Autolus Announces First-Dose Cohort Completed in APRIL Study of AUTO2: A Phase I/II Study in Patients with Multiple Myeloma

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AUTO2 is the first dual targeting CAR-T Cell therapy in clinical development for the treatment of multiple myeloma

Autolus Limited, a clinical-stage biopharmaceutical company focused on the development and commercialisation of next-generation engineered T-cell therapies, today announced completion of the first-dose cohort of its phase I/II study of its novel, dual-targeted Chimeric Antigen Receptor (CAR) in patients with relapsed/refractory multiple myeloma.

AUTO2 is a chimeric antigen receptor T-cell (CAR-T cell) therapy that targets both B-cell maturation antigen (BCMA) and transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI). The APRIL Study is a dose-escalation phase I/II study in which cohorts of patients receive ascending doses of AUTO2 to determine the maximum tolerated dose and establish a recommended dose. The second part of the study is an expansion phase where patients receive AUTO2 to further evaluate the safety, tolerability and clinical activity at this recommended dose.

Dr Jesus G. Berdeja, Director of Myeloma Research & Senior Investigator, Hematologic Malignancies, Sarah Cannon Research Institute said:

> "BCMA CAR-T cell therapies have shown considerable promise in early clinical studies. A dual-targeted approach may minimise the risk for antigen negative escape and extend CAR-T treatment to patients with low density of BCMA antigen on the surface their cancer cells."

Dr Christian Itin, Autolus' CEO added:

> "Breaking the defence mechanisms of cancers against T-cells is key to unlocking the curative potential of CAR-T cell therapies. AUTO2 is a first example of Autolus' approach to specifically re-programme the patient's own T-cells to minimise the risk of the cancer cells escaping treatment. With the start of the APRIL study we have transitioned to a clinical stage company; an important step on our path to build a fully integrated autologous CAR-T cell company with a portfolio of differentiated therapies for the treatment of patients with cancer."

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Notes for Editors:

About Autolus

Autolus is a clinical-stage, biopharmaceutical company, focused on the development and commercialisation of engineered T-cell immunotherapy products to combat cancer. Utilising its advanced cell programming and manufacturing technologies, Autolus has a pipeline of products in development for the treatment of both haematological malignancies and solid tumours. For further information please visit the Company's website at: www.autolus.com

About AUTO2

AUTO2 is a dual-targeting CAR-T cell product recognising BCMA and TACI with a natural human ligand (APRIL) that binds to both receptors. BCMA is an antigen with low and variable expression on multiple myeloma cells. By targeting TACI in addition to BCMA on the same cancer cell, more patients may be eligible for CAR-T treatment with patients being at risk of cancer relapse due to loss of BCMA expression on their cancer. In addition, AUTO2 carries an RQR8 safety switch which allows the T-cells to be removed with a single high dose of rituximab.

Data related to AUTO2 was presented at the American Society of Hematology Meeting, 2016:

Abstract: #379 https://ash.confex.com/

Autolus gratefully acknowledges the support of an Innovate UK Grant which partially-funded some of the early work on this product.

About the APRIL Study

A single-arm, open-label, multi-centre, phase I/II study evaluating the safety and clinical activity of AUTO2, a CAR-T Cell Treatment Targeting BCMA and TACI, in patients with relapsed or refractory multiple myeloma.

The APRIL Study is dose-escalation phase in which cohorts of patients will receive ascending doses of AUTO2 to determine the maximum tolerated dose and establish a recommended dose. The second portion of the study is an expansion phase where patients will receive AUTO2 to further evaluate the safety, tolerability and clinical activity at this recommended dose. The APRIL study is named after the month in which the study was initiated, which is also the ligand the cell utilises to target the cancer.

Further details of the study can be found at:

https://www.clinicaltrialsregister.eu

About Multiple Myeloma

Multiple myeloma is a type of blood cancer that affects the plasma cells and is the second most commonly diagnosed blood cancer, after non-Hodgkin lymphoma. In multiple myeloma, malignant plasma cells accumulate in the bone marrow, crowding out the normal plasma cells that help fight infections. These malignant plasma cells then produce abnormal proteins (m protein) which may cause tumours, damage the kidneys, and impair immune system function. In some cases, the malignant cells may cause a single tumour, called a solitary plasmacytoma, but if multiple tumours are formed the disease is then called multiple myeloma. There are a number of approved therapies to treat the disease but there is currently no cure.