**Media Release**

# MorphoSys and Incyte Announce Swissmedic Temporary Approval of Minjuvi® (tafasitamab) in Combination with Lenalidomide for the Treatment of Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

- *Minjuvi is a new therapeutic option for eligible DLBCL patients in Switzerland addressing an urgent unmet medical need*
- *In Switzerland each year approximately 500 patients are diagnosed DLBCL*[1]

**PLANEGG/MUNICH, Germany and MORGES, Switzerland – March 22, 2022 –** MorphoSys AG (FSE: MOR; NASDAQ: MOR) and Incyte (Nasdaq: INCY) today announced that the Swiss agency for therapeutic products (Swissmedic), has granted temporary approval for Minjuvi® (tafasitamab) in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after at least one prior line of systemic therapy including an anti-CD20 antibody, who are not eligible for autologous stem cell transplant (ASCT). Incyte holds exclusive commercialization rights for Minjuvi in Switzerland.

“The approval of Minjuvi by Swissmedic is excellent news,” said Jonathan Dickinson, Executive Vice President and General Manager, Incyte Europe. “There are a substantial number of people living with relapsed or refractory DLBCL in Switzerland and we’re pleased to be able to offer them a new treatment option.”

“DLBCL is a fast-growing cancer and can be very hard to treat. Up to 40% of DLBCL patients either relapse after they have been treated or don’t respond to initial treatment at all,” said Mike Akimov, M.D., Ph.D., Head of Global Drug Development, MorphoSys. “Minjuvi addresses this unmet need and its approval in Switzerland is a crucial milestone for these patients.”

The approval is based on the results from the L-MIND study evaluating the safety and efficacy of tafasitamab in combination with lenalidomide as a treatment for patients with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant (ASCT). The results showed a best objective response rate (ORR) of 56.8% (primary endpoint), including a complete response (CR) rate of 39.5% and a partial response rate (PR) of 17.3%, as assessed by an independent review committee. The median duration of response (mDOR) was 43.9 months after a minimum follow up of 35 months (secondary endpoint). Tafasitamab together with lenalidomide was shown to provide a clinically meaningful response and the side effects were manageable.[2]

Incyte and MorphoSys share global development rights to tafasitamab; Incyte has exclusive commercialization rights to tafasitamab outside the U.S. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® (tafasitamab-cxix) in the U.S., and is marketed by Incyte under the brand name Minjuvi in Europe, the UK and Canada.

**About Diffuse Large B-Cell Lymphoma**

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide, comprising 40% of all cases[3]. Each year around 16,000 patients in Europe are diagnosed with relapsed or refractory DLBCL[4,5,6]. The condition is characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs[7]. It is an aggressive disease with about one in three patients not responding to initial therapy or relapsing thereafter[8,9,10,11].

**About L-MIND**
The L-MIND trial is a single arm, open-label Phase 2 study (NCT02399085) investigating the combination of tafasitamab and lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who have had at least one, but no more than three prior lines of therapy, including an anti-CD20 targeting therapy (e.g., rituximab), who are not eligible for high-dose chemotherapy (HDC) or autologous stem cell transplant (ASCT). The study's primary endpoint is overall response rate (ORR). Secondary outcome measures include duration of response (DoR), progression-free survival (PFS) and overall survival (OS). The study reached its primary completion in May 2019.

For more information about L-MIND, visit https://clinicaltrials.gov/ct2/show/NCT02399085.

**About Minjuvi® (tafasitamab)**
Tafasitamab is a humanized Fc-modified CD19 targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP).

In the U.S., Monjuvi® (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional approval, in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

Minjuvi® and Monjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in Europe, the UK and Canada.

XmAb® is a registered trademark of Xencor, Inc.

**About MorphoSys**
At MorphoSys, we are driven by our mission to give more life for people with cancer. As a global commercial-stage biopharmaceutical company, we use groundbreaking science and technologies to discover, develop, and deliver innovative cancer medicines to patients. MorphoSys is headquartered in Planegg, Germany, and has its U.S. operations anchored in Boston, Massachusetts. To learn more, visit us at www.morphosys.com and follow us on Twitter and LinkedIn.

**About Incyte**
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. 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 that MorphoSys' expectations may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements, 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 U.S. 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 expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.*

**Incyte Forward-looking Statements**

*Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether and when Minjuvi might provide a successful treatment option for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), the Company's ongoing clinical development program for tafasitamab, and its DLBCL program generally, contain predictions, estimates, and other forward-looking statements. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain, and other third-party providers and development and discovery operations; determinations made by Swissmedic and other regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing, and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report for the year ending December 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.*

# # #

***For more information, please contact:***


**MorphoSys**

**Media contacts**
Thomas Biegi
Vice President
Tel.: +49 (0)89 / 89927 26079
Thomas.Biegi@morphosys.com

Jeanette Bressi
Director, U.S. Communications
Tel: +1 617-404-7816
jeanette.bressi@morphosys.com

**Investor contacts**
Dr. Julia Neugebauer
Senior Director
Tel: +49 (0)89 / 899 27 179
julia.neugebauer@morphosys.com

Myles Clouston
Senior Director
Tel: +1-857-772-0240
myles.clouston@morphosys.com

**Incyte**

**Media contacts**
Ela Zawislak
Tel: + 41 21 581 5200
ezawislak@incyte.com

**Investor contact**
Christine Chiou
Senior Director, Investor Relations
Tel: +1 302 274 4773

cchiou@incyte.com

Catalina Loveman
Executive Director, Public Affairs
Tel: +1 302 498 6171
cloveman@incyte.com

[1] Nationaler Krebsbericht; published 14th October 2021; https://www.bfs.admin.ch/bfs/de/home/aktuell/neueveroeffentlichungen.assetdetail.19305696.html;Accessed: March 2022

[2] Duell et al. Long-term outcomes from the phase II L-MIND study of tafasitamab (MOR208) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma. *Haematologica.* 2021. 106(9): 2417–2426. Doi: 10.3324/haematol.2020.275958

[3] Cancer Research UK. Diffuse large B cell lymphoma. Available at https://www.cancerresearchuk.org/about-cancer/non-hodgkin-lymphoma/types/diffuse-large-B-cell-lymphoma. Accessed: October 2021.

[4] DRG Epidemiology data.

[5] Kantar Market Research (TPP testing 2018).

[6] Friedberg, Jonathan W. Relapsed/Refractory Diffuse Large B-Cell Lymphoma. *Hematology Am Soc Hematol Educ Program* 2011; 2011:498-505. doi: 10.1182/asheducation-2011.1.498

[7] Sarkozy C, et al. Management of relapsed/refractory DLBCL. Best Practice Research & Clinical Haematology. 2018 31:209–16. doi.org/10.1016/j.beha.2018.07.014.

[8] Skrabek P, et al. Emerging therapies for the treatment of relapsed or refractory diffuse large B cell lymphoma. *Current Oncology*. 2019 26(4): 253–265. doi.org/10.3747/co.26.5421.

[9] DRG Epidemiology data

[10] Kantar Market Research (TPP testing 2018).

[11] Friedberg, Jonathan W. Relapsed/Refractory Diffuse Large B-Cell Lymphoma. *Hematology Am Soc Hematol Educ Program* 2011; 2011:498-505. doi: 10.1182/asheducation-2011.1.498.