BPR-516-X: A Novel Long-Acting Drug for Postoperative Analgesia

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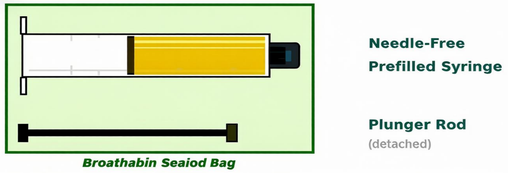
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Introduction

Effective postoperative analgesia during the first 72 hours after surgery remains challenging. Available local analgesic therapies may have limited duration or require preparation and handling by operating-room personnel before administration. **BPR-516-X is an investigational sustained-release formulation designed for local administration at the surgical site and analgesic activity for up to 96 hours after a single application. It is supplied in a sterile, ready-to-use prefilled syringe that requires no reconstitution, mixing, transfer, or other aseptic preparation before administration.**



Materials and Methods

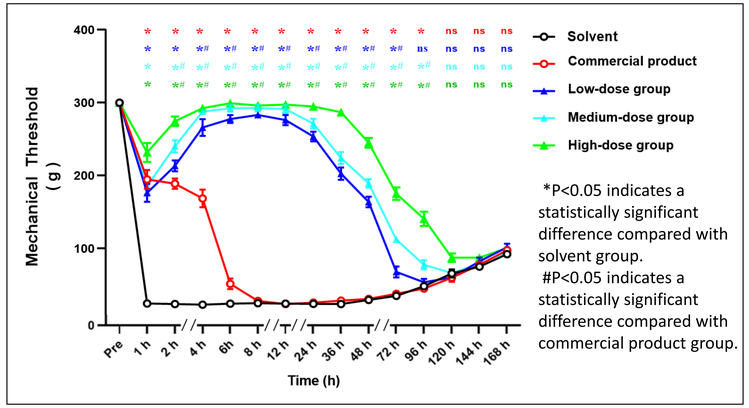
BPR-516-X contains an established analgesic active ingredient and compendial-grade excipients conforming to applicable USP–NF standards.

In a minipig incisional-pain model, BPR-516-X was administered once at the incision site. 30 animals were assigned to five groups receiving low-, medium-, or high-dose BPR-516-X, vehicle control, or a commercially available comparator （6 animals per group）. Mechanical pain thresholds and plasma drug concentrations were assessed through 96 hours after administration. Local tolerability, clinical observations, body weight, food consumption, and surgical-incision healing were evaluated through 168 hours.

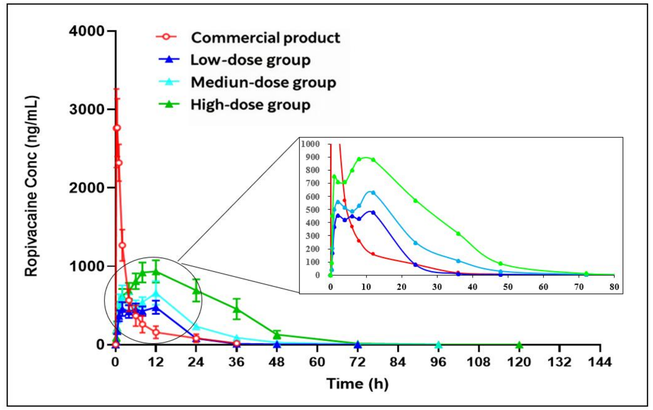
All animal procedures were reviewed and approved by the Institutional Animal Care and Use Committee (protocol no. IACUC-A2026144-P-01) and conducted in accordance with applicable institutional animal-welfare guidelines. Data are presented as mean ± SEM. Group and time effects were evaluated using two-way ANOVA. Statistical significance was defined as $P<0.05$.

Results and Discussion

PD Study of BPR-516-X A single administration of BPR-516-X produced a dose-dependent increase in mechanical pain threshold, with analgesic activity observed throughout the 96-hour assessment period. At 96 hours, mechanical pain thresholds in the BPR-516-X groups were 1.7- to 3.1-fold higher than in the commercially available comparator group .



PK Study of BPR-516-X Compared with the commercially available comparator, BPR-516-X reduced peak plasma concentration (Cmax) by 2477.61 ng/ml and total systemic exposure (AUC) by 1078.01 h*ng/ml while maintaining measurable plasma concentrations to 120 hours after a single administration.



Incision redness and swelling scores remained 0 in all groups throughout the 168-hour observation period. No deaths, moribundity, or treatment-related abnormalities in clinical observations, body weight, food consumption, or incision healing were observed. BPR-516-X was well tolerated under the conditions of this study.

In a minipig incisional-pain model, a single application of BPR-516-X produced higher mechanical withdrawal thresholds than the commercial comparator, with statistically significant differences maintained at 96 hours in the medium- and high-dose groups. No treatment-related abnormalities were observed in the monitored tolerability measures through 168 hours. These findings support further investigation of BPR-516-X for postoperative analgesia; efficacy and safety in humans remain to be established.

Limitations

BPR-516-X is currently undergoing additional animal studies, including safety evaluation and formulation toxicology research, and clinical studies will subsequently be conducted to determine its safety and efficacy in humans.