Fusion Pharmaceuticals Reports Progress And Provides Recent Corporate Highlights

FPI-2068 IND expected to be submitted in the first quarter of 2023

FPI-1434 Phase 1 data expected in the second quarter of 2023

FPI-1966 Phase 1 study open and enrolling patients; Company expects to provide clinical data update in 2024

New actinium-225 partnership with BWXT Medical, a global leader in medical isotope supply, supports growing pipeline opportunities

HAMILTON, ON and BOSTON, Jan. 6, 2023 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today reported continued progress across its pipeline of target alpha therapies (TATs) and provided recent corporate highlights.

Fusion Chief Executive Officer John Valliant, Ph.D., commented, "With three Phase 1 clinical programs developing TATs as next-generation radiopharmaceuticals, Fusion is leading a wave of excitement in the radiopharmaceutical sector. Fusion is poised for an exciting year, with data from the Phase 1 study of FPI-1434 in solid tumors expressing IGF-1R expected in the second quarter. Additionally, we expect to file an investigational new drug application (IND) for FPI-2068, our first novel TAT being developed in collaboration with AstraZeneca, in the first quarter of 2023.

"While advancing our clinical programs, we've continued to focus on ensuring adequate actinium supply, and recently announced a new partnership with established global medical isotope supplier BWXT Medical. We are well positioned to execute on our clinical programs and continue to advance a diversified pipeline of cancer therapies generated through Fusion's internal R&D capabilities and technologies."

Portfolio Update

FPI-1434

In the Phase 1 study, Fusion is exploring various dose levels of FPI-1434 as well as two dosing regimens: one with FPI-1434 alone, and another in which a small dose of cold antibody (naked IGF-1R antibody without the isotope) is administered prior to each dose of FPI-1434. The Company anticipates reporting safety, pharmacokinetics, and imaging data, including any evidence of anti-tumor activity, from the Phase 1 study in the second quarter of 2023. Fusion continues to anticipate the initiation of a Phase 1 combination study with FPI-1434 and KEYTRUDA® (pembrolizumab) to occur six to nine months following determination of the recommended Phase 2 dose of FPI-1434 monotherapy.

FPI-1966

The Phase 1, non-randomized, open-label clinical trial of FPI-1966 in patients with solid tumors expressing FGFR3 is intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. Patient enrollment and dosing is ongoing. The first cohort of the Phase 1 portion of this study is designed to evaluate various doses of vofatamb ("cold antibody") to assess the impact of pre-dosing on tumor uptake and will inform the dosing regimen for the remainder of the study. The Company anticipates providing a clinical data update in 2024.

FPI-2068

Fusion and AstraZeneca are jointly developing FPI-2068, the first novel TAT created under the companies' multi-asset collaboration agreement. FPI-2068 utilizes Fusion's Fast-Clear™ linker technology to radiolabel an AstraZeneca bispecific antibody with actinium. The investigational new drug (IND) filing is expected to be submitted in the first quarter of 2023.

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 first program, FPI-

1434 targeting insulin-like growth factor 1 receptor (IGF-1R), is currently in a Phase 1 clinical trial. The pipeline includes FPI-1966, targeting the fibroblast growth factor receptor 3 (FGFR3), currently in a Phase 1 study; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1), which has received FDA investigational new drug (IND) clearance and will begin a Phase 1 study. 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 agreements for actinium supply with TRIUMF, Niowave, Inc. and BWXT Medical Ltd.

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 any clinical product candidate or other component of its potential pipeline in or 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 September 30, 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.

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