasitamab to patients inside and outside of the U.S.," said Jean-Paul Kress, M.D., Chief Executive Officer of MorphoSys. "The combination of our strong antibody and drug development expertise partnered with Incyte's well-established hematology-oncology experience and their commercial operations in key territories has the potential to significantly broaden the tafasitamab opportunity. We are pleased to work with Incyte to jointly improve the lives of patients suffering from DLBCL and other devastating diseases."

"Bringing together Incyte's expertise and MorphoSys' commitment to innovation will allow us to make tafasitamab widely available to patients with cancer, upon approval," said Hervé Hoppenot, CEO of Incyte. "We look forward to collaborating closely with the team at MorphoSys and adding tafasitamab to our portfolio of oncology candidates as part of our commitment to bringing new, advanced treatment options to patients and the clinical community around the world."

Under the terms of the agreement, MorphoSys will receive an upfront payment of $750 million and, in addition, Incyte will make an equity investment into MorphoSys of $150 million in new American Depositary Shares (ADS) of MorphoSys at a premium to the share price at signing of the agreement. Depending on the achievement of certain developmental, regulatory and commercial milestones, MorphoSys will be eligible to receive milestone payments amounting to up to $1.1 billion. MorphoSys will also receive tiered royalties on ex-U.S. net sales of tafasitamab in a mid-teens to mid-twenties percentage range of net sales.

In the U.S., MorphoSys and Incyte will co-commercialize tafasitamab, with MorphoSys leading the commercialization strategy and booking all revenues from sales of tafasitamab. Incyte and MorphoSys will be jointly responsible for commercialization activities in the U.S. and will share profits and losses on a 50:50 basis. Outside the U.S., Incyte will have exclusive commercialization rights, and will lead the commercialization strategy and book all revenues from sales of tafasitamab, paying MorphoSys royalties on ex-U.S. net sales.

Furthermore, the companies will share development costs associated with global and U.S.-specific trials at a rate of 55% (Incyte) to 45% (MorphoSys); Incyte will cover 100% of the future development costs for trials that are specific to ex-U.S. countries.

Both parties have agreed to co-develop tafasitamab broadly in relapsed/refractory diffuse large B cell lymphoma (r/r DLBCL), frontline DLBCL as well as additional indications beyond DLBCL, such as follicular lymphoma (FL), marginal zone lymphoma (MZL) and chronic lymphocytic leukemia (CLL). Incyte will be responsible for initiating a combination study of its investigational PI3K-delta inhibitor parsaclisib and tafasitamab in r/r B cell malignancies. Further, Incyte will be responsible for leading any potential registration-enabling studies in CLL and a phase 3 trial in r/r FL/MZL. MorphoSys will continue to be responsible for its currently ongoing clinical trials of tafasitamab in non-Hodgkin lymphoma (NHL), CLL, r/r DLBCL and frontline DLBCL. The parties will share responsibility in starting additional global trials, and Incyte intends to pursue development in additional territories including Japan and China.

MorphoSys recently submitted a Biologics License Application (BLA) for tafasitamab, in combination with lenalidomide, to the U.S. Food and Drug Administration (FDA) for the treatment of r/r DLBCL; the FDA decision regarding a potential approval is expected by mid-2020. The submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in r/r DLBCL is planned for mid-2020.

The agreement between MorphoSys and Incyte, including the equity investment, is subject to clearance by the U.S. antitrust authorities under the Hart-Scott-Rodino Act as well as by the German and Austrian antitrust authorities, and will become effective as soon as these conditions have been met.

MorphoSys and Incyte will host a joint conference call on January 13, 2020 at 7:00am PST/ 4:00pm CET.

Dial-in numbers for the conference call on Monday, January 13, 2020 at 7:00am PST; 3:00pm GMT; 10:00am EST; 04:00pm CET:
For Germany: +49 69 201 744 220
For the U.K.: +44 203 009 2470
For the U.S.: +1 877 423 0830
Participant PIN: 55656540#

Please dial in 10 minutes before the beginning of the conference.

A live webcast will be made available at www.morphosys.com and at investor.incyte.com.

About Tafasitamab
Tafasitamab is an investigational humanized Fc-engineered monoclonal antibody directed against CD19. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor. Inc. Tafasitamab incorporates an XmAb(R) engineered Fc domain, which is intended to lead to a significant potentiation of antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), thus aiming to improve a key mechanism of tumor cell killing. MorphoSys is clinically investigating tafasitamab as a therapeutic option in B cell malignancies in a number of ongoing combination trials. An open-label phase 2 combination trial (L-MIND study) is investigating the safety and efficacy of tafasitamab in combination with lenalidomide in patients with relapsed/refractory DLBCL who are not eligible for high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT). Based on interim data from L-MIND, in October 2017 the U.S. FDA granted Breakthrough Therapy Designation for tafasitamab plus lenalidomide in this patient population. Re-MIND, the real-world data lenalidomide alone matched control cohort met its primary endpoint in October 2019, demonstrating clinical superiority of the tafasitamab/lenalidomide combination compared to lenalidomide alone. The ongoing phase 3 study B-MIND assesses the combination of tafasitamab and bendamustine versus rituximab and bendamustine in rit DLBCL. In addition, tafasitamab is currently being investigated in patients with relapsed/refractory CLL/SLL after discontinuation of a prior Bruton tyrosine kinase (BTK) inhibitor therapy (e.g. ibrutinib) in combination with idecislisib or venetoclax.

About MorphoSys
MorphoSys (FSE & NASDAQ: MOR) is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of exceptional, innovative therapies for patients suffering from serious diseases. The focus is on cancer. Based on its leading expertise in antibody, protein and peptide technologies, MorphoSys, together with its partners, has developed and contributed to the development of more than 100 product candidates, of which 28 are currently in clinical development. In 2017, Tremfya(R), marketed by Janssen for the treatment of plaque psoriasis, became the first drug based on MorphoSys’s antibody technology to receive regulatory approval. The Company’s most advanced proprietary product candidate, tafasitamab (MOR208), has been granted U.S. FDA breakthrough therapy designation for the treatment of patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Headquartered near Munich, Germany, the MorphoSys group, including the fully owned U.S. subsidiary MorphoSys US Inc., has approximately 405 employees. More information at https://www.morphosys.com.

HuCAL(R), HuCAL GOLD(R), HuCAL PLATINUM(R), CysDisplay(R), RapMAT(R), arYla(R), Ylanthia(R), 100 billion high potentials(R), Slonomics(R), Lanthio Pharma(R), Lanthio Pep(R) and ENFORCERTM are trademarks of the MorphoSys Group. Tremfya(R) is a trademark of Janssen Biotech, Inc. XmAb(R) is a trademark of Xencor, Inc.

About Parsaclisib
Parsaclisib (INCBB0485) is a highly selective and potent inhibitor of the phosphatidylinositol 3-kinase delta (PI3Kδ) isoform. PI3Kδ is an important target implicated in malignant B-cell growth, survival and proliferation, and its inhibition has potential as a mechanism to treat hematologic malignancies and a variety of B-cell mediated and antibody-driven diseases beyond oncology. The CITADEL (Clinical Investigation of TArgeted PI3K DELta Inhibition in Lymphomas) clinical trial program is currently evaluating parsaclisib in several ongoing Phase 2 trials as a treatment for non-Hodgkin lymphomas (follicular, marginal zone and mantle cell). Parsaclisib is also being studied for patients with autoimmune hemolytic anemia and as part of a combination therapy for patients with myeloproliferative neoplasms and non-Hodgkin lymphomas including diffuse large B-cell lymphoma.

About Incyte Corporation
Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

MorphoSys forward looking statements
This communication contains certain forward-looking statements concerning the MorphoSys group of companies, including the expectations regarding the licensing agreement for tafasitamab, the further clinical development of tafasitamab, interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for tafasitamab as well as the potential future commercialization of tafasitamab. The forward-looking statements contained herein represent the judgment of MorphoSys as of the date of this release and involve known and unknown risks and uncertainties, which might cause the actual results, financial condition and liquidity, performance or achievements of MorphoSys, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if MorphoSys’ results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are MorphoSys’ expectations regarding the licensing agreement for tafasitamab, the further clinical development of tafasitamab, interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for tafasitamab as well as the potential future commercialization of tafasitamab, MorphoSys’ reliance on collaborations with third parties, estimating the commercial potential of its development programs and other risks indicated in the risk factors included in MorphoSys’ Annual Report on Form 20-F and other filings with the US Securities and Exchange Commission. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. MorphoSys
Incyte forward looking statements
Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: whether the planned transaction will close within the expected timeframe or ever; whether tafasitamab will be approved for use in humans anywhere or will be commercialized anywhere successfully or at all; whether the MAA for tafasitamab will be submitted within the expected timeframe or at all; whether tafasitamab or parsaclisib will be effective in the treatment of the indications discussed in this press release; whether this collaboration will broaden the potential market for tafasitamab; and whether and when any of the milestone payments or royalties under this collaboration will ever be paid by Incyte. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: obtaining regulatory approval for this planned collaboration; research and development efforts related to the collaboration programs; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; other market or economic factors, including other scientific developments; unanticipated delays; the effects of market competition; risks associated with relationships between collaboration partners; the impact of governmental actions regarding pricing, importation and reimbursement for pharmaceuticals; and such other risks detailed from time to time in each company's reports filed with the Securities and Exchange Commission, including Incyte's quarterly report on Form 10-Q for the quarter ended September 30, 2019 and MorphoSys's Annual Report on Form 20-F for the fiscal year ended December 31, 2018. Each party disclaims any intent or obligation to update these forward-looking statements.

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