The Supreme Court's Action on Opioid Lawsuits has Unintended Consequences

An unintended consequence dissuades scientific and clinical developers from the analgesic category, discouraging development of new, safer pain medications.

DARIEN, CONN., USA, August 23, 2023 /EINPresswire.com/ -- Cytogel Pharma is dedicated to developing drug candidates derived from substances produced by the human brain for the safer management of moderate to severe pain. This innovative strategy has led to their primary drug candidate, CYT-1010, a novel analgesic with potential to provide relief from moderate to severe pain while avoiding addiction and respiratory depression.

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>
> *C. Dean Maglaris, CEO of Cytogel*

The opioid crisis in America is an epidemic and it has now risen to the attention of the U.S. Supreme Court, as the Nation's highest court rules on the settlements of opioid lawsuits. An unintended consequence of this heightened attention is to dissuade scientific and clinical developers from the analgesic category, discouraging development of new pain medications that might actually break the cycle of addiction and overdose deaths, giving patients safe, effective pain relief; thereby effectively addressing the opioid crisis.

"In spite of the lawsuits and settlements, there remains an important and urgent opportunity to eliminate the destructive addictions from opioid use by conducting new research and development of innovative, safer pain treatment solutions," stated C. Dean Maglaris, CEO of Cytogel. "CYT-1010 has demonstrated effects that provide significant relief from pain while avoiding addiction and respiratory depression."

- Sabrena Moreno wrote in "Health – Axios" (April 21, 2023) that the well-intended attempts to crack down on opioid prescribing hasn't stopped overdoses from rising but has had the unintended effect on patients with chronic pain, who say the result has been harder-to-fill prescriptions and heightened withdrawal and suicide risks.
- Crucially: The U.S. continues to grapple with how to address the addiction crisis while also helping hundreds of millions of Americans with chronic pain. Meanwhile both public health issues continue to get worse.

A safer drug, one without addiction potential and capable of providing potent pain relief, could effectively address the crisis while responding to the need for adequate relief from moderate to severe pain. Cytogel's CYT-1010 has the potential to become the breakthrough that this crisis demands.

"In this environment it is imperative to pursue development of drugs that won't contribute to the addiction crisis, novel drugs that are highly effective pain relievers and importantly safer, devoid of addiction potential and other serious adverse effects. This is Cytogel's strategy," commented Mr. Maglaris.

CYT-1010 is an endomorphin compound that targets receptors of the central nervous system to block pain, with minimal adverse effects: In a Phase 1 clinical study, CYT-1010 demonstrated safety from serious adverse events and significant analgesic activity. In preclinical studies, at therapeutic doses, it has been shown to provide:

- Safe and effective pain relief
- Impressive anti-inflammatory effects
- Little to no addiction potential
- No respiratory depression

This groundbreaking approach is backed by scientific evidence that elucidates the novel mechanism of action of CYT-1010, differentiating it from the existing opioids and presenting an attractive alternative treatment for people in pain. As well, the U.S. Department of Defense's Institute for Surgical Research indicated their interest in CYT-1010 by recently issuing Cytogel a Cooperative Research and Development Agreement (CRADA) to further study CYT-1010's potential.

Former Congressman Patrick Kennedy, advisor to Cytogel and a leading and long-standing advocate for improved substance use care, says "With its alternative to classical opioid treatment, Cytogel is on the cusp of a major medical breakthrough—one that will quite literally save lives," said Kennedy. "We need all hands-on-deck when it comes to battling the public health crisis of addiction. I'm proud to work with a company that is hyper-focused on changing the status quo."

Similar sentiments were expressed by Dr. A. Thomas McLellan, a career researcher in addiction and former Deputy Director of the White House Office of Drug Control Strategy. McLellan noted that "a highly effective analgesic that is non-addictive has been considered the holy grail of medicine for over a century; with CYT-1010, Cytogel seems to have discovered it."

Furthermore, the U.S. Trademark Certificate of Registration has been issued for Cytogel's, CYT-1010®. Cytogel also has a solid portfolio of issued patents and patent applications claiming multiple compositions and uses.

About Cytogel Pharma:
Cytogel Pharma is a clinical stage biopharmaceutical company focused on developing novel endomorphin molecules for treating moderate to severe pain, that could avoid the serious side effects of existing opioids and other analgesics.

The Company's lead product candidate is CYT-1010, an endomorphin analog, with a novel mechanism of action that in pre-clinical studies and one clinical study, has shown fewer of the serious side effects of the classical opioids. It is currently being developed for use in treating post-operative pain, by IV administration.

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 post-operative pain via IV administration. Any potential benefits that may be implied by these statements involves substantial risks and uncertainties and actual results could differ materially from those expressed or implied by such statements, including, 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 require additional data or may deny approval altogether; rejection by the regulatory authorities of the design and results from our clinical studies; the possibility that any new drug applications for CYT-1010 may never be filed with regulatory authorities in any jurisdictions and, if filed, may never be approved in any jurisdictions or, if approved, could be severely limited by negative and restrictive labeling to the extent that commercial forecasts for CYT-1010 may never be realized.

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Kimberly Weinrick
Cytogel
+1 917-224-5335
kweinrick@cytogelpharma.com
