

Fusion Pharmaceuticals Announces Presentation Of Preclinical Data Supporting FPI-2059 And Leading Targeted Alpha Therapy Platform At AACR Annual Meeting

FPI-2059 induces tumor growth inhibition in colorectal tumor model

TEM-1 and EGFRvIII demonstrate potential as TAT targets

HAMILTON, ON and BOSTON, April 19, 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 that provide further support of its clinical stage FPI-2059, a neurotensin receptor 1 (NTSR1) targeted alpha therapy (TAT), and additional preclinical development programs. The Company presented these data in three poster presentations at the American Association for Cancer Research (AACR) Annual Meeting.

"These data highlight the strong scientific rationale supporting clinical development of FPI-2059, demonstrating that targeting NTSR1 with the tumor killing power of actinium-225 has the potential to induce suppression in solid tumors. We are pleased to be progressing FPI-2059 in our ongoing Phase 1 study," said Fusion Chief Scientific Officer Christopher Leamon, Ph.D. "With our discovery platform, the Fusion team has quickly and efficiently developed TATs for various targets and progressed to multiple clinical programs. The data presented on exploratory targets, such as EGFRvIII and TEM-1, show the ability of our TATs to impact hard to treat cancers."

Data from preclinical studies of FPI-2059, a small molecule TAT designed to deliver actinium-225 to tumor sites expressing NTSR1, a protein expressed in gastrointestinal, prostate, pancreatic ductal adenocarcinoma (PDAC) and multiple other cancers, were presented in a poster presentation titled, "NTSR1-targeted alpha therapeutic [Ac-225]-FPI-2059 induces growth inhibition in a preclinical colorectal tumor model". Outcomes of the study demonstrate robust FPI-2059 tumor uptake and dose-dependent tumor growth inhibition and therapeutic efficacy in a preclinical colorectal tumor model. These data provide further evidence supporting the clinical development of FPI-2059, which is currently being evaluated in a Phase 1 study for the treatment of solid tumors expressing NTSR1.

Data from additional preclinical studies highlight the potential of tumor endothelial marker 1 (TEM-1) and epidermal growth factor receptor variant 3 (EGFRvIII) as targets for actinium-225 labelled TATs. In sarcoma xenograft models, TEM-1-targeted alpha therapy demonstrates strong dose-dependent and target level-dependent efficacy with no apparent toxicity. In glioblastoma multiforme (GBM) models, EGFRvIII-targeted alpha therapy demonstrates therapeutic efficacy as a single agent and in combination with standard of care. Further, EGFRvIII-targeted alpha therapy demonstrates efficacy in models with both leaky and intact blood-brain tumor barriers, suggesting that even low tumor uptake has potential anti-tumor effect.

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

About FPI-2059

FPI-2059 is a small molecule radiopharmaceutical targeting neurotensin receptor 1 (NTSR1) which is overexpressed in multiple solid tumors, including pancreatic ductal adenocarcinoma, colorectal, squamous cell carcinoma head & neck, gastric, Ewings sarcoma, and neuroendocrine differentiated prostate. FPI-2059 is based upon a compound previously referred to as IPN-1087 and 3BP-227 that had previously been studied in investigator sponsored studies and a Phase 1 clinical trial as a beta-emitting radiopharmaceutical. Fusion acquired the asset in 2021 and converted it to an alpha emitting radiopharmaceutical using actinium-225. The diagnostic analogue which uses indium-111 in place of actinium-225 is referred to as FPI-2058.

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; FPI-1966, targeting the fibroblast growth factor receptor 3 (FGFR3), 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 the first novel TAT under the collaboration, which targets EGFT-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's 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 Fusion'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: the ability to close the Offering; the timing and advancement of current and planned clinical trials; Fusion's ability to maintain its intellectual property portfolio; and the timing and success of our development and commercialization of its product candidates; risks relating to the regulatory process; unexpected patient recruitment delays or regulatory actions or delays; Fusion's ability to obtain additional funding required to conduct its research, development and commercialization activities; changes in Fusion's business plan or objectives; and Fusion's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries. 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 Fusion's quarterly report on Form 10-K for the year ended December 31, 2022, as filed with the U.S. Securities and Exchange Commission (the "SEC") and in any subsequent periodic or current report that Fusion files with the SEC. All forward-looking statements reflect Fusion's estimates only as of the date of this release (unless another date is indicated) and should not be relied upon as reflecting Fusion'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 Fusion's estimates change.

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