



## F-star updates on FS118 clinical trial and announces presentation at ASCO 2019

- Dose escalation phase of the study completed up to the maximum planned dose of 20 mg/kg without dose-limiting toxicities (DLT) to date
- Preliminary patient pharmacodynamic (PD) data support continued clinical development
- Phase 1 study design featured at ASCO 2019

**Cambridge, UK, 30 May 2019** – F-star, a clinical-stage biopharmaceutical company delivering tetravalent bispecific antibodies for a paradigm-shift in cancer therapy, today provides a Phase 1 clinical update on its wholly-owned lead programme FS118 and announces a presentation at the ASCO Annual Meeting (Chicago, 01 June 2019). The abstract is currently available on the [meeting library webpage](#).

FS118 is a LAG-3/PD-L1-targeting tetravalent bispecific antibody, in a Phase 1 study in patients with late stage solid tumours who have relapsed following prior PD-(L)1 therapy. The objectives of the study are to evaluate the safety and pharmacokinetics of FS118, as well as clinical activity and immunogenicity. Exploratory assessment of pharmacodynamic response markers are also included.

As a supplement to the ASCO presentation, F-star provides an update on the Phase 1 study, showing:

- FS118 weekly treatment is well tolerated at all dose levels tested to date and has reached the planned highest dose level without occurrence of DLT in the treatment of 29 subjects recruited to date
- Modulation of soluble LAG-3 in patients' serum as a PD marker of target engagement

*"We are very encouraged by the FS118 emerging safety profile and by the early pharmacodynamic observations in advanced cancer patients who have relapsed following PD-(L)1 containing treatments" said Neil Brewis, Chief Scientific Officer of F-star. "LAG-3 is an exciting target in clinical immunoncology as it is involved in the development of PD-(L)1-resistance in many indications. We believe FS118 is an important part of the exciting next wave of checkpoint therapies and we are looking forward to generating additional data to validate our approach."*

The study is advancing as expected and is currently recruiting in the expansion cohorts of the two highest dose levels. First study data, including six-month data on clinical response, are expected to be released in Q1 2020.

Details of the poster are below:

**A first-in-human phase I study of FS118, an anti-LAG-3/PD-L1 bispecific antibody in patients with solid tumors that have progressed on prior PD-1/PD-L1 therapy.**

Category: Developmental Immunotherapy and Tumor Immunobiology  
Date and Time: 01 June from 08:00 - 11:00  
Poster Session: Board #292a

Location: McCormick Place - Chicago, IL  
Abstract Number: TPS2652

The poster will be available on F-star's website at the end of the conference.

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**About F-star**

F-star is a leading clinical-stage biopharmaceutical company delivering tetravalent bispecific antibodies for a paradigm-shift in cancer therapy. By developing medicines that seek to block tumour immune evasion, the Company's goal is to offer patients greater and more durable benefits than current immuno-oncology treatments. Through its proprietary tetravalent, bispecific antibody (mAb<sup>2™</sup>) format, F-star is generating first- and best-in-class drug candidates with monoclonal antibody-like manufacturability. Building on the combined expertise of its world-class management team and scientific leadership, F-star is poised to deliver the next breakthrough immunotherapies for cancer patients.

Find out more at [www.f-star.com](http://www.f-star.com). Connect with us via [LinkedIn](#) and [Twitter](#)

**About FS118**

Currently in a Phase 1 trial at four clinical sites in the United States, FS118 is a potentially first-in-class medicine for the treatment of resistant and refractory cancer. This tetravalent, bispecific antibody is developed to overcome tumour evasion mechanisms promoted by two highly immuno-suppressive molecules: LAG-3 (Lymphocyte-Activation Gene 3) and PD-L1 (Programmed Death-Ligand 1). By simultaneously blocking both inhibitory pathways, FS118 has preclinically demonstrated a potent anti-tumour growth activity<sup>(1)</sup> as well as a highly differentiated mechanism of action<sup>(2)</sup> when compared to checkpoint monotherapies alone or in combinations.

In April 2018, a Phase 1 clinical study started in patients who have relapsed following a prior PD-(L)1-containing therapy. Information about the trial is available on [clinicaltrials.gov](http://clinicaltrials.gov) [NCT03440437](https://clinicaltrials.gov/ct2/show/study/NCT03440437). FS118 is manufactured at 2000L scale using standard mAb manufacturing processes.

- (1) [Dual blockade of PD-L1 and LAG-3 with FS118, a unique bispecific antibody, induces CD8+ T cell activation and modulates the tumour microenvironment to promote anti-tumour immune responses. Kraman et al. \(April 2018\) - Poster at the annual AACR meeting](#)
- (2) [LAG-3/PD-L1 mAb<sup>2</sup> can overcome PD-L1-mediated compensatory upregulation of LAG-3 induced by single-agent checkpoint blockade. Faroudi et al. \(March 2019\) - Poster at the annual AACR meeting](#)