

# HPR Fact-Sheet



## 30 Years Experience in Proof of Concept (PoC) Studies in Human Pain Research – using Human Pharmacodynamic (Laser) Algesimetry

### The Approach

- Multiple intra-individual cross-over study designs
- 2- up to 6-way crossover trial paradigms
- also with different skin conditions in the same trial conduct

### Time and Cost Aspects

- Programmed saving with regard to both aspects
- Full-service-testing of diverse nociceptive conditions – within one study setting
- Minor pool of participants (e.g. about 16 to 24 subjects only)

### Study Conduct

- Experimental part in well-defined time-lines
- 6-way (single-dose) trial in 6 weeks + Screening and ESV period
- 2 weeks for statistics and first results (with up to 2300 LEP sessions per study)
- Realtime recording and pre-analysis during study

### The Settings

- Laser Evoked Potentials (LEP) from normal and sensitized skin conditions (e.g. UVB- and capsaicin-irritation)
- Healthy volunteers (+ psychophysics/ electronic VAS/ QST & skin colorimetry)

### Validity & Comparability

- High - due to sophisticated (objective-quantitative) test paradigms and due to the high expertise with reference to results of former studies in many other marketed and experimental analgesic compounds -resulting in a large data base of analgesics (>50 compounds), done with the same or similar settings - over 30 years now

... laser-evoked potentials (LEPs) are the easiest and most reliable of the neurophysiological methods for assessing function of nociceptive pathways ...

EFNS\* citation from 2004, rev. 2009, and published 2010 in European Journal of Neurology 2010, 17: 1010-1018):

# HPR

Human  
Pharmacodynamic  
Research

**30**  
Years of  
experience

**>50**  
Compounds

**>150**  
Studies

**115k**  
LEP Sessions

**1.73m**  
Single laser stimuli

### Study Design



2 weeks

### Submission



6 weeks

### Screening



1/2 weeks

### Trial phase



2/6 weeks

### ESV Statistics / Results



1 week



2 weeks