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SPPM-8

Analgesic Effect and Tolerability of a Novel Sufentanil/Ketamine Nasal Spray (CT001) in Pediatric Acute Pain: Pivotal Results from the PDC 01-0202 Study Validating a Model-Informed Approach

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Background & Aims

Acute pain in children remains undertreated, often due to the limitations of current analgesics, which may be invasive (IV/IM), slow-acting (oral), or lack pediatric-specific formulations. A rapid-onset, non-invasive, and effective analgesic fills a significant unmet need in pediatric emergency and acute care settings. This abstract presents the pivotal efficacy and safety results for a novel sufentanil/ketamine nasal spray (CT001), developed using a model-informed approach.

Methods

The PDC 01-0202 study was an open-label, prospective, multicenter trial enrolling 155 pediatric patients (aged 1 to <18 years) with moderate-to-severe acute pain (baseline median pain score 8/10) in an emergency department setting. Patients received CT001 at a target dose of 0.5 mcg/kg sufentanil / 0.5 mg/kg ketamine, with an optional second dose after 10-15 minutes. This dosing regimen was established by the PDC 01-0208 modeling and simulation (M&S) study, which bridged adult-to-pediatric pharmacokinetic/pharmacodynamic (PK/PD) data and quantified the significant (≥50%) opioid-sparing effect of the combination.
We utilized clinical data obtained from 6 clinical trials and 2 modeling & Simulation studies (0207 & 0208): one PK/PD and safety study in children with procedural pain (study 0201), one PK/PD and safety study in adults having undergone impacted third molar extraction, with a wide range of SUF and KET dose combinations including CT001 and placebo (study 0205), one registry based safety and tolerability study in children in ambulatory care (study 0203), one nasal spray bioavailability study in adults (study 0204), and one PK and safety study in children with procedural pain (study 0206) and one open-label, prospective pediatric trial for moderate-severe acute pain (0202).

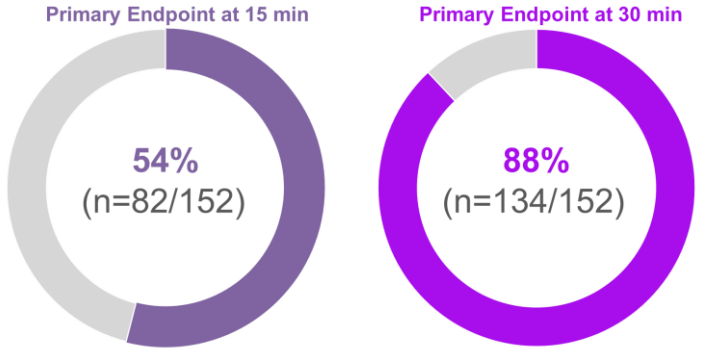
Results

The primary efficacy endpoint was percentage of patients reaching a pain intensity score of ≤4 within 30 minutes, achieved in 88% of patients (n=134/152, with 54% at 15 minutes). This clinical result closely validated the PDC 01-0208 simulation, which had predicted an 84% responder rate (≥ 50% pain reduction) at 30 minutes (vs. 86.2% observed in 0202).

Results cont'

The median percentage pain reduction from baseline was 75.0% at 30 minutes and 85.7% at 60 minutes. The treatment was well-tolerated. No IMP-related Serious Adverse Events (SAEs) were reported. All AEs were mild or moderate, with the most common being vomiting and dizziness.

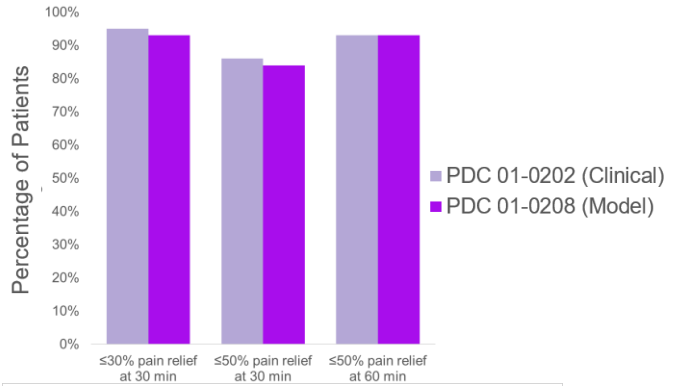
Primary Endpoint: Pain Score ≤4



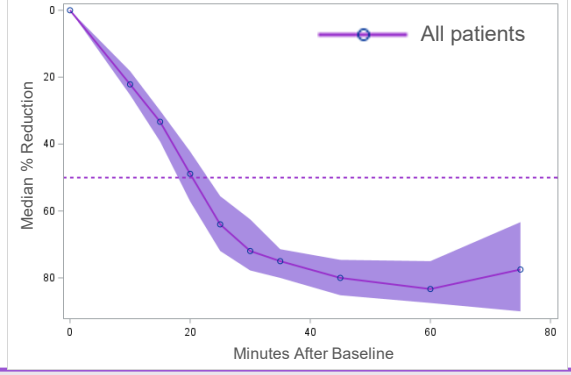
Study	Population	N	Objectives	Procedure
0201	Children	50	Efficacy, PK, safety, IN	Procedural pain
0203	Children	300	Registry study	Procedural pain
0204	Adults	15 (3-way crossover)	PK, bioavailability, IN vs IV	NA
0205	Adults	220	Efficacy, PK, IN	Molar extraction
0206	Children	25	PK, safety, IN	Procedural pain
0207 0208	Children & Adults	-	PK and PKPD modeling & Simulation studies	Acute pain
0202	Children	155	Safety, Efficacy	Acute pain

Table 1. All studies have been included in this PDCO approved development program of CT001. All pediatric studies included ages 1-17 yrs. PK: pharmacokinetics, IN: intranasal, IV: intravenous.

Model Prediction vs Clinical Validation



Percentage Reduction Over Time (All Patients)



Conclusion

The pivotal PDC 01-0202 study, supported by robust M&S data from PDC 01-0208, demonstrates that this novel sufentanil/ketamine nasal spray provides rapid, clinically significant analgesia for moderate-to-severe acute pain in children. The combination was well-tolerated and highly accepted, offering a promising non-invasive solution to address a critical unmet need in pediatric pain management.