Fusion Pharmaceuticals To Acquire Phase 2 Program For 225Ac-PSMA I&T, A Radiopharmaceutical Targeting Metastatic Castrate Resistant Prostate Cancer

Acquisition of Phase 2 program with established clinical proof of concept strengthens pipeline of innovative targeted alpha therapies

In connection with the transaction, Fusion announces $60.0 million private placement financing

Fusion to host conference call at 4:45 p.m. ET

HAMILTON, ON and BOSTON, Feb. 13, 2023 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN) ("Fusion"), a clinical-stage oncology company focused on developing next-generation targeted alpha therapies ("TATs") as precision medicines, today announced the acquisition from RadioMedix, Inc. ("RadioMedix") of the investigational new drug application ("IND") for an ongoing Phase 2 clinical trial (the "TATCIST" trial) evaluating ^{225}Ac-PSMA I&T, a small molecule targeting prostate specific membrane antigen ("PSMA") expressed on prostate cancers. Following the closing, the alpha-emitting radiopharmaceutical being evaluated in the TATCIST trial will be known as FPI-2265.

"We are pleased to announce this acquisition, which adds an ongoing Phase 2 program for a validated cancer target to our pipeline of innovative TATs," commented Fusion Chief Executive Officer John Valliant, Ph.D. "From our inception, Fusion has recognized the potential opportunity for actinium-based therapies to address unmet needs in cancer given the power and potency of alpha radiation. We believe that with Fusion's TAT development expertise, and early investments that provide us with our actinium supply advantage, we are uniquely positioned to be first-to-market with an actinium-based PSMA agent."

"A growing body of clinical data demonstrates the power of targeted alpha therapies in prostate cancer, including for patients who progress on or after lutetium-based PSMA therapies," said Oliver Sartor, M.D, Laborde Professor for Cancer Research and Medical Director at Tulane Cancer Center. "With more than 250 patients treated with actinium-based radiopharmaceuticals targeting PSMA in investigator sponsored studies, this class of therapy has both the efficacy data and safety profile that supports continued development. I believe ^{225}Ac-PSMA I&T will have the potential to target a growing patient population with significant unmet need. In addition, it has the potential to move into earlier lines of therapy as monotherapy as well as in combination with other agents."

The TATCIST trial is designed to evaluate patients with metastatic castration-resistant prostate cancer ("mCRPC") with progressive disease, including patients who are naïve to PSMA targeted radiopharmaceuticals and those who have been pre-treated with ^{177}Lu-based PSMA radiopharmaceuticals such as PLUVICTO™. The trial is expected to evaluate approximately 100 patients with four treatment cycles per patient occurring every eight weeks. Patients are initially dosed at 100 kBq/kg with dose de-escalation possible based on biochemical response. Efficacy will be assessed using change in PSA levels and radiographic response.

Fusion plans to expand the Phase 2 program to additional sites and expects to report data on 20 to 30 patients in the first quarter of 2024.

"Having treated mCRPC patients for many years, I initiated the TATCIST trial to address the unmet needs for the many patients who are not adequately addressed with currently available therapies," said Ebrahim Delpassand, M.D., Chairman and CEO of RadioMedix and Medical Director of Excel Diagnostics & Nuclear Oncology Center. "Given Fusion's radiopharmaceutical development capabilities, leadership in Actinium supply and established infrastructure, we look forward to this preeminent partnership to advance FPI-2265 through the Phase 2 program for the benefit of our patients."

Dr. Valliant continued, "With one Phase 2 program, three ongoing Phase 1 programs, and an IND submission through our collaboration with AstraZeneca expected in the first quarter of 2023, Fusion continues to extend its leadership in targeted alpha therapy development. Following the encouraging data we reported from the cold antibody sub-study of the FPI-1434 trial in June, we continue to dose escalate and we look forward to reporting the preliminary Phase 1 data in the second quarter of this year. The FPI-1434 data will be the first in what we expect will be multiple clinical updates generated from our pipeline over the next 24 months."

Private Placement Financing

In connection with the closing of the acquisition of the TATCIST trial and related assets, Fusion has agreed to sell an aggregate of approximately 17.6 million common shares to certain accredited institutional investors in a private placement in public equity financing (the "Offering"). The Offering is expected to result in gross proceeds to Fusion of approximately $60.0 million, before deducting placement agent fees and other offering expenses payable by Fusion.

Pursuant to the terms of the securities purchase agreement, at the closing of the Offering, Fusion will issue approximately 17.6 million of its common shares at a price of $3.40 per share, equal to the closing price of Fusion's common shares, as reported by Nasdaq on February 10, 2023. The closing of the Offering is subject to customary closing conditions and is expected to occur on or about February 16, 2023.

Morgan Stanley and Jefferies served as co-placement agents for the Offering. New and existing investors in the Offering include Avidity Partners, Federated Hermes Kaufmann Funds, a fund affiliated with Deerfield Management Company, L.P., Invus, Perceptive Advisors, and Woodline Master Fund LP.

Upon the closing of the Offering, Fusion anticipates having $248.0 million in cash and cash equivalents, which it believes will be sufficient to fund its planned operating expenses and capital expenditure requirements into the first quarter of 2025.

The offer and sale of the foregoing shares are being made in a transaction not involving a public offering and have not been registered under the Securities Act of 1933, as amended (the "Securities Act"). The shares being issued in the private placement may not be offered or sold in the United States or Canada absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws or pursuant to an exemption from the prospectus requirements of Canadian securities laws, as applicable. Fusion has agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares acquired by the investors in the private placement.

This press release does not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any state in which such offer or sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the shares under the resale registration statement will only be by means of a prospectus.

Fusion Conference Call Information

Fusion will host a live conference call and webcast today beginning at 4:45 p.m. ET to discuss the acquisition. To access the live call, please dial 1-877-870-4263 (U.S.), 1-855-669-9657 (Canada) or 1-412-317-0790 (international) and reference Fusion Pharmaceuticals. A webcast of the conference call will be available under "Events and Presentations" in the Investors & Media section of Fusion's website at https://ir.fusionpharma.com/overview. The archived webcast will be available on Fusion's website shortly after the conclusion and will be available for 90 days following the event.

About RadioMedix

RadioMedix, Inc. is a clinical-stage biotechnology company, focused on innovative radiopharmaceuticals for diagnosis, monitoring, and Targeted Alpha Therapy ("TAT") of cancer. The company has also established facilities including a drug discovery center for the early probe development, a pre-clinical core facility for in vitro and in vivo evaluation of radiopharmaceuticals, and 27,500 SQF cGMP manufacturing and analytical suite for Phase I-III clinical trials, and the large-scale post-approval commercial manufacturing, also known as the Spica Center. To learn more, visit www.radiomedix.com

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, is currently in a Phase 1 clinical trial. The pipeline includes FPI-1966, targeting the fibroblast growth factor receptor 3, currently in a Phase 1 study; and FPI-2059, a small molecule targeting neurotensin receptor 1, which has received FDA 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 and combination programs between Fusion's TATs and AstraZeneca's DNA Damage Response Inhibitors 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'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 replicate results achieved in its preclinical studies or clinical trials, or that of RadioMedix in any future studies or 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-Q for the quarter ended September 30, 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.

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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