



F-star Therapeutics to Present FS120 Phase 1 Trial-in-Progress Update at ESMO 2021

September 16, 2021

Preclinical Data Indicates a Broad Therapeutic Window for F-star's First-in-Class Tetravalent Dual T cell Agonist

CAMBRIDGE, United Kingdom and CAMBRIDGE, Mass., Sept. 16, 2021 (GLOBE NEWSWIRE) -- **F-star Therapeutics, Inc. (NASDAQ: FSTX)**, a clinical-stage biopharmaceutical company dedicated to developing next generation bispecific immunotherapies to transform the lives of patients with cancer, today announces that the Company will present a trial in progress update on FS120, a first-in-class OX40 and CD137 tetravalent dual T cell agonist, at [the European Society for Medical Oncology 2021 Conference](#), taking place virtually, September 16th-21st.

The poster, entitled "A First-in-Human Phase 1 Study of FS120, an OX40/CD137 tetravalent bispecific antibody, in patients with advanced malignancies" is presented by Kyriakos P. Papadopoulos (START, San Antonio, Texas) and describes the design of a first-in-human Phase 1 clinical trial (NCT04648202) to assess the safety, pharmacokinetics/pharmacodynamics (PK/PD) and efficacy of FS120 in patients with advanced malignancies.

This study comprises an Accelerated Dose Titration (ADT) component followed by a 3+3 design. Enrollment of the ADT portion of the study is [complete](#), and the Company anticipates providing a further update on the study progress later this year.

Key findings include:

- Preclinical data from pivotal GLP Non-Human primate (NHP) study indicate a wide therapeutic window supporting the clinical study design. FS120 was well tolerated in NHP with a HNSTD (highest non-severely toxic dose) of 30mg/kg with limited and minimal changes in clinical chemistry measurements relating to liver model function.
- Pharmacodynamic biomarkers indicative of FS120 pharmacology, including increases in proliferation of CD4+ and CD8+ T cell and NK cell models, were observed in the NHP study and plateaued at the highest dose level. These pharmacodynamic markers are being used in the clinical study to determine a pharmacologically active dose in humans.

Safety and PK/PD data from this study will be used to trigger the initiation of the previously announced FS120 and [KEYTRUDA® \(pembrolizumab\) combination study](#), scheduled to start in Q3 2022.

Louis Kayitalire, Chief Medical Officer of F-star, said, "We are pleased to share this update on our first-in-class OX40 and CD137 tetravalent dual T cell agonist, FS120. In contrast to first generation T cell agonists, FS120 activates through concurrent binding to both CD4 and CD8 T cells. These latest data on FS120 are encouraging, and indicate that FS120 has the potential to be active and well-tolerated at high dose levels. With enrollment in the Accelerated Dose Titration study completed, we look forward to providing additional updates later this year and initiating the next study of FS120 in combination with KEYTRUDA (MSD's anti-PD-1 therapy), in 2022."

About FS120

In early clinical studies, agonistic antibodies targeting the T cell costimulatory receptors OX40 and CD137 have shown immune-stimulatory effects. Dose-limiting hepatotoxicity significantly hindered further development of CD137 monotherapies. [FS120](#) is a first-in-class dual-agonist tetravalent bispecific antibody incorporating OX40 binding into the Fc-region (termed an Fcab) and CD137 Fabs in a natural human IgG1 antibody and with silenced FcγR activity for reduced toxicity, as shown in preclinical safety studies. FS120 crosslinks and clusters the receptors eliciting a robust immune stimulation and activity in mouse tumor models, independent of FcγR crosslinking. FS120 has the potential to deliver tumor-agnostic clinical efficacy with good tolerability.

About F-star Therapeutics, Inc.

F-star is a clinical-stage biopharmaceutical company developing tetravalent bispecific antibodies for a paradigm shift in cancer therapy. By developing medicines that seek to block tumor immune evasion, the Company's goal is to offer patients greater and more durable benefits than current immunology treatments. Through its proprietary tetravalent, bispecific natural antibody (mAb^{2™}) format, F-star's mission is to generate highly differentiated best-in-class drug candidates with monoclonal antibody-like manufacturability. For more information visit www.f-star.com and follow us on [LinkedIn](#) and [Twitter](#).

Forward Looking Statements

Certain statements contained in this communication regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. F-star undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. In some cases, you can identify forward-looking statements by terminology such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," or the negative of these terms or other comparable terminology, which are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, the cash balances of F-star, the ability of F-star to remain listed on the Nasdaq Capital Market, F-star's status as a clinical

stage immuno-oncology company and its need for substantial additional funding in order to complete the development and commercialization of its product candidates, that F-star may experience delays in completing, or ultimately be unable to complete, the development and commercialization of its product candidates, that F-star's clinical trials may fail to adequately demonstrate the safety and efficacy of its product candidates, that preclinical drug development is uncertain, and some of F-star's product candidates may never advance to clinical trials, that results of preclinical studies and early stage clinical trials may not be predictive of the results of later stage clinical trials, that F-star relies on patents and other intellectual property rights to protect its product candidates, and the enforcement, defense and maintenance of such rights may be challenging and costly, and that F-star faces significant competition in its drug discovery and development efforts.

New factors emerge from time to time and it is not possible for us to predict all such factors, nor can we assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These risks are more fully discussed in F-star's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC. Forward-looking statements included in this communication are based on information available to F-star as of the date of this communication. F-star does not assume any obligation to update such forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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