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Field Trip Receives Notice of Allowance for US Patent Application Covering FT-104 (Isoprocin Glutarate), its Novel Psychedelic Molecule in Development

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The Allowed Claims include Composition of FT-104, which is a more soluble, stable prodrug form of the psychedelic molecule 4-HO-DiPT

TORONTO, Jan. 11, 2022 (GLOBE NEWSWIRE) -- Field Trip Health Ltd. (NASDAQ: FTRP, TSX: FTRP) ("Field Trip"), a global leader in the development and delivery of psychedelic therapies, today announced that the U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for Field Trip's patent application No. 17/364,047 for claims related to FT-104 (informally known as "Isoprocin Glutarate"), Field Trip's first novel psychedelic molecule in development. Claims in the allowed patent application titled, "Tryptamine Prodrugs", cover composition of matter, use and manufacturing of a family of hemi-ester compounds of hydroxytryptamines, including FT-104.

Notices of Allowance are issued by the USPTO after it has thoroughly examined a patent application to ensure it complies with all requirements under United States patent law. This includes a rigorous evaluation to confirm that the claimed subject material is both novel and non-obvious with respect to prior art. The formal granting of the patent will occur in a subsequent administrative step.

The international (PCT) patent application relating to FT-104, which was filed in June 2020, has also published (WO 2022/000091) together with the International Search Report (ISR), a first step before expansion into National Phase filings to protect FT-104 in future major markets where Field Trip intends to pursue commercialization should FT-104 achieve regulatory approval. The international (PCT) patent application provides Field Trip with deferred patent filing rights in 150+ countries.

Dr. Nathan Bryson, Field Trip's Chief Science Officer, commented: "Since inception, the strategy at Field Trip for our first development project was to create a novel drug substance that could produce a consistent trip time, in the range of three hours. We achieved this by combining a novel prodrug strategy to make demonstrable improvements on a known class of psychedelic substances. To further derisk the project, we filed a Track One U.S. patent application on June 30, 2021 in order to accelerate the decision by examiners and achieve allowance, and granting, as early as possible in the development process. We are elated that the USPTO has formally allowed our patent application within seven months of filing and are now poised to continue development of FT-104 knowing that we have a robust intellectual property position to build on."

FT-104: A More Soluble, Stable Form of 4-HO-DiPT

The allowed patent application describes a family of hemi-ester compounds of hydroxytryptamines, including FT-104, a more soluble, more stable prodrug form of 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT or "Isoprocin"). The preferred prodrug, FT-104, comprises the endogenous, natural compound glutaric acid as a hemi-ester. As such, FT-104 has been given a common name, Isoprocin Glutarate, for simplicity.

The psychedelic compound, 4-HO-DiPT, was previously synthesized by Alexander (Sasha) Shulgin, a chemist and psychopharmacologist, who not only self-administered many of the substances he made but also reported their psychoactive effects in the collective works called "Tryptamines I Have Known and Loved," or TIHKAL for short. In his works, Shulgin stated: "I truly doubt that there is another psychedelic drug, anywhere, that can match [4-HO-DiPT] for speed, intensity, brevity, and sensitive to dose, at least one that is active orally," adding that "To be on a trip, then to be back pretty much in two hours and really baseline in another hour? Most unusual. If there will ever be an acceptance of drugs such as these, in a psychotherapeutic context, a short duration is of extreme value to both the patient and the therapist."

FT-104 demonstrates improved stability and more importantly improved solubility relative to 4-HO-DiPT. As a prodrug, FT-104 converts rapidly and completely to 4-HO-DiPT after administration. Combined, these properties result in improved drug absorption, more reproducible pharmacokinetic profiles and improved bioavailability relative to 4-HO-DiPT, making it a superior development candidate.

Joseph del Moral, Field Trip's CEO added: "We designed FT-104 to provide a more convenient, practical and consistent experience, while retaining the characteristics of a classical serotonin psychedelic. These aspects are important therapeutic and commercial differentiators which may truly separate FT-104 from psilocybin for clinical operators and for patients seeking psychedelic psychotherapy."

Field Trip is currently closing out final reports relating to preclinical assessments of safety and toxicology in view of initiating a Phase 1 pharmacokinetic trial in the first half of 2022.

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Field Trip expects the patent for "Tryptamine Prodrugs" to be issued in February 2022 and it will expire in 2040.

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This release includes forward-looking information (within the meaning of Canadian securities laws and within the meaning of the United States Private Securities Litigation Reform Act of 1995) regarding Field Trip and its business. Often but not always, forward-looking information can be identified by the use of words such as "expect", "intends", "anticipated", "believes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would" or "will" be taken, occur or be achieved. Such statements are based on the current expectations and views of future events of the management of Field Trip, and are based on assumptions and subject to risks and uncertainties. Although the management of Field Trip believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this release may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting the companies, including the uncertainties inherent in research and development as well as risks associated with preclinical and clinical data, including the possibility of unfavorable new preclinical, clinical or safety data, further analyses of existing preclinical data, the ability to produce comparable results as hypothesized, if, when and whether any drug applications maybe submitted and/or approved, decisions by regulatory authorities, and/or other matters that could affect the availability or commercial potential of FT-104, including development of products or therapies by other companies, availability and price of raw materials, availability of manufacturing capacity on a timely basis and access to logistics or supply channels commensurate with demand, the COVID-19 epidemic, market conditions, economic factors, management's ability to manage and to operate the business and the equity markets generally. Although Field Trip has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Accordingly, readers should not place undue reliance on any forward-looking statements or information. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Field Trip does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

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