Fusion Pharmaceuticals Announces Presentation Of Preclinical Data Supporting Its FPI-1966 And FPI-2059 Targeted Alpha Therapies

Single and multiple doses of FPI-1966 demonstrated therapeutic efficacy in a preclinical bladder xenograft model

[^{225}Ac]-FPI-2059 demonstrated superior efficacy against [^{177}Lu]-IPN-1087 in a head-to-head comparison in a mouse xenograft model of colorectal cancer

Data featured in oral presentation sessions at the 34th Annual EANM Congress

HAMILTON, Ontario and BOSTON, Oct. 20, 2021 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced the presentation of preclinical data that provide further support of its FPI-1966 and FPI-2059 targeted alpha therapies (TATs) at the 34th Annual European Association of Nuclear Medicine Congress. These data reinforce the clinical dosing regimen of FPI-1966 and highlight the potential of FPI-2059 as an actinium-225 labelled precision medicine targeting NTSR1.

"These data demonstrate the broad potential of our TAT platform across multiple validated targets overexpressed in a variety of solid tumors," said Chief Executive Officer John Valliant, Ph.D. "We are pleased to share preclinical efficacy and tumor uptake data resulting from the administration of FPI-1966, and we believe strongly that this data will translate into meaningful results for patients with solid tumors overexpressing FGFR3 – a population with high unmet medical need. We look forward to initiating the Phase 1 study around the end of this year."

Data from preclinical studies of FPI-1966, a TAT designed to target and deliver actinium-225 to cancer cells expressing FGFR3, were presented in an oral presentation titled, "FGFR3 Targeted Alpha Therapeutic [225Ac]-FPI-1966 induces regression in preclinical bladder xenograft model". Outcomes demonstrated that FPI-1966 when administered with vofatamab results in high tumor delivery and low off-target uptake. Further, the data showed therapeutic efficacy of FPI-1966 at both single and multiple doses in a preclinical bladder cancer xenograft model.

Data from preclinical studies of FPI-2059, a TAT designed to target and deliver actinium-225 to cancer cells expressing neurotensin receptor 1 (NTSR1), were presented in an oral presentation titled "NTSR1 Targeted Alpha Therapeutic [^{225}Ac]-FPI-2059 induces regression in preclinical colorectal xenograft model". The study results include a head-to-head comparison of therapeutic efficacy obtained from FPI-2059, which delivers an alpha emitting isotope, with [^{177}Lu]-IPN-1087, which delivers a beta emitting isotope on the same targeting molecule. Results demonstrate superior efficacy with [^{225}Ac]-FPI-2059 in a mouse xenograft model of colorectal cancer.

Dr. Valliant continued, "Our science is based on the belief that alpha-emitting isotopes can provide significant therapeutic advantages compared to other commonly used radioisotopes. Preclinical results from our FPI-2059 product candidate provide further validation of this belief and support the diversification of our product portfolio to comprise multiple targeting vehicle types, including small molecules. We are pleased to be advancing further preclinical studies of FPI-2059 as we approach an investigational new drug (IND) filing in the first half of 2022."

About FPI-1966
[^{225}Ac]-FPI-1966 is a targeted alpha therapy designed to target and deliver an alpha emitting medical isotope, actinium-225, to cancer cells expressing FGFR3; a receptor that is overexpressed on several tumor types, including head and neck and bladder cancers. FPI-1966 utilizes Fusion's Fast-Clear™ linker to connect vofatamab, the human monoclonal antibody that targets FGFR3, with actinium-225. Vofatamab was previously evaluated as a therapeutic agent in a Phase 1b/2 trial and was reportedly well-tolerated. FPI-1966 is advancing to a Phase 1 study following the recent investigational new drug (IND) clearance

About FPI-2059
FPI-2059 is a targeted alpha therapy combining actinium-225 with IPN-1087, for development as a targeted alpha therapy for various solid tumors. The molecule targets NTSR1, a promising target for cancer treatment, that is overexpressed in multiple solid tumors. IPN-1087 was in Phase 1 clinical development as a lutetium-177-

based radiopharmaceutical for pancreatic ductal adenocarcinoma, colorectal cancer and gastric cancers expressing NTSR1. Fusion expects to submit an IND for FPI-2059 in the first half of 2022.

About Fusion
Fusion Pharmaceuticals is a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines. Employing a proprietary Fast-Clear™ linker technology, Fusion connects alpha particle emitting isotopes to various targeting molecules in order to selectively deliver the alpha emitting payloads to tumors. Fusion's lead program, FPI-1434 targeting insulin-like growth factor 1 receptor, is currently in a Phase 1 clinical trial. The pipeline includes FPI-1966, targeting the fibroblast growth factor receptor 3 (FGFR3), advancing to a Phase 1 study following the recent investigational new drug (IND) clearance; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1). In addition to a robust proprietary pipeline, Fusion has a collaboration with AstraZeneca to jointly develop novel targeted alpha therapies (TATs) and combination programs between Fusion's TATs and AstraZeneca's DNA Damage Repair Inhibitors (DDRis) and immuno-oncology agents. Fusion has also entered into a collaboration with Merck to evaluate FPI-1434 in combination with Merck's KEYTRUDA® (pembrolizumab) in patients with solid tumors expressing IGF-1R. Fusion and Hamilton, Ontario-based McMaster University are building a current Good Manufacturing Practice (GMP) compliant radiopharmaceutical manufacturing facility designed to support manufacturing of the Company's growing pipeline of TATs.

Forward Looking Statements
This press release contains "forward-looking statements" for purposes of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, including but not limited to the statements regarding Fusion Pharmaceuticals Inc.'s (the "Company") future business and financial performance. For this purpose, any statements contained herein that are not statements of historical fact may be deemed forward-looking statements. Without limiting the foregoing, the words "expect," "plans," "anticipates," "intends," "will," and similar expressions are also intended to identify forward-looking statements, as are expressed or implied statements with respect to the uncertainties inherent in the drug development process, including FPI-1966 and FPI-2059 early stage of development; the ability to move in-licensed targets forward in the clinic; the process of designing and conducting preclinical and clinical trials; the regulatory approval processes; the timing of regulatory filings; and the challenges associated with manufacturing drug products generally and radiopharmaceuticals specifically. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. These and other risks which may impact management's expectations are described in greater detail under the heading "Risk Factors" in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021 as filed with the SEC and in any subsequent periodic or current report that the Company files with the SEC. All forward-looking statements reflect the Company's estimates only as of the date of this release (unless another date is indicated) and should not be relied upon as reflecting the Company's views, expectations or beliefs at any date subsequent to the date of this release. While Fusion may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if the Company's estimates change.

SOURCE Fusion Pharmaceuticals Inc.

For further information: Fusion Contact: Amanda Cray, Senior Director of Investor Relations & Corporate Communications, 617-967-0207, cray@fusionpharma.com

---

https://ir.fusionpharma.com/2021-10-20-Fusion-Pharmaceuticals-Announces-Presentation-of-Preclinical-Data-Supporting-its-FPI-1966-and-FPI-2059-Targeted-Alpha-Therapies