Cytogel Pharma Enters into CRADA with the U.S. Army Institute of Surgical Research to Cooperate in an R&D Project

DARIEN, CONNECTICUT, USA, May 16, 2023 /EINPresswire.com/ -- Cytogel Pharma Enters into CRADA with the U.S. Army Institute of Surgical Research, to cooperate in a research and development project, “The evaluation of Cytogel’s novel analgesic, CYT-1010, for battlefield injury-induced pain”.

Cytogel Pharma, LLC. is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented endomorphin family of endogenous compounds, announced today that it has entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Institute of Surgical Research (USAISR).

This work is in support of the requirement to develop and evaluate improved analgesic medications that deliver effective pain relief and are free of performance-limiting side effects. There is an acute need for an efficacious, shelf-stable, easily administered battlefield analgesic with minimal side effects.

Cytogel has developed a new class of analgesics, the endomorphins. One of those, CYT-1010, is a highly selective mu opioid receptor (MOR) agonist with a unique chemical structure and novel mechanism of action that involves preferential binding to the truncated splice variants of the MOR initiated at Exon 11 that produce analgesic effects with reduced side effects. CYT-1010 is highly stable and demonstrated to be more potent than morphine in animal pain models. Further, it possesses anti-inflammatory effects, and has reduced side effects including no significant nausea/vomiting, no respiratory depression, at doses up to 9-fold the effective dose for pain relief, and little to no reward in animal testing, indicating a relative lack of addiction potential. CYT-1010 is not a precursor for, or convertible to, any current opioid drug or related drug of abuse which should support a less restrictive DEA classification. Pre-clinical and phase 1 human acute pain models of CYT-1010 suggest analgesic properties for several types of pain (e.g., acute, neuropathic, inflammatory).

“This research and development agreement with USAISR, an evaluation of Cytogel’s technology, is occurring as we prepare to begin phase 2 clinical testing of CYT-1010 to provide a non-addictive, safe and effective option for pain management” said Dean Maglaris, CEO of Cytogel Pharma.

About Cytogel Pharma:
Cytogel Pharma is a clinical stage biopharmaceutical company focused on developing promising early-stage, novel products from the endomorphin family of molecules for the treatment of moderate to severe pain, that could avoid the serious side effects of existing opioids and other analgesics.
The Company has identified and protected a number of product candidates that hold promise for success in this arena. Its lead product candidate is CYT-1010, an endomorphin 1 analog, an atypical analgesic with a demonstrated novel mechanism of action that in pre-clinical studies and one early clinical study, has shown fewer of the serious side effects of the classical opioids. This groundbreaking approach is backed by scientific evidence that differentiates it from the existing opioids and presents an attractive alternative treatment for people in pain. It is currently being developed for use in treating post-operative pain, by IV administration.

Furthermore, the U.S. Trademark Certificate of Registration has been issued for Cytogel's groundbreaking investigational stage pain medicine, CYT-1010®. Cytogel also has a solid portfolio of issued patents and patent applications claiming multiple compositions and uses of the primary molecular structure, salt forms, novel formulations, related species, and new molecules.

Disclosure Notice:
CYT-1010 is an investigational new drug and has not been approved by the FDA or any regulatory body for use in humans or animals. This release contains forward-looking information about CYT-1010 and a potential new indication for the treatment of patients with moderate to severe pain via injectable administration. Any potential benefits that may be implied by these statements involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the possibility of unfavorable clinical trial results, unfavorable additional analyses of existing data; uncertainties regarding the commercial success of CYT-1010; the risk that regulatory authorities may not share our views on the safety and/or effectiveness of this product candidate and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any new drug applications for CYT-1010 may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications that may be filed or pending for CYT-1010, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of CYT-1010.

[The information contained in this press release does not necessarily reflect the position or the policy of the Government and no official endorsement should be inferred.]

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