

Fusion Pharmaceuticals Announces Presentation Of Preclinical Data Supporting FPI-2068, A Novel Targeted Alpha Therapy For EGFR-CMET Expressing Cancers

Data presented at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

FPI-2068 demonstrates anti-tumor activity in colorectal and lung tumor xenograft mouse models

FPI-2068, developed as part of collaboration agreement with AstraZeneca, received IND clearance in 2Q 2023

HAMILTON, ON and BOSTON, Oct. 12, 2023 /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 for FPI-2068, a clinical stage bispecific IgG-based targeted alpha therapy (TAT) designed to deliver actinium-225 to various solid tumors that co-express EGFR-cMET. Fusion is jointly developing FPI-2068 with AstraZeneca (LSE/STO/Nasdaq: AZN) under the companies' multi-asset collaboration agreement. The data are being presented in a poster presentation at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, being held October 11-15 in Boston, Massachusetts.

"We are pleased to share preclinical data demonstrating potent anti-tumor activity and evidence of mechanism of action of FPI-2068. EGFR and cMET are each validated targets, widely expressed in multiple solid tumor types. FPI-2068 combines the potency of an alpha-emitting isotope with the dual antigen targeting capability of the bispecific antibody to deliver a differentiated mechanism of action molecule that we believe has the potential to enhance therapeutic index, said Fusion Pharmaceuticals Chief Scientific Officer Christopher Leamon, Ph.D. "Following the IND clearance obtained earlier this year, we look forward to advancing FPI-2068 into clinical trials given the substantial unmet need for patients with non-small cell lung cancer and other cancer types that are known to co-express EGFR-cMET."

Data from a preclinical study of FPI-2068 are being presented in a poster presentation titled, "FPI-2068: A novel anti-EGFR/cMET, alpha-particle emitting, radioimmunoconjugate for cancer therapy."

In the preclinical study, FPI-2068 demonstrated anti-tumor efficacy in colorectal and lung tumor xenograft mouse models, and single dose administration of FPI-2068 led to prolonged tumor regression. Further, FPI-2068 caused activation of the DNA damage response (DDR) pathway as well as apoptosis, suggesting an inability of the cellular machinery to repair the DNA damage induced by the alpha radiation, consistent with the proposed primary mechanism of action.

These data provide further evidence supporting the clinical development of FPI-2068, which is expected to enter a Phase 1 study for the treatment of solid tumors co-expressing EGFR-cMET. EGFR and cMET are both validated targets that are co-expressed in multiple tumor types, including head and neck squamous cell carcinoma, non-small cell lung cancer, colorectal cancer, and pancreatic ductal adenocarcinoma.

Copies of the poster presentation can be found at: <https://fusionpharma.com/fusion-scientific-presentations/> following the conclusion of the AACR-NCI-EORTC Annual Meeting.

About FPI-2068

[²²⁵Ac]-FPI-2068 (FPI-2068) is a targeted alpha therapy (TAT) designed to deliver actinium-225 to various solid tumors that co-express EGFR and cMET. EGFR and cMET are validated cancer targets that are co-expressed in multiple tumor types, including head and neck squamous cell carcinoma, non-small cell lung cancer, colorectal cancer, and pancreatic ductal adenocarcinoma.

About Fusion

Fusion Pharmaceuticals is a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines. Fusion connects alpha particle emitting isotopes to various targeting molecules to selectively deliver the alpha emitting payloads to tumors. Fusion's clinical portfolio includes: FPI-2265 targeting prostate specific membrane antigen (PSMA) for metastatic castration resistant prostate cancer currently in a Phase 2 trial; FPI-1434 targeting insulin-like growth factor 1 receptor currently in

a Phase 1 trial; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1), currently in a Phase 1 trial. 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 Response Inhibitors (DDRIs) and immuno-oncology agents. The Company recently received IND clearance for FPI-2068, the first novel TAT under the collaboration, which targets EGFR-cMET. 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. To support Fusion's growing pipeline of TATs, the Company has signed strategic actinium supply agreements with TRIUMF, Niowave, Inc. and BWXT Medical.

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. 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 Company's potential drug candidates, including any expressed or implied statements regarding the successful development of its product candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of risks and uncertainties, including but not limited to the following: there can be no guarantees that the Company will advance any clinical product candidate or other component of its potential pipeline to the clinic, to the regulatory process or to commercialization; management's expectations could be affected by unexpected patient recruitment delays, regulatory actions or delays, or changes in the competitive landscape; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; and competition in general. 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 year ended June 30, 2023, 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.

Investors and others should note that Fusion communicates with its investors and the public using the Fusion website, www.fusionpharma.com, including, but not limited to, company disclosures, investor presentations, SEC filings, and press releases. The information that Fusion posts on this website could be deemed to be material information. As a result, Fusion encourages investors, media and others interested to review the information that Fusion posts there on a regular basis.

Contact:

Amanda Cray
Senior Director of Investor Relations & Corporate Communications
(617) 967-0207
cray@fusionpharma.com

SOURCE Fusion Pharmaceuticals

<https://ir.fusionpharma.com/2023-10-12-Fusion-Pharmaceuticals-Announces-Presentation-of-Preclinical-Data-Supporting-FPI-2068,-a-Novel-Targeted-Alpha-Therapy-for-EGFR-cMET-Expressing-Cancers>