

# Real World Evidence of Sustained Improvements Following Percutaneous PNS: A Cross-Sectional Follow-Up Survey of 354 Patients



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#### BACKGROUND

- A percutaneous PNS system was designed to provide PNS treatment for up to 60 days without the need for permanent implantation of hardware.
- In prospective studies across multiple common pain indications, a majority of patients experienced sustained pain relief following up to 60-days of PNS treatment. 1-8
- This retrospective, cross-sectional, follow-up survey of patients that previously underwent implantation of 60-day PNS presents the largest set of real-world data to date regarding the effectiveness and long-term impact of the 60-day PNS treatment.

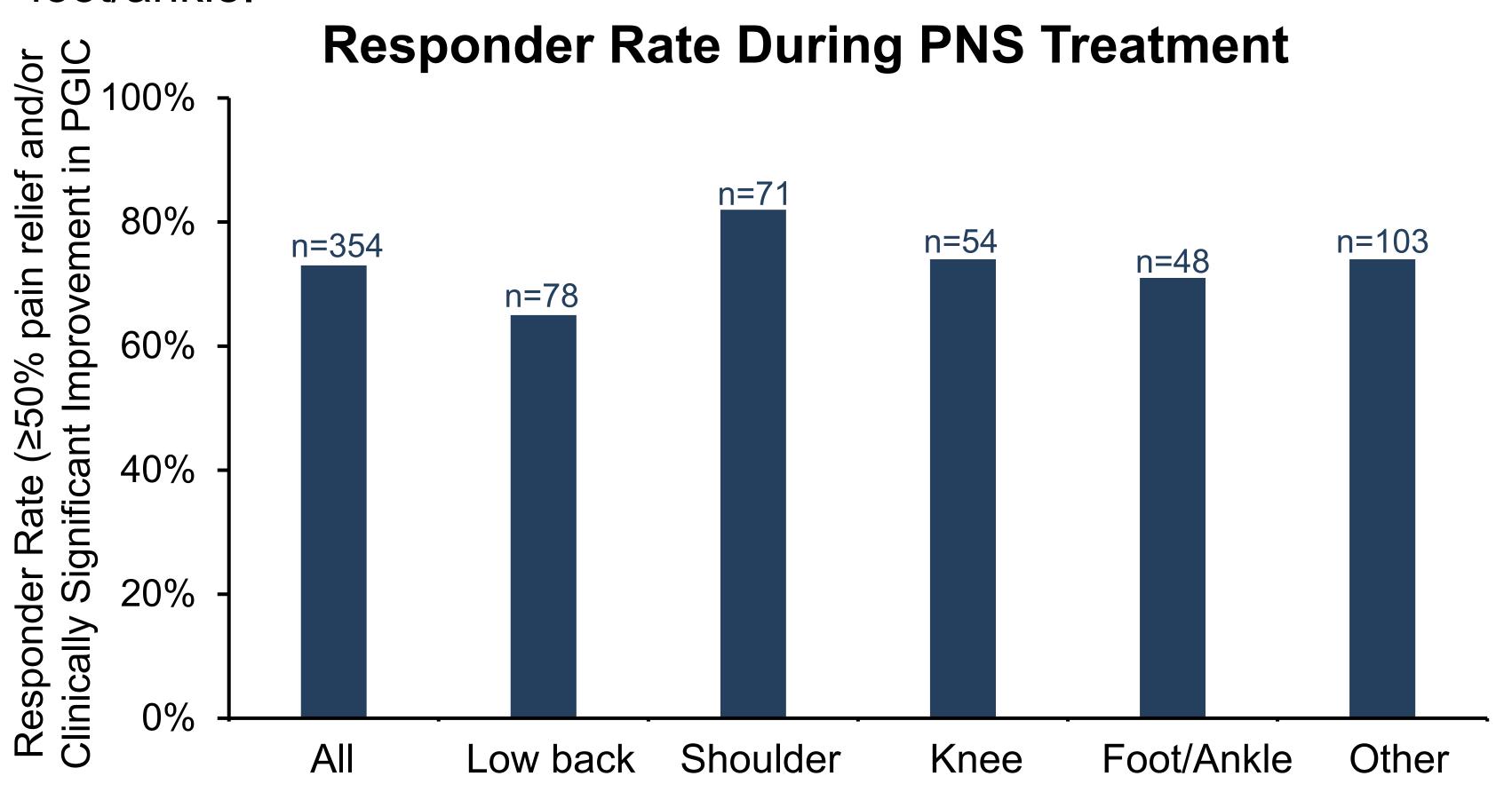
#### METHODS

- Cross-sectional, follow-up survey distributed via email by device manufacturer to 2,028 patients who underwent treatment from 03/2018 to 12/2020. Respondents were compensated \$15 for their time to complete the survey.
- Survey data were combined with baseline and treatment data from the existing database.
- Survey items included:
  - Worst pain (BPI-3)
  - Average pain (BPI-5)
  - Percent pain relief (BPI-8)
  - PGIC
  - Changes in medication usage
- Responders defined by ≥50% reduction in patient-reported percent pain relief and/or clinically significant improvement in PGIC
- Studies suggest composite endpoints that account for multiple domains can provide a more comprehensive and sensitive assessment of patient responses.<sup>9,10</sup>

#### RESULTS

#### **60-Day PNS Treatment Outcomes**

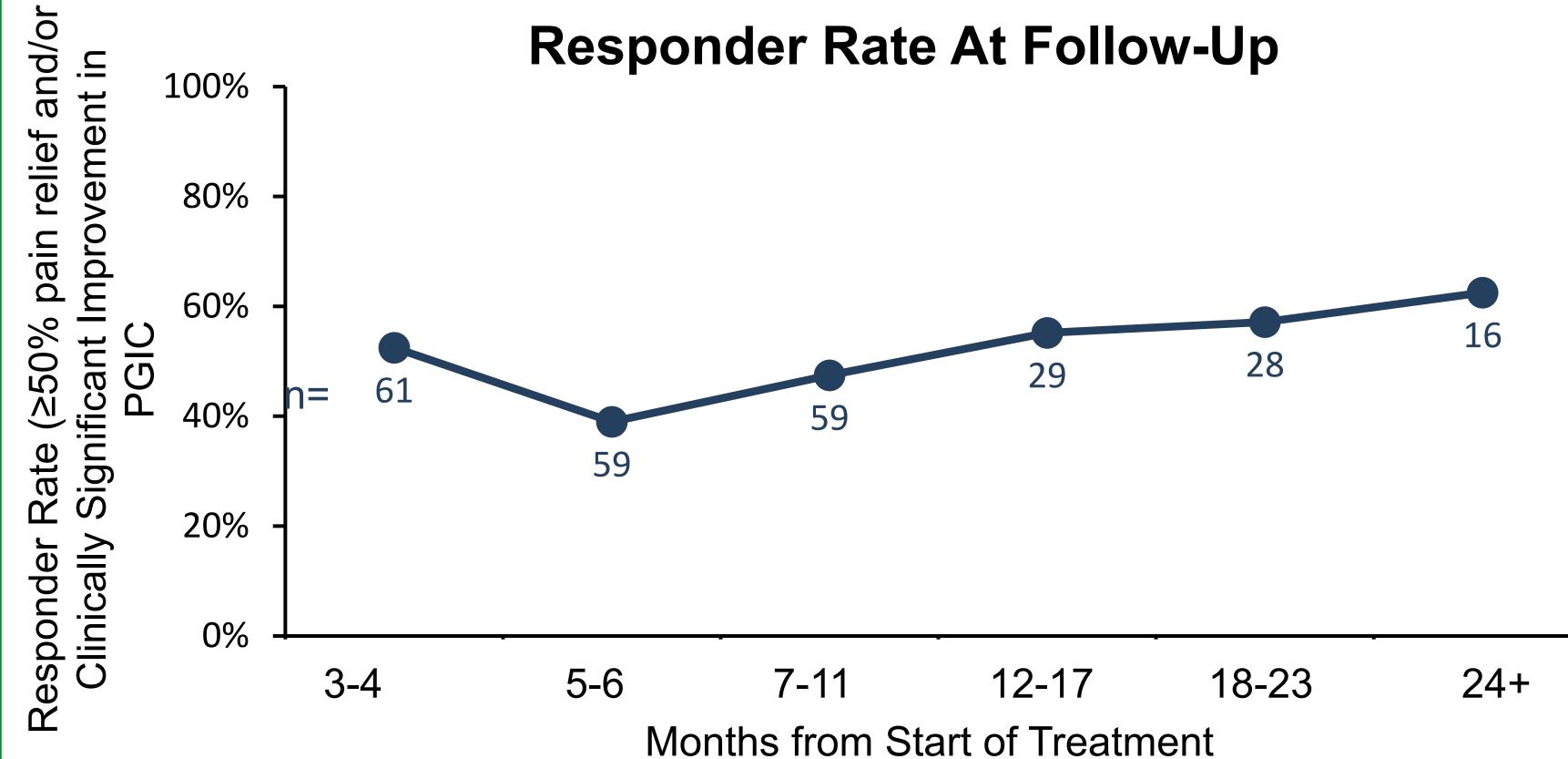
- •354 survey respondents with average duration of follow up 7.6 ± 6.9 months from the start of PNS treatment.
- Most common treatment areas were low back, shoulder, knee, and foot/ankle.



- •Mean average pain (BPI-5) rating dropped from severe at baseline (6.2 ± 1.9) to a mild severity (3.5 ± 2.4).
- •Mean worst pain (BPI-3) decreased from severe (8.8  $\pm$  1.5) at baseline to moderate severity (5.5  $\pm$  2.8).

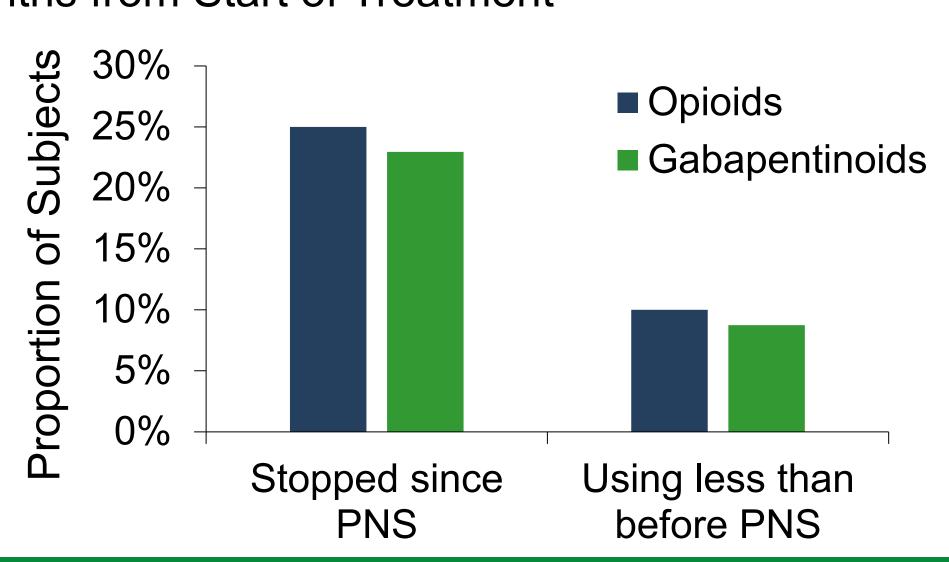
### Long-term Follow-up Outcomes

• A majority of patients had sustained long-term improvements at the time of survey completion, including those 24+ months post-PNS.



# Among those using opioids or gabapentin at baseline:

- •35% had stopped or reduced opioid usage at the time of the survey (n=56/160)
- •32% had stopped or reduced gabapentin usage at the time of the survey (n=58/183)



#### CONCLUSIONS

- This study presents the largest body of real-world evidence to-date supporting the prolonged effectiveness of 60-day PNS treatment for pain previously published across multiple clinical trials.
- These real-world data coupled with published clinical trial outcomes support the use of a 60-day PNS treatment across a wide range of pain conditions in broader clinical practice.

## REFERENCES

1. Yu et al., 2001; 2. Chae et al., 2005; 3. Rauck et al., 2014; 4. Chae et al., 2013; 5. Wilson et al., 2014a; 6. Wilson et al., 2014b; 7. Gilmore et al., 2020a; 8. Gilmore et al., 2020b; 9. Patel et al., 2018; 10. Pilitsis et al., 2021 11. Woo et al. 2015

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