Human Study of the *Safety* and *Efficacy* of 500 mcg of BPC-157 in a Delayed Capsule

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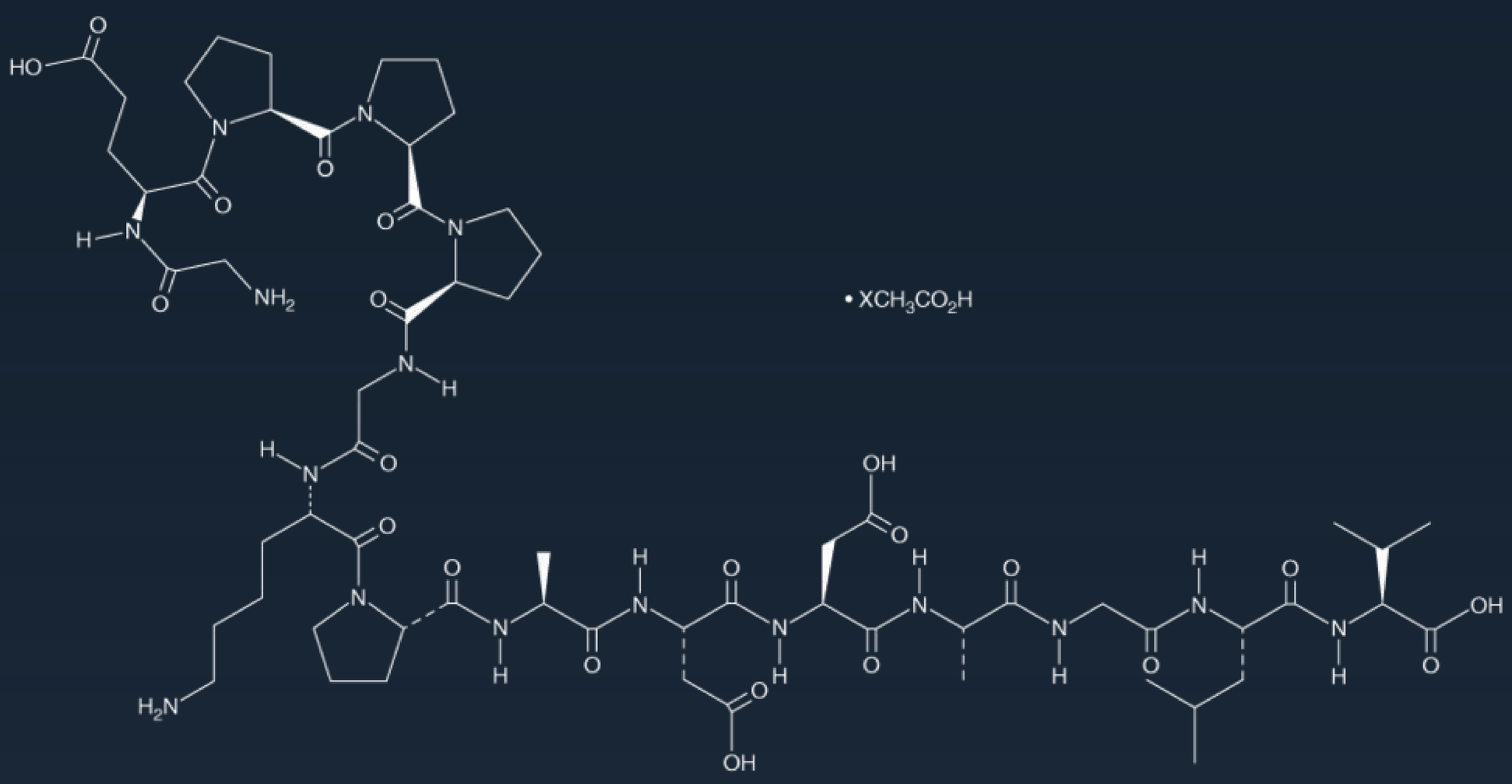
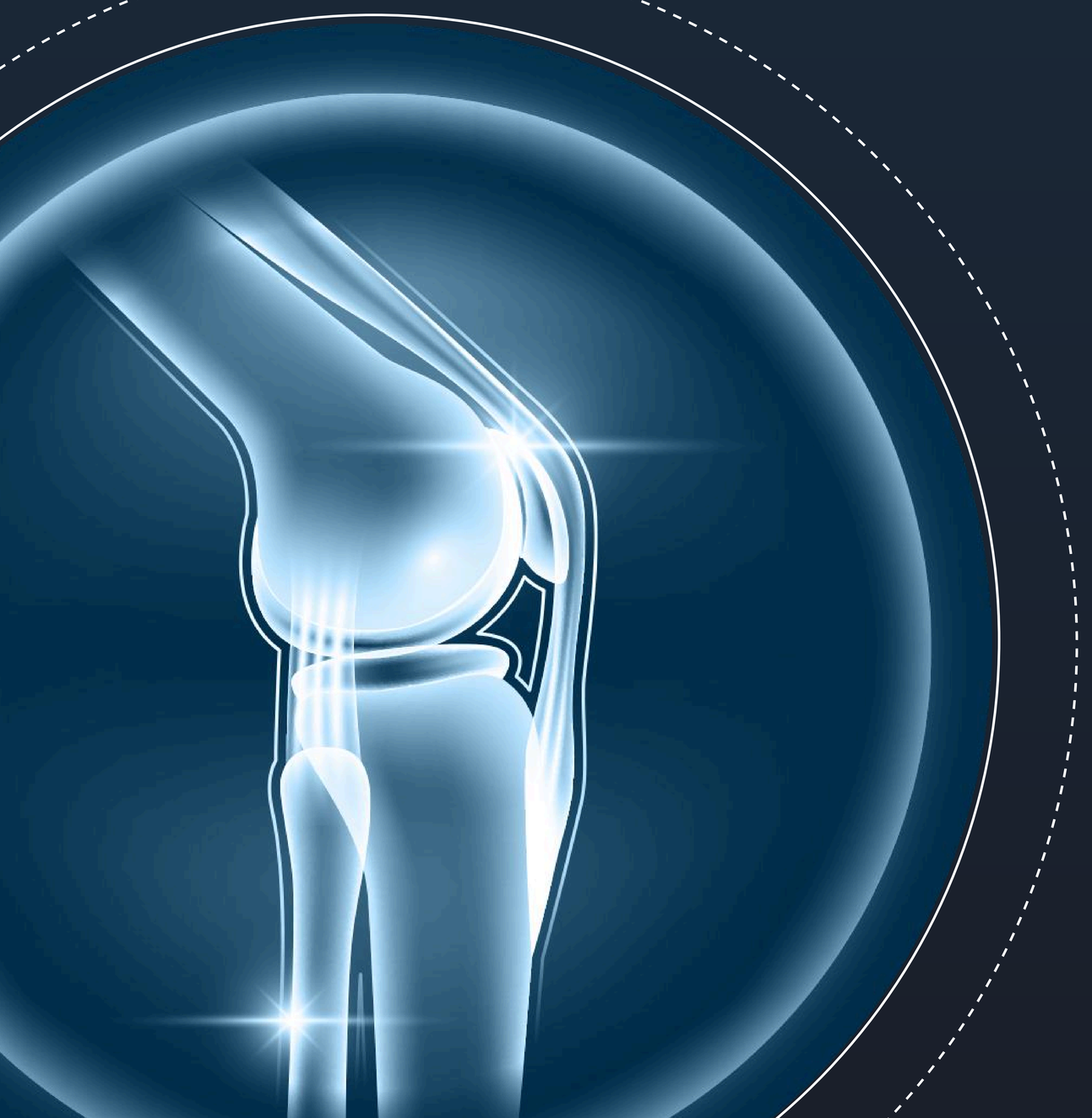
Summary of Results August 22, 2024





Abstract

This first-ever human study on oral BPC-157 evaluated the safety and efficacy of 500 mcg of BPC-157 in a delayed release capsule among adults with chronic pain, offering groundbreaking insight into a novel delivery method. Over one month, participants demonstrated statistically significant reductions in pain intensity, interference, and quality—particularly beneficial for individuals who have suffered from chronic severe low back pain and neuropathic pain in the feet, two conditions that affect vast patient populations. With high compliance, NO ADVERSE EVENTS, and strong participant satisfaction, these findings suggest a promising new therapeutic option for chronic pain management.

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Study Sample

n=101
Provided baseline & end of study outcomes data

Demographic characteristics:

Age

Average 57.7 years

- 30-54 = 36.6%
- 55-64 = 33.7%
- 65-75 = 29.7%

Sex

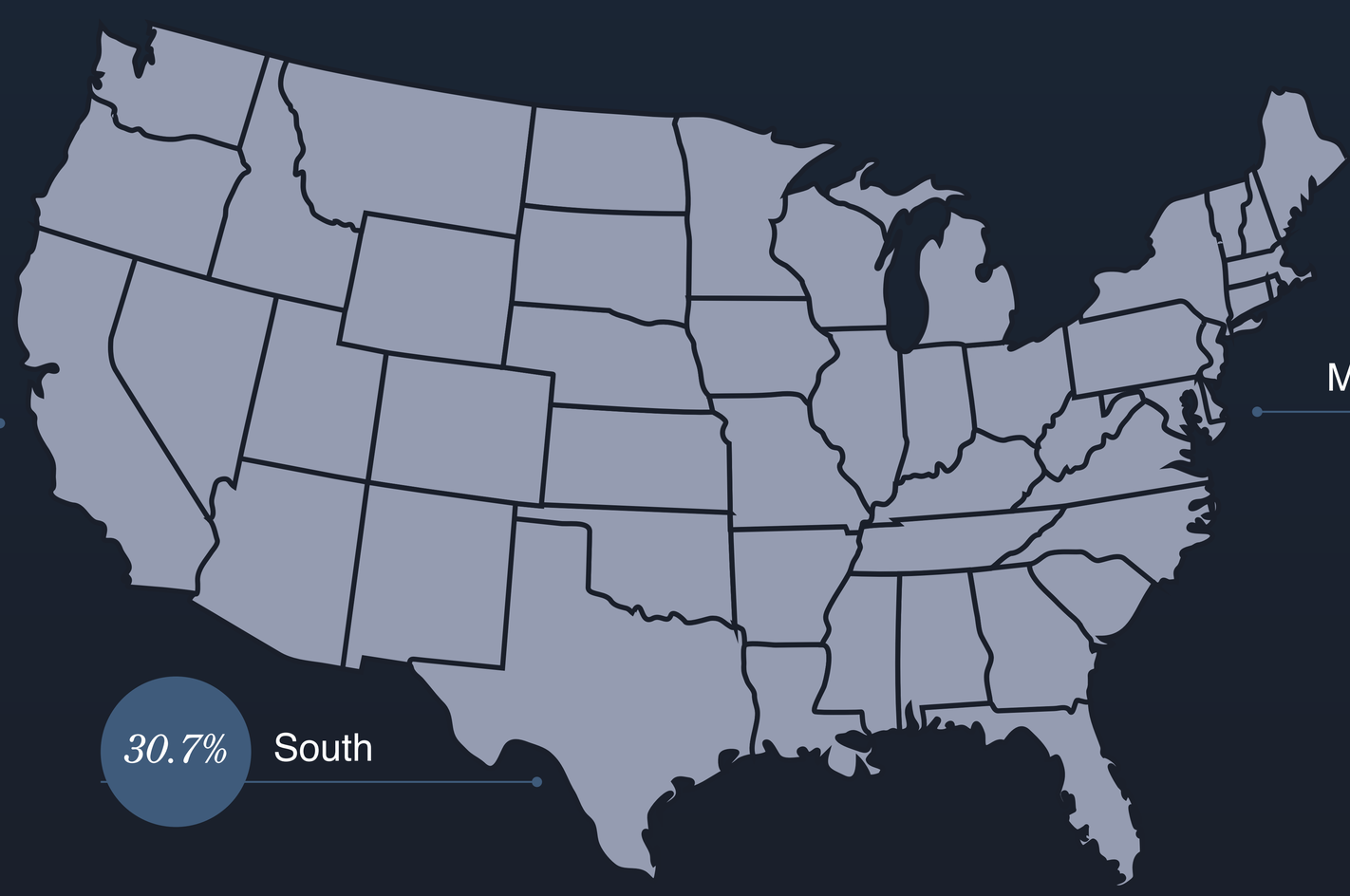
Male 52.5%

Female 47.5%

Ethnicity

- *75.2%* Caucasian
- *10.9%* African-American
- *6.9%* Hispanic
- *4.0%* Asian/Pacific Islander
- *3.0%* Other

Region



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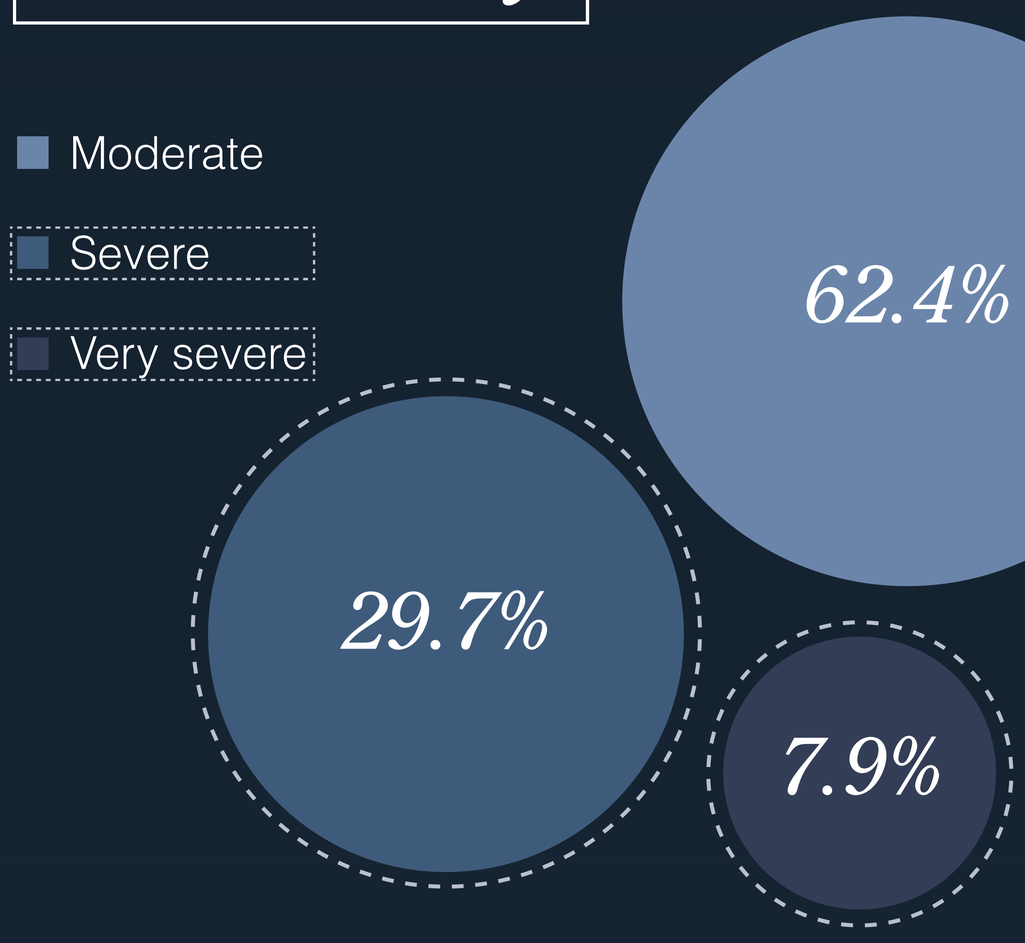
Pain characteristics:

Pain severity



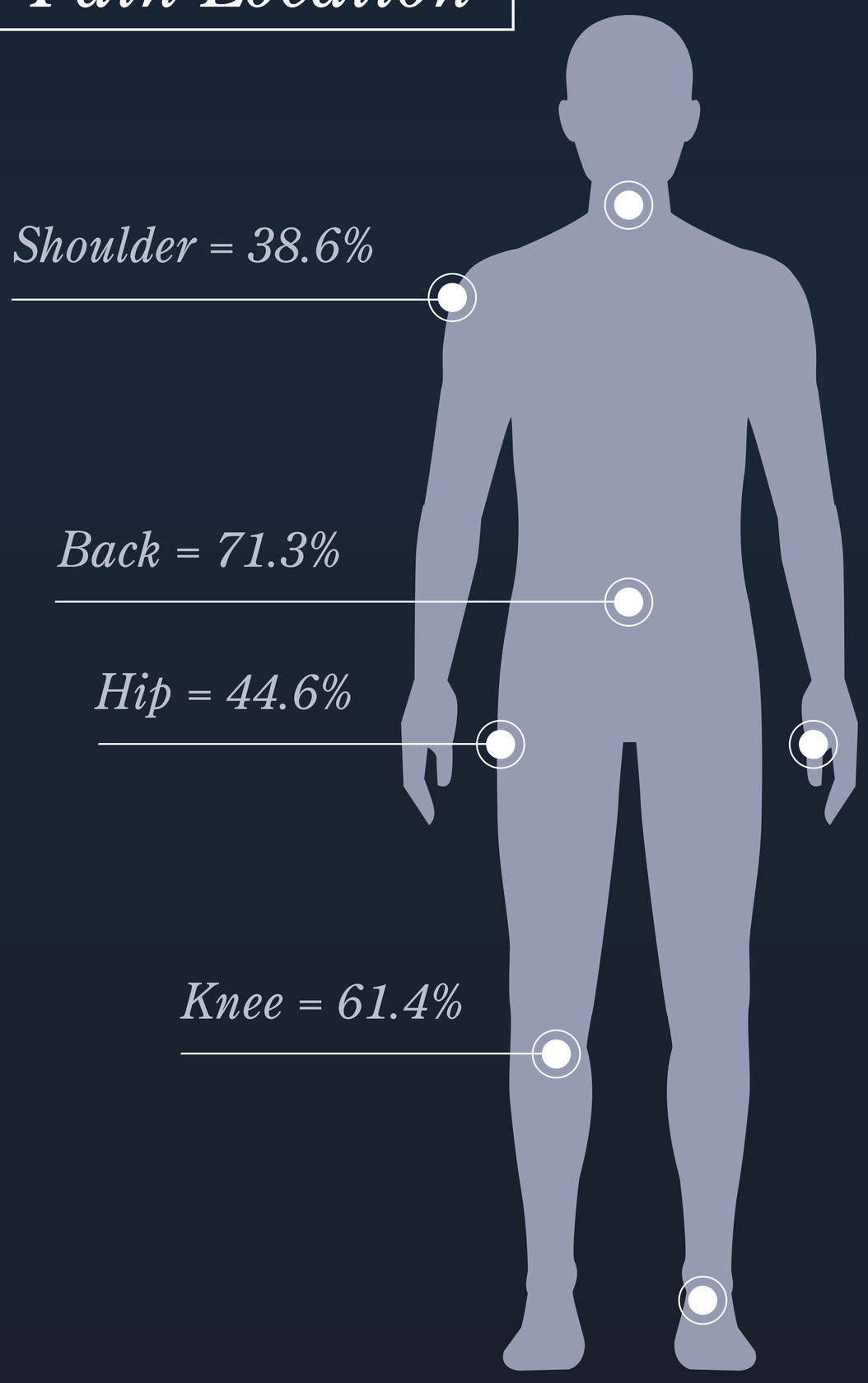
Pain Duration

1-3 months = 3.0%

3-6 months = 6.9%

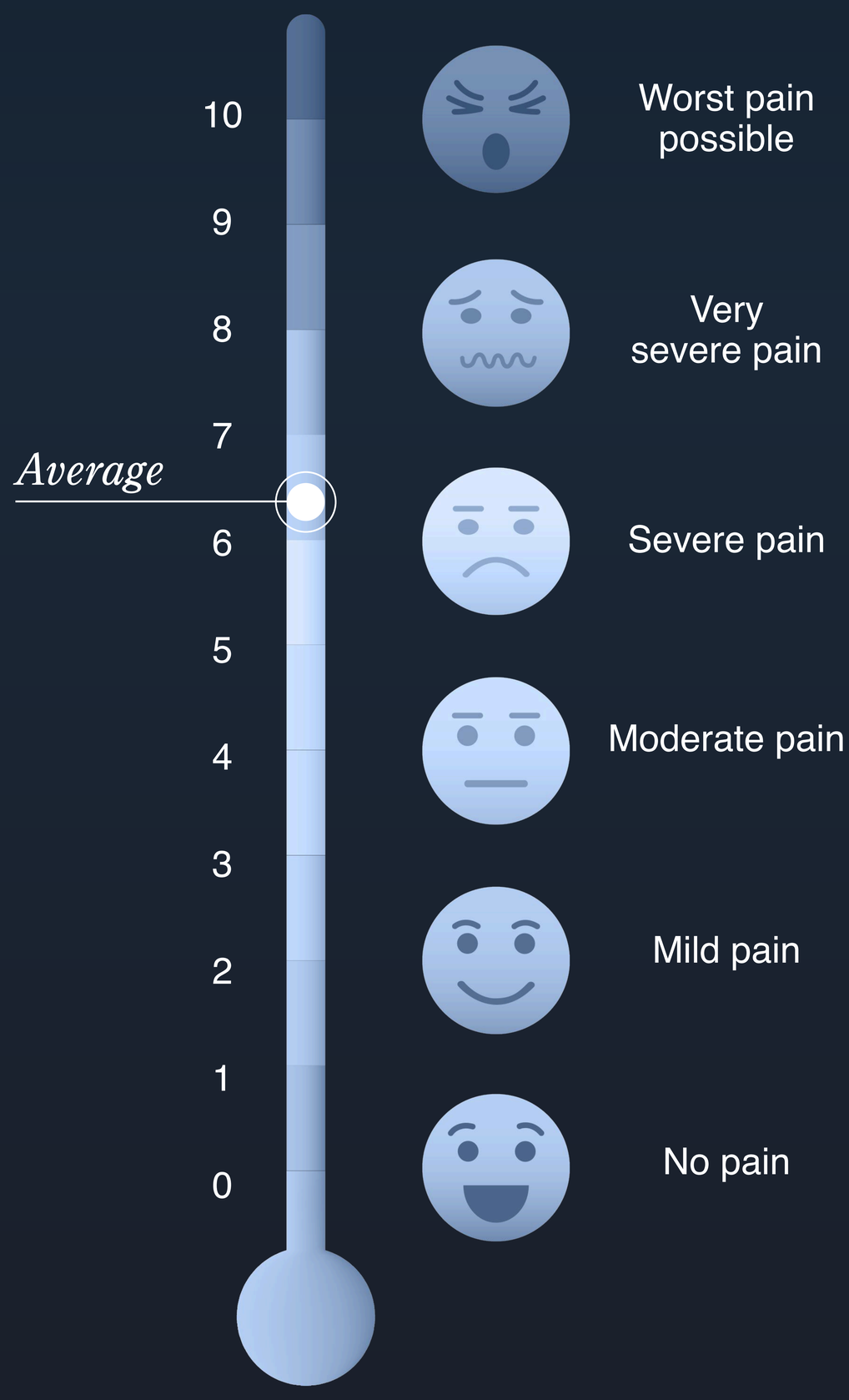
> 6 months = 90.1%

Pain Location



Pain rating

Average = 6.01



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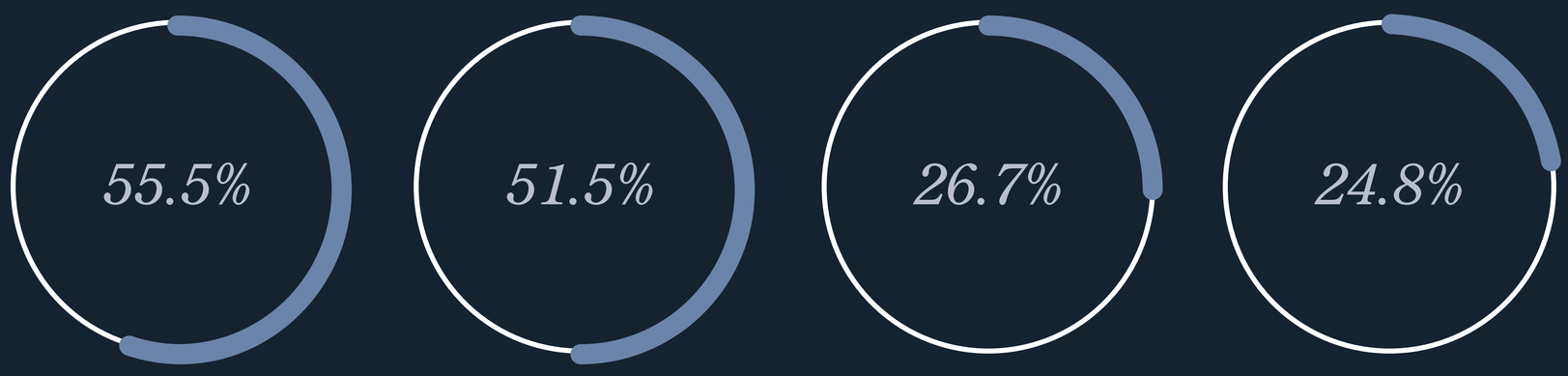
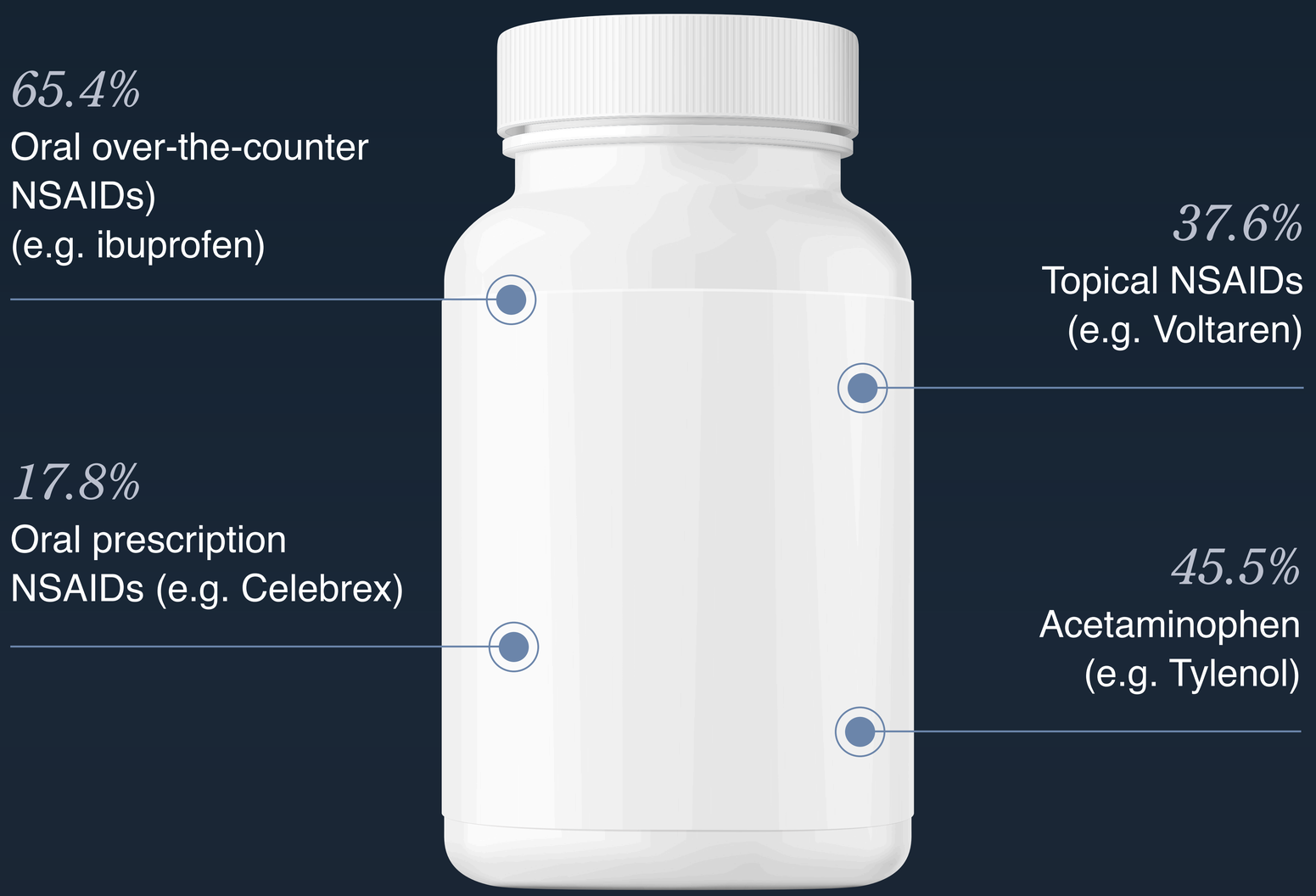
Type of pain



*Neuropathic Pain is often associated with blood sugar dysregulation and results in a variety of intense pain in the lower extremities, most commonly the feet.

Pain medication use



Materials & Methods

Compound: BPC-157 Arginate Salt with enhancement of Salcoprozate Sodium (SNAC) for optimized absorption.

Suggested Use: 500 mcg BID; 1 capsule in AM, 1 capsule in PM

Duration of Use: 4 weeks

Results

Excellent compliance – 85.2% took product as directed

Perfect SAFETY – no adverse events reported!

Primary Analysis - PROMIS T-Scores amoung Entire Study Sample (n=101)*

	Baseline	*End of Study*	*Difference*	*p value*
Pain Intensity	65.0	58.7	6.3	<0.0001
Pain Interference	62.8	57.8	5.0	<0.0001
Pain Quality	53.7	47.2	6.5	<0.0001

*Since pain is subjective, a change of 3+ points on the PROMIS scale is considered a clinically significant improvement, meaning a all reductions represent reductions in pain parameters as well as important improvement in quality of life for the study participants.

90%+ Of participants had an improvement in pain intensity and pain interference.

72.2% Had a clinically meaningful improvement in pain intensity

51.5% Had a clinically meaningful improvement in pain interference ***(how pain interferes with life)***

66.3% Of participants ***satisfied*** or ***very satisfied***
Only ***6.0%*** dissatisfied

52.5% Of participants likely or ***very likely to purchase*** *product* ***again***
Only ***13.9%*** not likely or not at all likely to purchase product

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Improvements in Activities of Daily Living:

In the Participants Own Words

- 'Because of the decrease in pain, I was able to do everyday, basic things much easier.'
- ‘Could walk for longer distances.'
- 'Was able to sleep far more comfortably.'
- 'I felt more energy and my sleep was better.'
- 'It helped with my dental pain.'
- 'Made my stomach calmer.'

Conclusion

500 mcg BPC-157 in a delayed release capsule offers statistically significant & clinically meaningful reduction in validated metrics of pain

- Diverse sample of adults with chronic pain
- Benefits all pain types… relatively unique among natural products
- Particularly beneficial for severe pain & lower-body pain (specifically low back & feet)
- Placebo effect possible… though participants long-standing pain & on many medications