

SCOLR Pharma

Ibuprofen Overview



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Program Objectives:

- Develop a novel, competitive 12-hour extended-release ibuprofen tablet formulation based on SCOLR's proprietary and patented CDT® delivery technology

Tablet Approval Requirements:

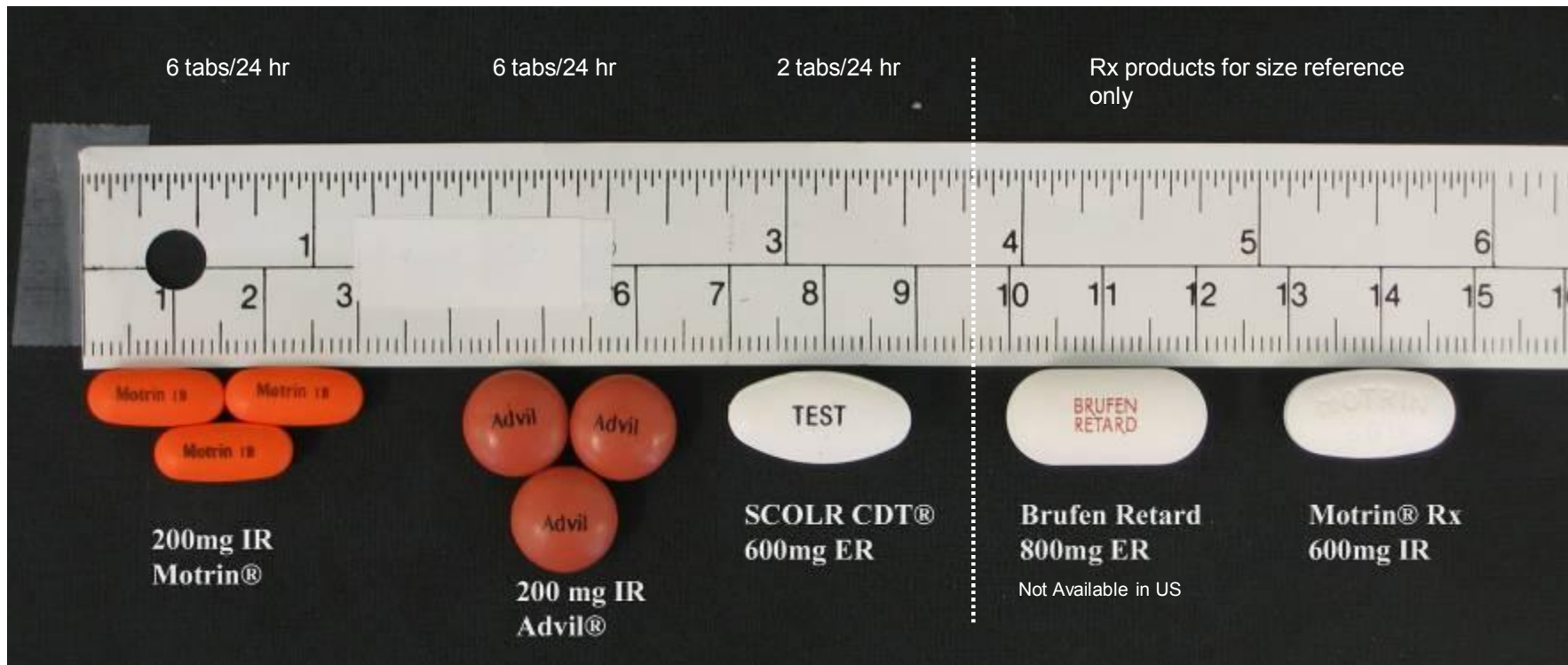
- Must be Bioequivalent to three 200 mg immediate release (IR) RLD tablets (Motrin®)*
- Must stay below C_{max} or safety studies will be required*
- Must provide onset of pain relief in less than 60 minutes*
- Must demonstrate efficacy for the full 12 hours, especially over the last four hours (8-12)**

*As discussed at type "b" meetings with FDA in 2004, 2006

**Responses during special protocol assessment (SPA) with FDA

Commercial/Late-Stage Programs: Ibuprofen

SCOLR CDT® Ibuprofen tablet compared to existing OTC and Rx products.

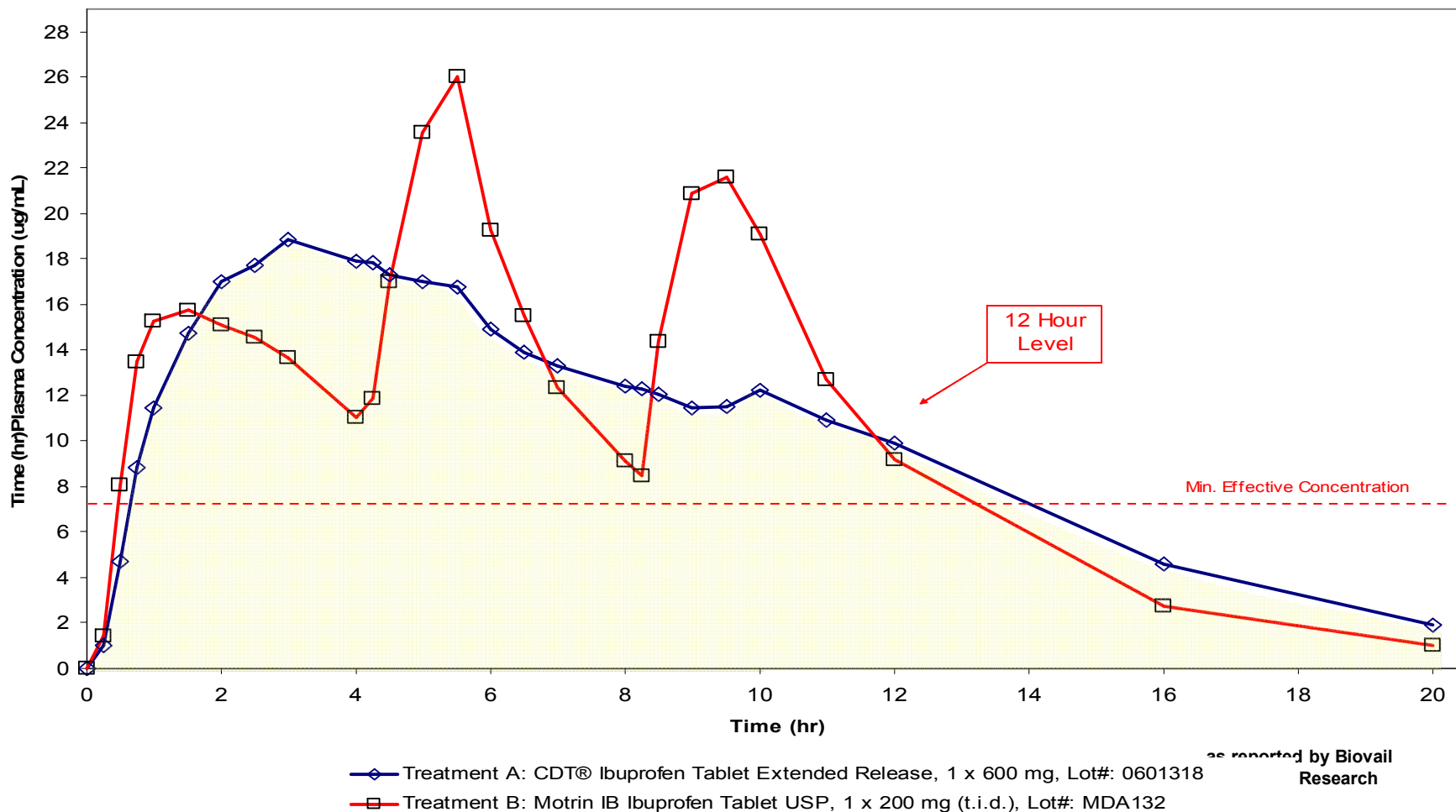


Ibuprofen - Reproducible PK response

Biovail Contract Research
A Division of Biovail Corporation

Study No.: 3313
Ibuprofen Tablets Extended Release 600 mg
Study Reported: November 20, 2006

Figure 11.1 - Mean plasma ibuprofen concentration versus time (n=34)



Ibuprofen - Successful pivotal phase III clinical

Multiple dose, Dental Pain Trial, Safety & Efficacy trial

- 256 subject randomized (169 active : 87 placebo)
- Extraction of 1-2 impacted molars with confirmed moderate pain (>5)
- Subjects given study medication every 12 hours for 48 hours total

Co-Primary Endpoints Achieved:

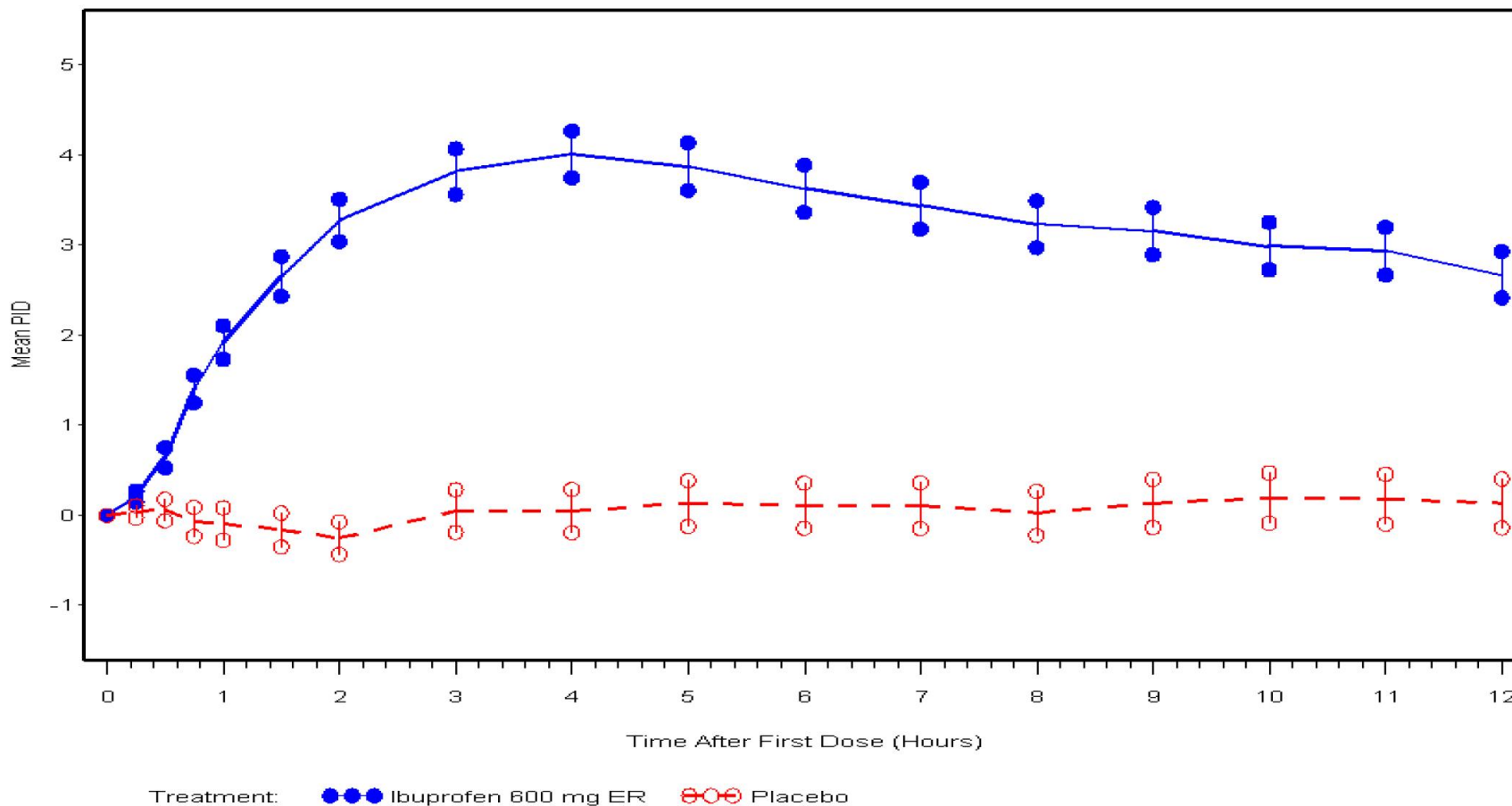
- Demonstration of effective pain relief over a full 12 hours
- Durability of effect with repeat doses over 48 hours
- Demonstrated at least a 20% improvement over baseline (starting) pain

Key Secondary Endpoint:

- “Confirmed” onset of effect in less than 1 hour

SCOLR formulation showed significant (>20%) reduction in pain over 12 hours compared to baseline (starting) pain.

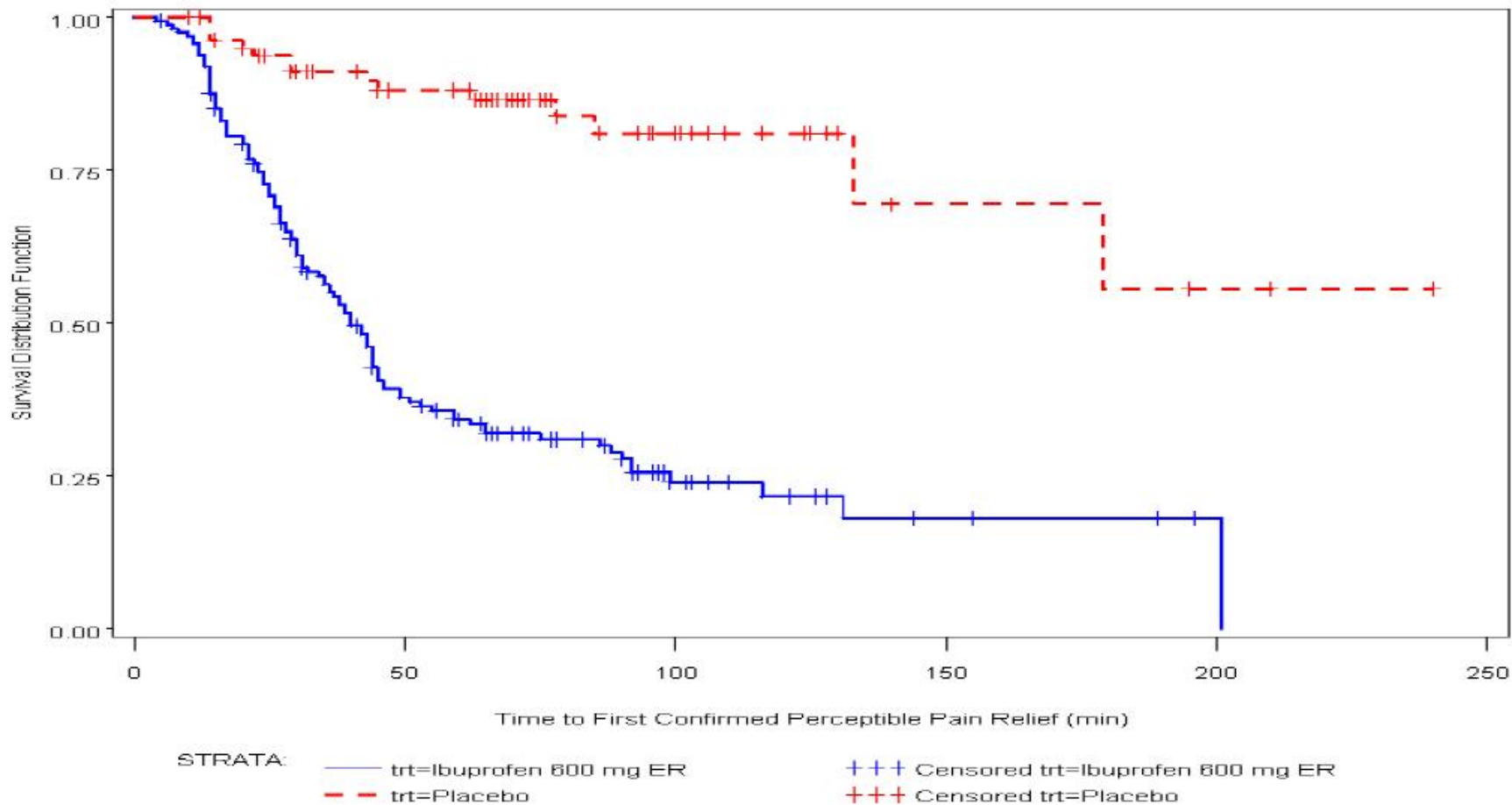
Figure 14.2.11.2
Mean Pain Intensity Difference (PID) Scores by Time After First Dose (Completed Group)



Note: Upper/Lower Limit = Mean PID +/- 1 x Standard Error.

SCOLR formulation showed strong response for onset of effect (time to initial pain relief) as compared to placebo

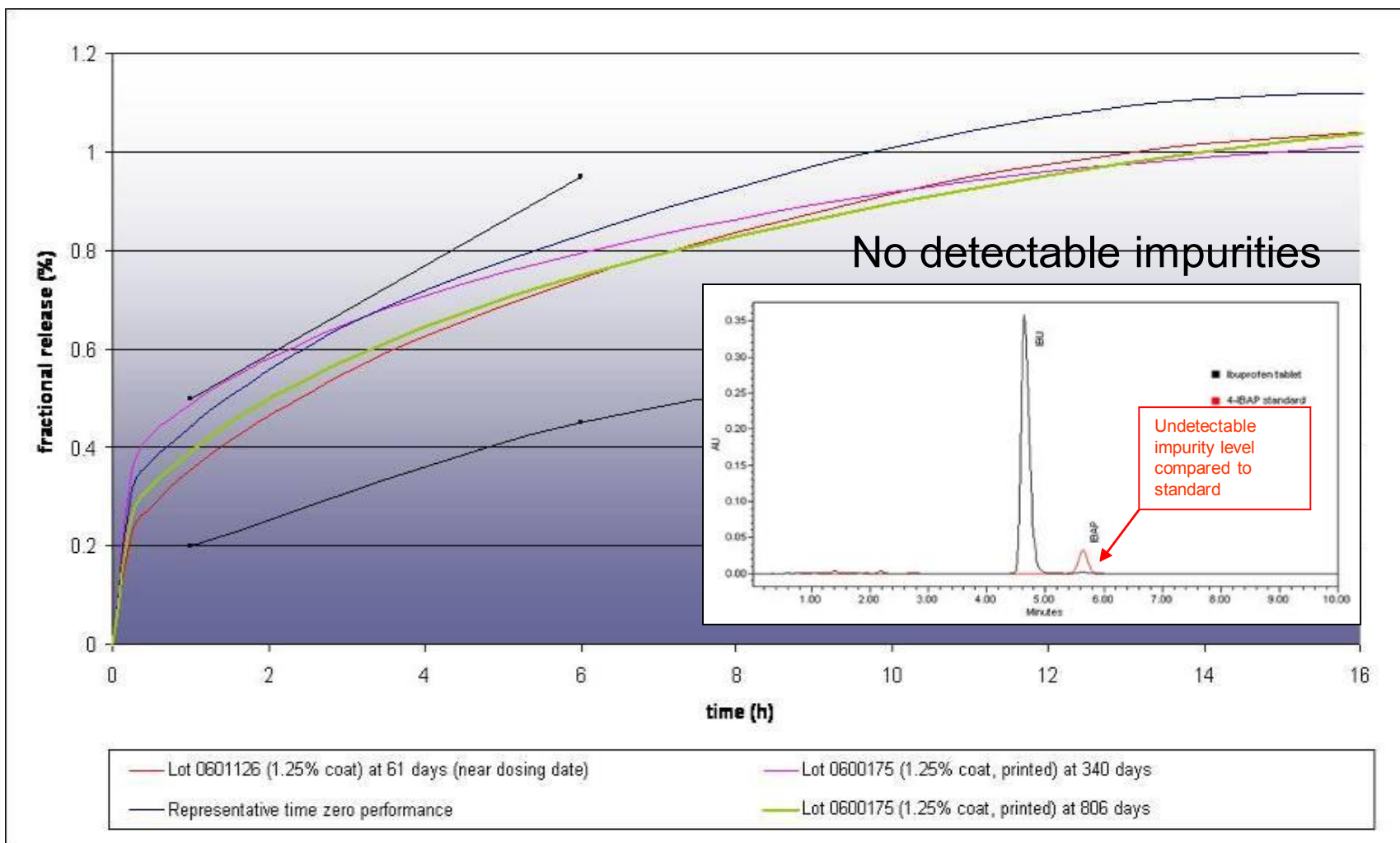
Figure 14.2.15.2
Time to First Confirmed Perceptible Pain Relief (min) After First Dose (Completed Group)



Note: Subjects who took rescue medication were censored at the time of rescue medication or the last evaluation.

Ibuprofen - Proven stability required for commercialization

(Ambient storage conditions, 25°C/60%RH, over 806 days)



Formulation meets all proposed specifications under ICH stability storage conditions

Room Temperature (Ambient):

- 25°C / 60% RH, through 12 months. Testing ongoing through 36 months

Intermediate:

- 30°C / 65% RH, complete through 12 months

Accelerated:

- 40°C / 75% RH, complete through 3 months

Ibuprofen - Patent and Exclusivity Potential:

- Formulations utilize proprietary formulation and manufacturing process

- Patent applications currently under examination:
 - Modified release ibuprofen dosage form - filed 9/2005
 - Modified release ibuprofen dosage form - filed 12/2006
 - Method of forming a tablet - filed 10/2007

- Efficacy Clinical trial positions product for three years exclusivity versus any follow on ANDA submissions

Competitive Landscape:

- Ibuprofen was first marketed in the U.S. in 1974 as a prescription drug and then in 1984 as an over-the-counter (OTC) product.
- OTC - 200 mg tablet taken every 4 hours as needed. No more than 1200 mg per day
- RX - 400, 600 & 800 mg tablets taken every 4 hours as needed. No more than 3200 mg per day
- SCOLR Formulation - 600 mg tablet taken once every 12 hours. Only ibuprofen providing both immediate and sustained relief for 12 hours

Ibuprofen is a more effective analgesic:

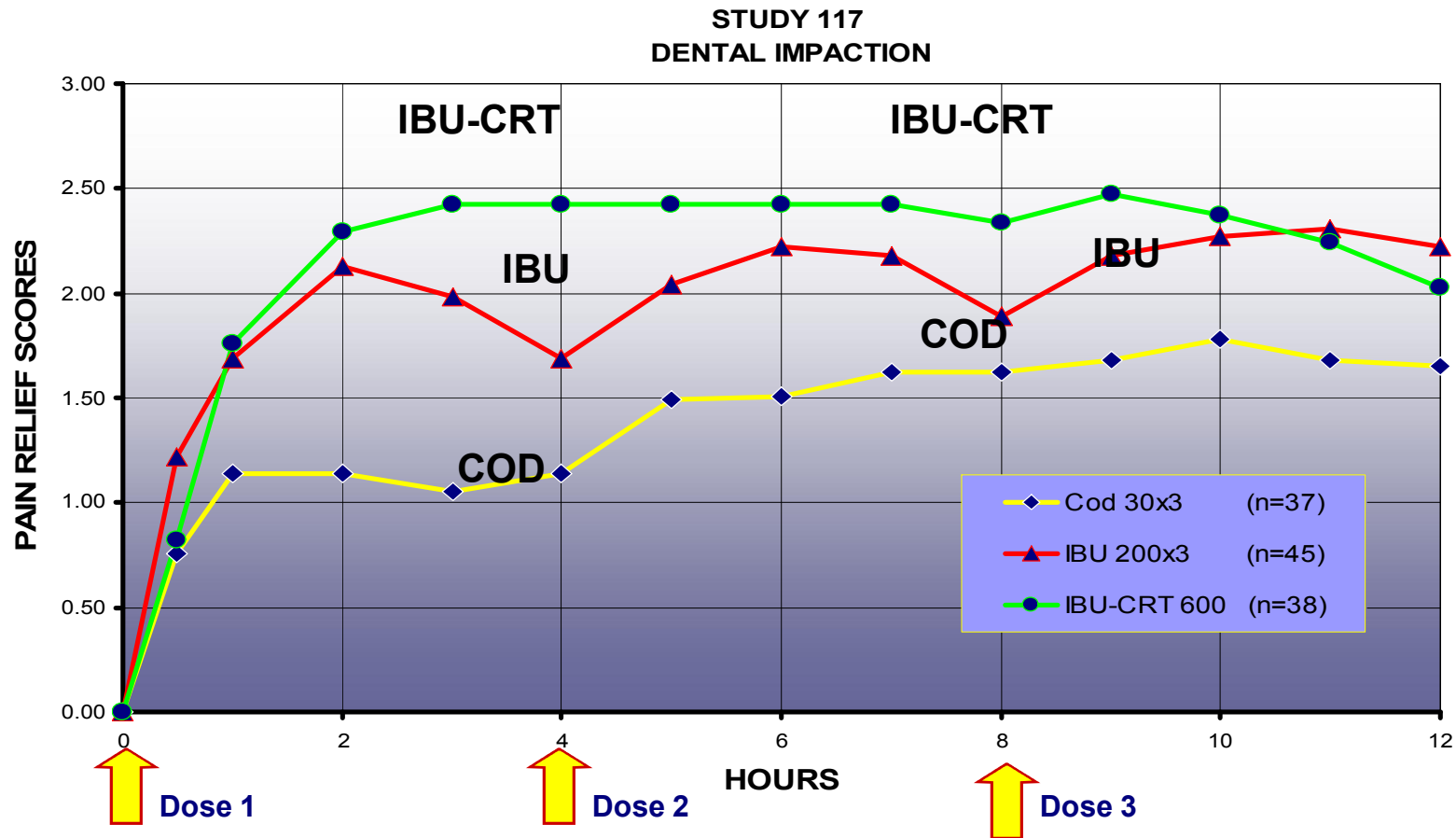
- Analgesic efficacy of OTC ibuprofen has been evaluated extensively.
- A single dose of ibuprofen provides superior analgesic relief compared to acetaminophen and aspirin.*
- Marketed formulations of OTC ibuprofen are indicated for re-dosing every 4 to 6 hours.
- Longer-lasting pain relief requires numerous and frequent doses

A 12-hour ibuprofen would provide continuous pain relief in addition to dosing convenience

*Citations available upon request

SR Ibuprofen - potential for superiority claims

Literature data: Previous controlled-release formulation (IBU-CRT) provides superior relief vs. immediate-release (IBU) or codeine (COD) 30 mg.



SA Cooper, et al; Oral Surg, Oral Med, Oral Path
75:677-683, 1993.

Superiority Trial concept:

- SCOLR's 600 mg 12-hour ibuprofen vs. commercially available OTC analgesics
- Utilize a similar pain model and general design as SCOLR's recently completed pivotal phase III efficacy study
- Relatively short duration and low cost
 - Estimated 8 weeks in the clinic, \$750 K per arm
 - Total trial: Estimated 8 months, \$3 million
- Trial assumptions:
 - 150 subjects per group, Tylenol®, Advil®, Motrin® and SCOLR. Additional groups could be added.
 - Single site, 24 hours in clinic
 - No long term repeat doses (could do longer study)

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Tylenol® & Motrin® are registered trademarks of McNeil Consumer Healthcare

Market for SCOLR Pharma CDT® Ibuprofen OTC Product

- Addressable Global OTC analgesic market of >\$2.5b
 - Ibuprofen >\$1b
 - Advil® >\$600m
 - Motrin® >\$100m
 - Private-label / store brands >\$300m
 - Acetaminophen® > \$1b
 - Tylenol® > \$500m and Tylenol-Arthritis® >\$100m
 - Private-label / store brands >\$400m
 - Naproxen > \$500m
 - Aleve® >\$350m
 - Private-label / store brands >\$150m
- Significant upside potential if SCOLR CDT® Ibuprofen demonstrates superiority to other OTC NSAIDs

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Market for SCOLR Pharma Ibuprofen OTC Combination Products

- Novel Ibuprofen-antihistamines
 - Addressable Global market of >\$1b
 - Combinations applicable to the following antihistamines
 - Cetirizine (Zyrtec®) >\$300m
 - Desloratadine (Clarinox®) >\$790m
 - Loratadine (Claritin®) >\$400m
 - Fexofenadine (Allegra®) >\$900m
- Ibuprofen-pseudoephedrine
 - Advil Cold & Sinus® >\$70m, Tylenol Cold® >\$175m
- Ibuprofen-diphenhydramine
 - Advil PM® >\$75m, Tylenol PM® >\$200m
- Novel ibuprofen-guaifenesin (Mucinex®) >\$300m

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Market for SCOLR Pharma Ibuprofen Rx and Combo Products

- Ibuprofen Rx
 - Addressable Global market of >\$350m
- Ibuprofen-Hydrocodone
 - Addressable Global market of >\$500m
 - ER formulation of popular opioid combination for dental pain
 - Ibuprofen/Hydrocodone (Vicoprofen®) >\$150m
 - APAP/Hydrocodone (Vicodin®) >\$2b
 - Technology applicable to other analgesics
 - Tramadol ER (Ultram ER®) >\$250m
 - APAP/Tramadol (Ultracet®) >\$300m
- Ibuprofen-Sumatriptan
 - Novel ibuprofen/anti-migraine formulation
 - Addressable Global market of >\$1b
 - Naproxen/Sumatriptan (Treximet®) >\$250m

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Summary: 600 mg 12-hour Ibuprofen

- Simple dry blend and directly compressed tablet
- Cost effective three step process, (blend, compress & coat): Efficient process transfer
- True bimodal (fast then slow) release satisfies needs without incorporating complex layers or coatings
- Reproducible PK performance, demonstrates robust and rugged formulation
- Successful phase III efficacy study
- Formulation and process scaled to 1.0 million tablets batches (~1200 kg blend).
- Demonstrated stability