Galapagos announces start of PAPILIO-1 Phase 1/2 multiple myeloma study of point-of-care manufactured BCMA CAR-T candidate, GLPG5301

Mechelen, Belgium; 19 December 2023, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the first patient has been dosed in PAPILIO-1, the Phase 1/2 study to evaluate the safety, efficacy, and feasibility of our seven-day vein-to-vein, point-of-care manufactured BCMA CAR-T candidate, GLPG5301, in adult patients with relapsed/refractory multiple myeloma (rrMM). This is Galapagos' third oncology CAR-T program in clinical development.

GLPG5301 is an autologous, second-generation/4-1BB B-cell maturation antigen (BCMA)-directed CAR-T product candidate, administered as an intravenous infusion of a fresh product in a single fixed dose, at point-of-care.

"Patients living with relapsed/refractory multiple myeloma have a very poor prognosis and a significant high unmet medical need for novel treatment options. CAR-T therapy is one such option. By combining innovative science with breakthrough point-of-care delivery of novel CAR-T therapies, we aim to enhance patient outcomes and improve their quality of life," said Jeevan Shetty, Head of Clinical Development Oncology at Galapagos. "We are very pleased that the first patient with rrMM in PAPILIO-1 has been dosed with our BCMA CAR-T candidate, GLPG5301. This marks another milestone in the roll-out of our point-of-care network and the build-up of our CAR-T portfolio, which now consists of three ongoing clinical programs in severe hemato-oncology indications."

About the PAPILIO-1 Phase 1/2 study (EU CT 2022-500782-27-00)
PAPILIO-1 is a Phase 1/2, open-label, multi-center study to evaluate the feasibility, safety, and efficacy of point-of-care manufactured GLPG5301, our BCMA CAR-T product candidate, in patients with relapsed/refractory multiple myeloma (rrMM) after ≥2 prior lines therapy. The primary objective of the Phase 1 part of the PAPILIO-1 study is to evaluate safety and determine the recommended dose for the Phase 2 part of the study. The primary objective of the Phase 2 part of the study is to evaluate the efficacy of GLPG5301, as measured by the objective response rate (ORR). Secondary objectives for both Phase 1 and Phase 2 include further assessment of the safety of GLPG5301, additional efficacy endpoints, including assessment of minimal residual disease (MRD), as well as the feasibility of point-of-care manufacture of GLPG5301 in rrMM patients. Each enrolled patient will be followed for 24 months.

During Phase 1, up to 3 dose levels will be evaluated and at least 12 patients will be enrolled to establish the recommended Phase 2 dose. Approximately 30 additional patients will be enrolled in the Phase 2 part of the study to confirm the safety and efficacy of GLPG5301.

About Galapagos' innovative approach to CAR-T manufacturing near the point-of-care
Galapagos' decentralized, innovative point-of-care CAR-T manufacturing 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 (QC) testing and release strategy. The combination of these three core components offers the potential for administration of a fresh product, a median vein-to-vein

time of 7 days (i.e. the time between T-cell collection and CAR-T infusion), and greater physicians oversight throughout the process.

About Relapsed/refractory multiple myeloma (rrMM)

Multiple myeloma (MM) is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and may result in extensive skeletal destruction with osteopenia, and osteolytic lesions with or without pathologic fractures. The diagnosis of MM is made when one (or more) of the following clinical presentations are present: bone pain with lytic lesions discovered on routine skeletal films or other imaging modalities, an increased total serum protein concentration with the presence of a monoclonal protein in the urine or serum, and anemia, hypercalcemia or renal failure. The patient may be either symptomatic or their disease may be discovered incidentally.

Despite improvements in treatment, patient with MM ultimately relapse or become refractory to available regiments. Triple-refractory (refractory to CD38 monoclonal antibodies [mAbs], proteasome inhibitor [PI] and immunomodulatory drug [IMiD] or penta-refractory (refractory to CD38 mAbs, 2 Pls and 2 IMiDs) patients have a poor prognosis and are in urgent need of novel treatment options.

About Galapagos

We are a global biotechnology company with operations in Europe and the US dedicated to developing transformational medicines for more years of life and quality of life. Focusing on high unmet medical needs, we synergize the most compelling science, technology, and collaborative approaches to create a deep pipeline of best-in-class small molecules, CAR-T therapies, and biologics in oncology and immunology. With capabilities from lab to patient, including a decentralized, point-of-care CAR-T manufacturing network, we are committed to challenging the status quo and delivering results for our patients, employees and shareholders. For additional information, please visit www.glpg.com or follow us on LinkedIn or X (formerly Twitter).

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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. These statements are often, but not always, made through the use of words or phrases such as "will," and "evaluate," and any similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding our plans and strategy with respect to the PAPILIO-1 study and BCMA CAR-T, statements regarding the expected timing and design of the PAPILIO-1 study, including the expected trial recruitment for the PAPILIO-1 study, statements regarding the collaboration with Lonza, and statements regarding our strategy, portfolio goals, business plans, focus. Any forward-looking statements in this release are based on our management's current expectations and beliefs, and are not guarantees of future performance. In addition, even if our results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. Forward-looking statements may involve unknown and known risks, uncertainties and other factors which might cause our actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies may not be completed in the currently envisaged timelines or at all, risks associated with clinical trials, recruitment of patients for trials, and product development activities, including the BCMA CAR-

T clinical program and the PAPILIO-1 study, the inherent risks and uncertainties associated with competitive developments, risks related to regulatory approval requirements (including, but not limited to, the risk that data from the ongoing PAPILIO-1 study may not support registration or further development due to safety, efficacy concerns, or other reasons), risks related to the acquisition of CellPoint, including the risk that we may not achieve the anticipated benefits of the acquisition of CellPoint, the inherent risks and uncertainties associated with target discovery and validation or drug discovery and development activities, the risk that the preliminary and topline data from the PAPILIO-1 study may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including CellPoint's collaboration partner Lonza), the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, including the risk that our plans with respect to our CAR-T program may not be achieved on the currently anticipated timeline or at all. A further list and description of these or other risks and uncertainties can be found in our filings and reports with the US Securities and Exchange Commission (SEC), including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. Given these risks and 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 release. We expressly disclaim any obligation to update any forward-looking statements in this release, unless required by law or regulation.