



## Media Release

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# MorphoSys' Licensing Partner Roche Received Breakthrough Therapy Designation for Gantenerumab in Alzheimer's Disease

MorphoSys AG (FSE: MOR; NASDAQ: MOR) announced today that its licensing partner Roche (SIX: RO, ROG; OTCQX: RHHBY) [received Breakthrough Therapy Designation by the U.S. Food and Drug Administration \(FDA\) for gantenerumab](#), an anti-amyloid beta antibody developed for subcutaneous administration, for the treatment of people living with Alzheimer's disease (AD). This designation is based on data showing that gantenerumab significantly reduced brain amyloid plaque, a pathological hallmark of AD, in the ongoing SCarlet RoAD and Marguerite RoAD open-label extension trials, as well as other studies. Learnings from these studies have been incorporated into the optimised design of two ongoing parallel, global, placebo-controlled and randomised Phase III trials, GRADUATE 1 and 2. Roche is evaluating the safety and efficacy of gantenerumab in these two pivotal trials with more than 2,000 participants for more than two years. The trials are expected to be completed in the second half of 2022.

The FDA Breakthrough Therapy Designation is a process designed to expedite the development and review of drug candidates that are intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate a substantial improvement over available therapies that have received full FDA approval.

Gantenerumab is an investigational IgG1 antibody designed to bind to aggregated forms of beta-amyloid and remove brain amyloid plaques, a pathological hallmark of Alzheimer's disease (AD). The fully human monoclonal antibody was generated by MorphoSys using its proprietary HuCAL antibody technology. Under the terms of the licencing agreement, Roche is fully responsible for the clinical development and potential commercialisation of gantenerumab.

MorphoSys is entitled to receive tiered royalties, ranging from 5.5% to 7.0%, on net product sales and potential success-based regulatory milestone payments related to gantenerumab. MorphoSys will retain 40% of future royalties on gantenerumab, as outlined in the funding partnership between MorphoSys and Royalty Pharma.

## About MorphoSys

MorphoSys (FSE & NASDAQ: MOR) is a biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for people living with cancer and autoimmune diseases. Based on its leading expertise in antibody and protein technologies, MorphoSys is advancing its own pipeline of new drug candidates and has created antibodies that are developed by partners in different areas of unmet medical need. In 2017, Tremfya® (guselkumab) – developed by Janssen Research & Development, LLC and marketed by Janssen Biotech, Inc. for the treatment of plaque psoriasis – became the first drug based on MorphoSys' antibody technology to receive regulatory approval. In July 2020, the U.S. Food and Drug Administration granted accelerated approval of the company's proprietary product Monjuvi® (tafasitamab-cxix) in combination with lenalidomide for patients with a certain type of lymphoma. Headquartered near Munich, Germany, the MorphoSys Group, including the fully owned U.S. subsidiaries MorphoSys US Inc. and Constellation Pharmaceuticals, Inc., has more than 750 employees. For more information visit [www.morphosys.com](http://www.morphosys.com) or [www.morphosys-us.com](http://www.morphosys-us.com).

Monjuvi® is a registered trademark of MorphoSys AG.

Tremfya® is a registered trademark of Janssen Biotech, Inc.

**MorphoSys Forward-Looking Statements**

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