Fusion Pharmaceuticals Announces IND Clearance For FPI-2068, A Jointly Developed Novel Targeted Alpha Therapy

FPI-2068 is a Bispecific Targeted Alpha Therapy (TAT) designed to Precisely Deliver Radiation to Tumor Cells

HAMILTON, ON and BOSTON, April 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 clearance of investigational new drug (IND) applications for [^{225}Ac]-FPI-2068 (FPI-2068) and corresponding imaging analogue [^{111}In]-FPI-2107 (FPI-2107) to the U.S. Food and Drug Administration (FDA). Fusion is jointly developing FPI-2068 with AstraZeneca (LSE/STO/Nasdaq: AZN) under the companies' multi-asset collaboration agreement.

FPI-2068 is a targeted alpha therapy (TAT) designed to deliver actinium-225 to various solid tumors that express EGFR and 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.

"The IND filing for FPI-2068 is an important milestone for Fusion as we advance this novel TAT, created by combining our radiopharmaceutical expertise, actinium supply and manufacturing infrastructure with AstraZeneca's bispecific antibody which preferentially binds to cancer cells that express both EGFR and cMET," said Fusion Pharmaceuticals Chief Executive Officer John Valliant, Ph.D. "FPI-2068, which we believe will be the first TAT for two validated targets to enter the clinic, was designed to provide enhanced tumor specificity resulting from the co-expression of the two targets when compared to individual monoclonal antibodies against each of these targets. We are excited about the innovative work with AstraZeneca as we advance this and other programs under our broad collaboration agreement."

Fusion's radiopharmaceuticals are a type of precision medicine whereby the cancer-targeted vector (e.g., the bispecific antibody) can be used to screen patients for expression of a tumor biomarker when combined with a corresponding imaging isotope (e.g., indium-111), and subsequently used for therapy when combined with the alpha-emitting radionuclide, actinium-225. Using imaging to identify patients who show uptake of the drug in tumors increases the likelihood of response to therapy. Fusion plans to provide additional guidance on timelines for the FPI-2068 program following initial experience with patient screening in order to better predict the cadence of patient enrollment.

FPI-2068 will be the first program to enter clinical development under the Company's previously announced collaboration agreement with AstraZeneca, which includes joint discovery, development and the option to co-commercialize novel TATs leveraging Fusion's proprietary Fast-Clear™ linker technology platform with antibodies from AstraZeneca's oncology portfolio, as well as exploration of potential combination strategies involving existing assets in their respective portfolios. Fusion will be operationally responsible for the Phase 1 study, while AstraZeneca will be responsible for subsequent clinical development. The companies will share costs equally through clinical development.

About FPI-2068

[^{225}Ac]-FPI-2068 (FPI-2068) is a targeted alpha therapy (TAT) designed to deliver actinium-225 to various solid tumors that 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. FPI-2068 will be 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. 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. 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 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 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 FPI-2068 in the clinic, through 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; the Company's ability to obtain additional funding required to conduct its business activities; and changes in the Company's business plan or objectives. 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 annual report on Form 10-K for the year ended December 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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