F-star Therapeutics Announces FDA Acceptance of IND Application for FS120

F-star's first-in-class dual-agonist tetravalent bispecific antibody targeting CD137 and OX40 set to enter the clinic

Cambridge, UK and Cambridge, MA, January 30, 2020 – F-star Therapeutics Ltd., a clinical-stage biopharmaceutical company focused on transforming the lives of patients with cancer through the development of innovative tetravalent bispecific (mAb^{2}™) antibodies, today announces that the United States Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for FS120, F-star's proprietary tetravalent bispecific antibody targeting CD137 and OX40.

FS120 is a first-in-class dual agonist bispecific antibody that has the potential to overcome cancer resistance by simultaneously targeting CD137 (4-1BB) and OX40 (CD134, TNFRSF4), two receptors present on the surface of tumor-infiltrating lymphocytes. Unlike checkpoint inhibitors, the mechanism of action of FS120 triggers a positive signal that enhances several cellular functions essential for killing tumor cells. FS120 has a natural antibody format with silenced Fc effector functions, providing increased specificity and superior performance while reducing toxicity through conditional, crosslink-dependent activation upon binding to both CD137 and OX40, when compared to traditional monoclonal antibodies.

F-star expects to enroll 70 patients in a Phase 1 dose escalation clinical trial to assess the safety, tolerability and efficacy of FS120 in patients with advanced malignancies.

Dr Louis Kayitalire, CMO of F-star, said: *"The FDA acceptance of our IND application is a crucial milestone for this first-in-class dual agonist, as well as significant validation for the program. Advancing our pipeline and moving our second asset into the clinic brings us another step closer to providing more effective therapies for patients with otherwise difficult-to-treat cancers. Preclinically FS120 has demonstrated an effective tumor-killing response and, importantly, a good tolerability profile."*

Preclinical data recently presented at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting demonstrated that FS120's conditional, unique crosslink-dependent activation approach has the potential to provide therapeutic benefit, for example in combination with checkpoint inhibitors, and reverse T cell exhaustion in immunosuppressive tumor environments.

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About F-star Therapeutics Ltd

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 tumor 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 (mAb²™) 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 patients with cancer.