# Galapagos NV Announces U.S. FDA Regenerative Medicine Advanced Therapy (RMAT) Designation Granted to GLPG5101 for the Treatment of Relapsed/Refractory Mantle Cell Lymphoma

**Mechelen, Belgium; August 6, 2025, 7:30 CET; regulated information – inside information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the United States Food and Drug Administration (FDA) has granted RMAT designation to GLPG5101, a second generation anti-CD19/4-1BB CAR-T product candidate for the treatment of relapsed/refractory mantle cell lymphoma (R/R MCL).**

The RMAT designation was established under the U.S. 21st Century Cures Act to accelerate development and review of promising cell and gene therapies for serious or life-threatening conditions. To qualify for RMAT designation, GLPG5101 demonstrated preliminary clinical evidence suggesting it has the potential to treat, modify, reverse, or cure a serious or life-threatening disease.

Clinical data derived from the ongoing ATALANTA-1 study with GLPG5101 in patients with R/R B-cell Non-Hodgkin Lymphoma (B-NHL), including a subset of patients with MCL, supported the RMAT designation. These data[1] demonstrated both high objective and high complete response rates, with a manageable safety profile, including low rates of high-grade cytokine release syndrome (CRS), immune effector cell associated neurotoxicity syndrome (ICANS) and low dropout rates.

“This designation reflects the promising clinical activity and safety profile observed in our ongoing Phase 1/2 study and supports our commitment to delivering an effective and timely treatment option to patients in need,” said Omotayo Fasan, M.D., Clinical Development Program Head at Galapagos. “With RMAT status allowing for closer collaboration with the FDA, this will enable additional opportunities for accelerated development and assessment timelines.”

Benefits of RMAT designation include increased FDA guidance and more frequent interactions during development, eligibility for accelerated approval based on surrogate or intermediate endpoints, all Fast Track and Breakthrough Therapy advantages such as priority review and rolling submissions, and early discussions of potential study endpoints.

Galapagos intends to report updated data from the ATALANTA-1 study at a future medical conference.

**About GLPG5101 and ATALANTA-1**

GLPG5101 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as a single fixed intravenous dose. The safety, efficacy and feasibility of decentralized manufactured GLPG5101 are currently being evaluated in the ATALANTA-1 Phase 1/2 study in eight hematological malignancies with high unmet need. The primary objective of the Phase 1 part of the study is to evaluate safety and to determine the recommended dose for the Phase 2 part of the study. Secondary objectives include

[1] Data cut-off: January 21, 2025

assessment of efficacy and feasibility of decentralized manufacturing of GLPG5101. The dose levels that were evaluated in Phase 1 are $50\times10^6$ (DL1), $110\times10^6$ (DL2) and $250\times10^6$ (DL3) CAR+ viable T-cells. The primary objective of the Phase 2 part of the study is to evaluate the Objective Response Rate (ORR) while the secondary objectives include Complete Response Rate (CRR), duration of response, progression free survival, overall survival, safety, pharmacokinetic profile, and the feasibility of decentralized manufacturing. Each enrolled patient will be followed for 24 months. The ATALANTA-1 study is currently enrolling patients in the U.S. and Europe.

**About relapsed/refractory mantle cell lymphoma**

Mantle cell lymphoma is a rare and aggressive subtype of non-Hodgkin lymphoma originating from B cells. Patients with relapsed or refractory disease have progressed after standard therapies and face limited treatment options and reduced survival rates.

**About Galapagos' cell therapy manufacturing platform**

Galapagos' innovative decentralized cell therapy manufacturing platform is designed to enable the administration of fresh, fit, stem-like early memory cells with a median vein-to-vein time of seven days, greater physician visibility, and improved patient experience. The platform consists of an end-to-end xCellit® workflow management and monitoring software system, a decentralized, functionally closed, automated manufacturing platform for cell therapies (using Lonza's Cocoon®) and a proprietary quality control testing and release strategy.

**About Galapagos**

Galapagos is a biotechnology company with operations in Europe, the U.S., and Asia, dedicated to transforming patient outcomes through life-changing science and innovation for more years of life and quality of life. Focusing on high unmet medical needs, we synergize compelling science, technology, and collaborative approaches to create a deep pipeline of best-in-class medicines. With capabilities from lab to patient, including a decentralized cell therapy manufacturing platform, we are committed to challenging the status quo and delivering results for our patients, employees, and shareholders. Our goal is to meet current medical needs, and to anticipate and shape the future of healthcare, ensuring that our innovations reach those who need them most. For additional information, please visit www.glpg.com or follow us on LinkedIn or X.

*This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).*

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## Forward-looking statements

*This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "expect," "plan," "estimate," "will," "continue," "aim," "intend," "future," "potential," "could," "indicate," "forward," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding the expectations regarding the benefits of RMAT designation, statements regarding the expected timing, design and readouts of the ATALANTA-1 study, statements regarding Galapagos' cell therapy manufacturing platform, and statements regarding the clinical development and potential benefits of, and regulatory interactions regarding, GLPG5101. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause Galapagos' actual results to be materially different from those expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that preliminary or interim clinical results may not be replicated in ongoing or subsequent clinical trials, the risk that ongoing and future clinical studies with GLPG5101 may not be completed in the currently envisaged timelines or at all, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research program may not support registration or further development of GLPG5101 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner Lonza), and that Galapagos' estimations regarding its GLPG5101 development program and regarding the commercial potential of GLPG5101 may be incorrect,, as well as those risks and uncertainties identified in Galapagos' Annual Report on Form 20-F for the year ended 31 December 2024 filed with the U.S. Securities and Exchange Commission (SEC) and its subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances, or changes in expectations, unless specifically required by law or regulation.*