

US FDA accepts TheraQuest's pain drug IND application

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Blue Bell, Pennsylvania

TheraQuest Biosciences, Inc. a development stage pain management company announced that the US Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for TQ-1015, its abuse deterrent extended release strong opioid. TQ-1015 is being developed using Securel, TheraQuest's proprietary abuse deterrent technology.

Najib Babul, chief executive officer of TheraQuest stated, "Sustained release opioids are the standard of care for the management of chronic pain. Unfortunately, it is easy to defeat the sustained release mechanism of such dosage forms, making them subject to drug diversion and drug abuse. The TQ-1015 dosage form is highly tamper resistant, when compared to OxyContin, thereby minimizing abuse by recreational drug users and drug addicts."

TQ-1015 is a once-a-day extended release opioid analgesic for the treatment of chronic pain. It has been developed using TheraQuest's proprietary abuse deterrent extended release drug delivery system (Securel). TQ-1015 is significantly more potent than many current oral therapies, including morphine and oxycodone. It shows robust efficacy in various animal models of acute pain, inflammatory pain and neuropathic pain. TQ-1015 will compete in the \$8.3 billion US opioid market.

Recent experience with extended release opioid pain relievers has shown that intentional crushing or extraction of the active ingredient from the dosage form by addicts and recreational drug users can destroy the timed-release mechanism and result in a rapid surge of drug into the bloodstream. Serious side-effects and death have been reported from such misuse.

Securel is TheraQuest's proprietary abuse deterrent extended release technology for oral abusable drugs. Securel dosage forms cannot be easily crushed for inhalation or to obtain rapid euphoria from high blood levels when swallowed. It is also exceedingly difficult for I.V. abusers to extract the active drug from the dosage form using common solvents, including alcohol.

TheraQuest Biosciences, Inc. is a private, development-stage pain management company building a diversified portfolio of pharmaceutical products to address a critical area of unmet medical need.