

Adaptimmune and Galapagos Sign Clinical Collaboration Agreement with an Option to Exclusively License Adaptimmune's TCR T-cell Therapy Candidate, uza-cel, in Head & Neck Cancer and Potential Future Solid Tumor Indications

- Adaptimmune and Galapagos to conduct clinical proof-of-concept trial to evaluate the safety and efficacy of uza-cel (next-generation MAGE-A4 TCR T-cell therapy) produced on Galapagos' decentralized manufacturing platform in patients with head & neck cancer
- Uza-cel has shown encouraging results in head & neck cancer with partial responses in four out of five patients to date in a Phase 1 trial using Adaptimmune's centralized manufacturing platform
- Initial *in vitro* testing of uza-cel produced on Galapagos' decentralized manufacturing platform has shown encouraging data that support further clinical development
- Adaptimmune to receive initial payments of \$100 million, comprising \$70 million upfront and \$30 million of R&D funding, option exercise fees of up to \$100 million, additional development and sales milestone payments of up to a maximum of \$465 million, plus tiered royalties on net sales
- Galapagos has been granted an option to exclusively license uza-cel for global development and commercialization in head & neck cancer, and potential future solid tumor cancer indications

Adaptimmune will hold a conference call tomorrow (May 31st) at 8 a.m. EDT (webcast link [here](#) and more details below)

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - May 30, 2024) - **Adaptimmune Therapeutics plc (NASDAQ: ADAP), and Galapagos NV (NA: GLPG) (NASDAQ: GLPG)** announced today that they have entered into a clinical collaboration agreement with an option to exclusively license Adaptimmune's next-generation TCR T-cell therapy (uza-cel) targeting MAGE-A4 for head & neck cancer and potential future solid tumor indications, using Galapagos' decentralized cell manufacturing platform.

Uza-cel is a next-generation clinical-stage engineered TCR T-cell therapy developed by Adaptimmune, targeting the MAGE-A4 cancer antigen expressed in various solid tumors. Uza-cel is engineered to express the CD8 α co-receptor alongside the engineered TCR that targets MAGE-A4. Data indicate that co-expression of CD8 α may broaden and increase the immune response against solid tumors.¹

The Adaptimmune sponsored Phase 1 SURPASS trial with centrally manufactured uza-cel has shown encouraging results in head & neck cancer with an overall response rate of 80%. Initial *in vitro* results suggest that uza-cel, produced on Galapagos' decentralized manufacturing platform, yields early phenotype T-cells that could improve efficacy and durability compared to uza-cel centrally manufactured on Adaptimmune's platform.² In addition, Galapagos' decentralized manufacturing platform offers the potential for the delivery of fresh, fit cells with a vein-to-vein time of seven days in a patient population in which rapid access to treatment is vital.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "Data with uza-cel from our Phase 1 SURPASS trial has demonstrated compelling early results in ovarian, bladder, and head & neck cancers. In head & neck cancer, we have seen reductions in target lesions across all five patients treated to date, and there have been four confirmed partial responses. Combining uza-cel with Galapagos' unique decentralized manufacturing platform is a natural synergy and has the potential to deliver an even more effective TCR T-cell therapy for people with critical late-stage cancers."

Dr. Paul Stoffels³, Galapagos' Chief Executive Officer and Chairman: "We are excited to partner with Adaptimmune, a pioneer in TCR T-cell therapy, as this fully aligns with our strategic vision to advance novel cell therapies. This collaboration enables us to expand our oncology cell therapy portfolio to include treatments for solid tumors and next-generation therapies, leveraging our innovative, decentralized cell therapy manufacturing platform. For patients with head & neck cancer, an area with significant unmet medical needs, this collaboration offers the promise for faster access to a potentially transformative treatment."

Under the terms of the agreement, Adaptimmune will receive an upfront exclusivity payment of \$70 million, plus \$15 million in R&D funding at signing. A further \$15 million in R&D funding will follow subject to the start of dosing in the proof-of-concept trial. Adaptimmune will be responsible for the clinical proof-of-concept trial in head & neck cancer and the supply of the vector for the manufacturing of uza-cel. Galapagos will be responsible for the delivery of fresh uza-cel product for the head & neck cancer proof-of-concept trial using its innovative, decentralized cell therapy manufacturing platform.

Adaptimmune will retain the right to develop, manufacture, commercialize, and otherwise exploit uza-cel for platinum-resistant ovarian cancer (currently being developed in the SURPASS-3 trial).

Following completion of the proof-of-concept trial, Galapagos has an exclusive option to license global rights to uza-cel for a maximum of \$100 million, depending on the number of indications in relation to which the option is exercised. In addition, Adaptimmune is eligible to receive development, regulatory and sales milestone payments of up to \$465 million, unless the agreement is terminated, and tiered royalties on net sales in the mid-single to low-double digit range.

Conference call / webcast details - 8 a.m. EDT May 31st

A live webcast and replay can be accessed at <https://www.gowebcasting.com/13364>. Call in information is as follows: 1-844-763-8274 (US or Canada) or +1-647-484-8814. Callers should dial in 5-10 minutes prior to the scheduled start time and simply ask to join the

Adaptimmune call.

About Galapagos' T-cell manufacturing platform

Galapagos' decentralized, innovative T-cell manufacturing platform has the potential for the administration of fresh, fit cells within a median vein-to-vein time of seven days, greater physician control 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

We are a 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 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 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.glp.com or follow us on LinkedIn or X (formerly Twitter).

About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on designing, developing, and delivering cell therapies to transform the lives of people with cancer. The Company's unique engineered T-cell receptor (TCR) platform enables the engineering of T-cells to target and destroy cancers across multiple solid tumor types.

Forward-looking statement

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended 31 December, 2023, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

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¹ Poster presentation ESMO 2021: Safety and efficacy from the SURPASS trial with ADP-A2M4CD8, a SPEAR T-cell therapy incorporating a CD8 α co-receptor and an affinity optimized TCR targeting MAGE-A4, *Annals of Oncology*, vol. 32, suppl. 5, pp. S604-S605. Poster presentation SITC 2021: Enhancement of TCR-engineered T-cells targeting MAGE-A4 antigen by co-expression of CD8 α and inhibition of AKT signaling during *ex vivo* T-cell expansion. *SITC Annual Meeting*. Nov. 10-14, 2021. Washington, DC and virtual. Emily Schmidt, PhD, et al.

² Data on file

³ Throughout this press release, 'Dr. Paul Stoffels' should be read as 'Dr. Paul Stoffels, acting via Stoffels IMC BV'



To view the source version of this press release, please visit
<https://www.newsfilecorp.com/release/211023>

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