Fusion Pharmaceuticals Enters Into Exclusive Worldwide License Agreement With Heidelberg University And Euratom For Actinium-Based PSMA Targeted Radiotherapy

FPI-2265 positioned to be the first approved PSMA targeted alpha therapy

HAMILTON, ON and BOSTON, Feb. 16, 2024 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced that it has entered into an exclusive worldwide license agreement with Heidelberg University and Euratom represented by the European Commission, Joint Research Centre (together, the "Licensors"). The license agreement grants Fusion exclusive worldwide rights to utilize, develop, manufacture and commercialize compounds covered by the patent, which includes ^{225}Ac-PSMA I&T ("FPI-2265") for the treatment of prostate specific membrane antigen (PSMA)-expressing cancers. In addition, Fusion and the Licensors have signed an agreement to settle the parties' dispute related to an *inter partes* review ("IPR") of a U.S. patent owned by the Licensors which was instituted in August 2023 by the United States Patent and Trademark Board.

Fusion President and Chief Business Officer Mohit Rawat said, "We are pleased to enter into this exclusive license agreement with Heidelberg University and Euratom for their existing patent as we progress FPI-2265, the most advanced actinium-based PSMA targeted radiotherapy currently in development. With Fusion's expertise in the development and manufacturing of alpha-emitting radiopharmaceuticals, an operational radiopharmaceutical manufacturing facility, and our advantageous actinium supply, we are well positioned to execute this program. We look forward to providing updates as we reach anticipated upcoming milestones in 2024, including data from the TATCIST study in April and the initiation of our Phase 2/3 registrational study in the second quarter."

As announced in January 2024, Fusion and the U.S. Food and Drug Administration reached alignment on Fusion's Phase 2/3 protocol for FPI-2265 in patients with mCRPC who have progressed following treatment with lutetium-based radiopharmaceuticals. The updated development plan includes a Phase 2 dose optimization lead-in, expected to complete enrollment by the end of 2024, and a Phase 3 registrational trial expected to begin in 2025.

Under the terms of the license agreement, Fusion will pay the Licensors an aggregate upfront fee of €1.0 million, in addition to certain regulatory milestones upon potential approval and low single-digit royalties on future net sales of applicable products.

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 in order to selectively deliver the alpha emitting payloads to tumors. Fusion's clinical portfolio includes: FPI-2265 targeting prostate specific membrane antigen 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 clinical trial; and FPI-2059, a small molecule targeting neurotensin receptor 1, 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 and immuno-oncology agents. The Company 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. Fusion has a Good Manufacturing Practice compliant radiopharmaceutical manufacturing facility designed to support manufacturing of the Company's growing pipeline of TATs. The Company has signed strategic actinium supply agreements with 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 the future business and financial performance of Fusion Pharmaceuticals Inc. (the "Company"). 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 financial condition, liquidity, and potential drug candidates, including any expressed or implied statements regarding the successful development of FPI-2265 or timing of updates. 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 in 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; competition in general; the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries; and the Company ability to secure sufficient amounts of actinium-225 for its clinical and commercial activities. 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 period ended September 30, 2023, as filed with the Securities and Exchange Commission (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.

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