Fusion Pharmaceuticals Announces FDA Clearance Of IND For FPI-2059, An Investigational Small Molecule-Based Radiopharmaceutical Targeting Solid Tumors Expressing NTSR1

HAMILTON, ON and BOSTON, June 23, 2022 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) applications for [^{225}Ac]-FPI-2059 (FPI-2059) and the corresponding imaging analogue [^{111}In]-FPI-2058 (FPI-2058). FPI-2059 is a targeted alpha therapy (TAT) designed to use a small molecule to target and deliver actinium-225 to tumor sites expressing neurotensin receptor 1 (NTSR1), a protein that is overexpressed in multiple solid tumor types, including colorectal, pancreatic, gastric, neuroendocrine differentiated prostate, head and neck squamous cell carcinoma, and Ewing sarcoma cancers.

"The FPI-2059 program showcases Fusion's ability to use our platform technology and R&D expertise to efficiently convert different classes of targeting molecules into TATs against innovative targets that are designed to address cancers with high unmet need," said John Valliant, Ph.D. "With FPI-2059, we believe there is significant opportunity to address multiple solid tumor types, including neuroendocrine differentiated prostate cancer where PSMA expression is typically low and therefore patients are not adequately treated by existing radioligand therapies. We look forward to progressing FPI-2059, Fusion's first small molecule-based TAT and third clinical program, into a Phase 1 study."

Fusion acquired [^{177}Lu]-IPN-1087 (IPN-1087), a lutetium-based beta-emitting radiopharmaceutical, from Ipsen in April 2021, and converted the compound to the alpha-emitting [^{225}Ac]-FPI-2059. In clinical studies, IPN-1087 showed promising early safety data and good uptake in multiple tumor types. In a head-to-head in vivo comparison of therapeutic efficacy in a mouse xenograft model of colorectal cancer between FPI-2059 and IPN-1087, results show tumor regression with FPI-2059 is achieved at doses of approximately 1500 times lower than IPN-1087.

Fusion plans to initiate a Phase 1, non-randomized, open-label clinical trial in patients with solid tumors expressing NTSR1, intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. The study will prioritize six solid tumor indications, including head and neck squamous cell carcinoma, pancreatic, neuroendocrine prostate, colorectal, gastric and Ewing sarcoma. The study employs a 3 + 3 dose escalation design to evaluate multiple ascending doses of FPI-2059. As part of the screening process, patients will be administered an imaging analogue of FPI-2059, FPI-2058, and only those who meet predefined tumor uptake and safety criteria will go on to receive FPI-2059.

Radiopharmaceuticals are a precision medicine in that the alpha therapeutic can be converted into a corresponding imaging analogue with a different radionuclide (in this case indium), used to screen for a biomarker in patients with tumors that express the cancer target, increasing the likelihood of response to therapy. Fusion plans to provide additional guidance on timelines for the FPI-2059 program following initial experience with patient screening in order to better predict the cadence of patient enrollment.

About FPI-2059

[^{225}Ac]-FPI-2059 (FPI-2059) is a targeted alpha therapy combining actinium-225 with a small molecule designed to target neurotensin receptor 1 (NTSR1), in development as a potential treatment for various solid tumors. NTSR1 is a promising target for cancer treatment that is overexpressed in multiple solid tumors including colorectal, pancreatic, gastric, neuroendocrine differentiated prostate, head and neck squamous cell carcinoma and Ewing sarcoma cancers. FPI-2059 is currently being evaluated in a Phase 1 study.

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, and leveraging the Company's actinium supply and manufacturing expertise, 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) and FPI-2059, a small molecule acquired from Ipsen, targeting neurotensin receptor 1 (NTSR1). In addition to a robust proprietary pipeline, Fusion has a collaboration with AstraZeneca to jointly develop up to three novel targeted alpha therapies (TATs), the first of which is currently in IND enabling studies, and explore up to five combination programs between Fusion's TATs and AstraZeneca's DNA Damage Repair Inhibitors (DDRis) and immuno-oncology agents. Fusion also recently 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.

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 Company's potential drug candidates, including any expressed or implied statements regarding the successful development of product candidate FPI-2059. 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 or regulatory actions or delays; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; the Company's ability to obtain additional funding required to conduct its research, development and commercialization activities; changes in the Company's business plan or objectives; the ability of the Company to attract and retain qualified personnel; competition in general; and the Company'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 the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2022 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

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