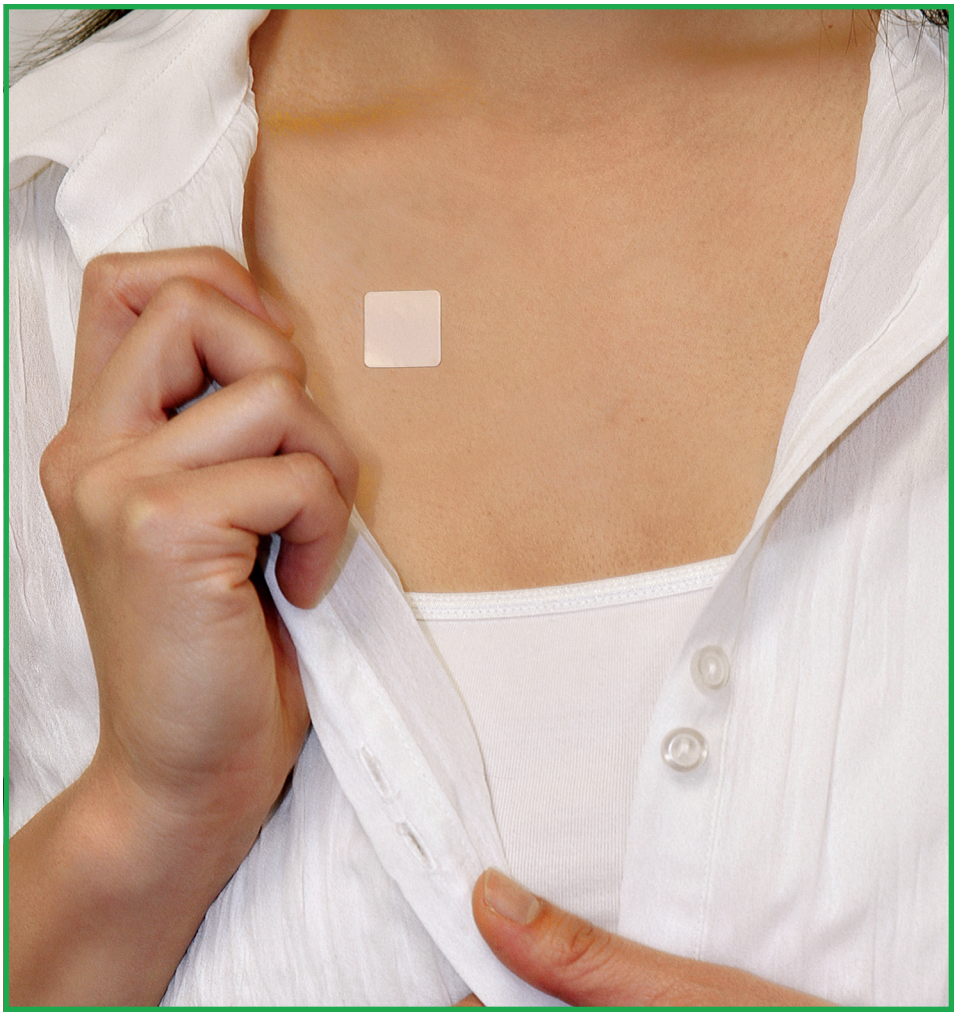
DURECT

TRANSDUR®
Transdermal Technology

DURECT has expertise and product development experience in all aspects of developing local and systemic therapeutics using our TRANSDUR® transdermal drug delivery technology. DURECT's capabilities include transdermal product feasibility, product design, formulation, pre-clinical and clinical studies, regulatory and clinical-scale manufacturing. In addition, DURECT's staff has played critical roles in the development of a number of commercially successful transdermal products currently on the market including Transderm-Nitro®, Nicoderm®, Catapres TTS®, and Duragesic®.



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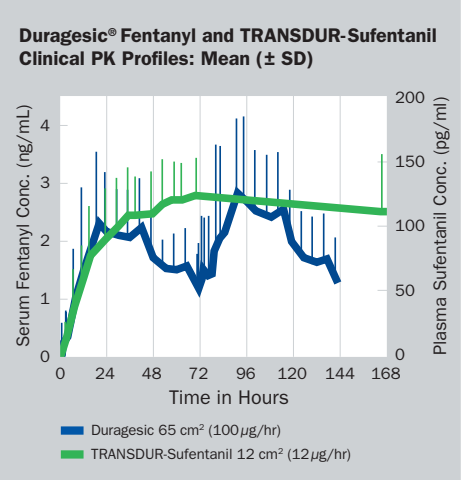
TRANSDUR® Transdermal Technology

Transdermal delivery in general, and our TRANSDUR® technology in particular, can be a solution for those drugs which are not suitable for oral administration due to low bioavailability, short half-lives, frequent dosing requirements, or unacceptable side-effect profiles.

Examples of TRANSDUR in use: TRANSDUR-Sufentanil

Figure 1 depicts the pharmacokinetic reasons why commercially available fentanyl patches are not fully effective for 3 days in a significant number of patients.

FIGURE 1

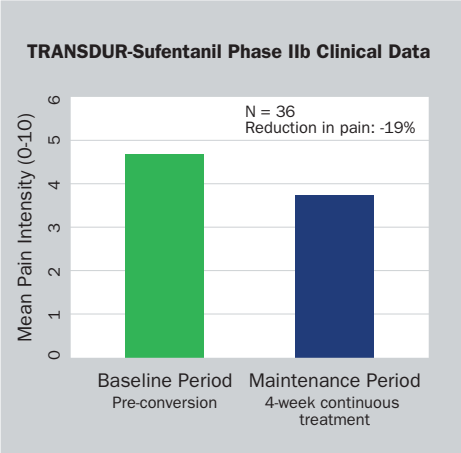


DURECT has completed a Phase IIb study as outlined below with a successful outcome, including superior pain control during the maintenance period as compared to baseline.

Highlights of Phase IIb Clinical Study

- Open label study in 74 chronic pain patients, evaluating conversion from oral (OxyContin®) and transdermal (Duragesic® Fentanyl) opioids to TRANSDUR-Sufentanil
- All primary and secondary endpoints achieved:
  1. Dose titration intervals established
  2. Potency relationship for conversion established
  3. Good safety and tolerability over the 4-week maintenance period
  4. Superior pain control during maintenance period as compared to baseline (See Figure 2)

FIGURE 2



Potential Advantages of TRANSDUR-Sufentanil may Include:

Patient advantages:

- Uninterrupted delivery of pain relief (7 days vs. 2-3 day fentanyl patches)
- Smaller size (~1/5 size of Duragesic®)
- Potential for less irritation due to formulation
- May have wider therapeutic index with potential side effect advantages over fentanyl and oxycodone

Healthcare system advantages:

- REMS: less potential for diversion, only 4 patches per month vs. 10-15 for other patches or 60 pills
- Potential reduced cost of therapy
- Potential reduced need for break-through meds

Commercial advantages:

- Best-in-class therapy, opportunity to capture market share from fentanyl patches and oral ER opioids
- Manufacturing cost, 1 patch a week vs. 2-3 patches

Examples of TRANSDUR® in use: ELADUR® (TRANSDUR-Bupivacaine)

DURECT is also developing a transdermal bupivacaine patch (ELADUR) based on our proprietary TRANSDUR topical technology. The product is to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available local analgesic (lidocaine) patches. DURECT anticipates that the ELADUR product will have several potential differentiating attributes compared with currently marketed patches, including extended duration of action and better wearability.

DURECT successfully completed a 60-patient Phase IIa clinical trial for the ELADUR product. In this study of patients suffering from post-herpetic neuralgia (PHN), the ELADUR patch showed improved pain control versus placebo during the 3 day continuous treatment period. In a Phase II clinical study in chronic low back pain, the primary efficacy endpoint of demonstrating a positive treatment difference for the mean change in pain intensity scores from baseline to the mean of weeks 11 and 12 between ELADUR as compared to placebo was not met. Future development of ELADUR will re-focus on the original purpose of treating PHN and other neuropathic pain conditions.

DURECT's TRANSDUR technology is adaptive and can provide a number of unique advantages, including:

- Skin friendly adhesive materials for 1-7 day drug administration
- Elegant formulations for rate-controlling adhesive drug matrices
- Rate controlling technologies for modulating systemic and topical drug delivery
- Skin permeation enhancing technologies