Early Prediction of Response to INP104 for the Acute Treatment of Migraine

Sara Sacco, MD, FAHS[1]; Robert Vann, PhD[2]; TinaMarie Lieu, PhD[2]; Sutapa Ray, PhD[2]; Stephen B. Shrewsbury, MB ChB[2]; Sheena K. Aurora, MD[2]

[1]Carolinas Headache Clinic, Matthews, NC, USA; [2]Impel Pharmaceuticals, Seattle, WA, USA

AHS Annual Scientific Meeting; June 9-12, 2022; Denver, CO, USA

Impel PHARMACEUTICALS

Disclosures

- Sara Sacco served on advisory boards for Allergan/AbbVie, Biohaven Pharmaceuticals, Eli Lilly, Impel Pharmaceuticals, Inc., and Teva Pharmaceuticals. She was a speaker for Allergan/AbbVie, Amgen, Biohaven, Eli Lilly, Impel Pharmaceuticals, Inc., and Teva Pharmaceuticals and as a contributing author for Eli Lilly

- Robert Vann, TinaMarie Lieu, Sutapa Ray, Stephen B. Shrewsbury, and Sheena K. Aurora are full-time employees of Impel Pharmaceuticals, Inc. and are stockholders in Impel Pharmaceuticals, Inc. Stephen B. Shrewsbury is an officer of Impel Pharmaceuticals, Inc.

- Editorial support was provided by IMPRINT Science and funded by Impel Pharmaceuticals, Inc.

Impel PHARMACEUTICALS

Introduction

Migraine is a highly prevalent and debilitating disorder, and it can result in significant patient burden[1-4]

The main goals of acute treatment include rapid relief of pain and associated symptoms with minimal recurrence, reduced use of additional rescue medications, restoration of function, reduced need for subsequent resource use, and minimized occurrence of adverse events[5]

However, many patients with migraine report dissatisfaction with the available acute treatments and may cycle through many therapies before achieving effective and adequate relief[6-8]

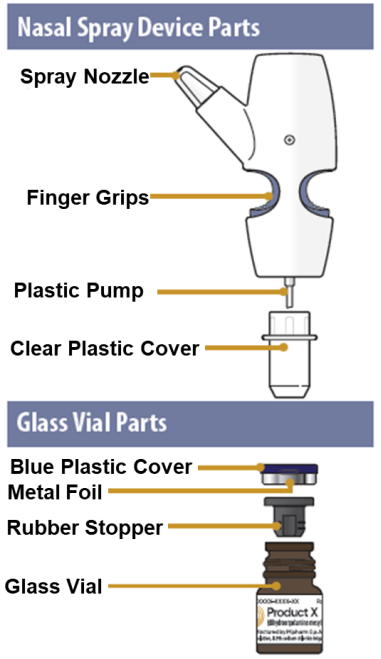
Therefore, understanding the **early prediction of response** to acute therapies for migraine may help patients and health care providers optimize the acute management of migraine

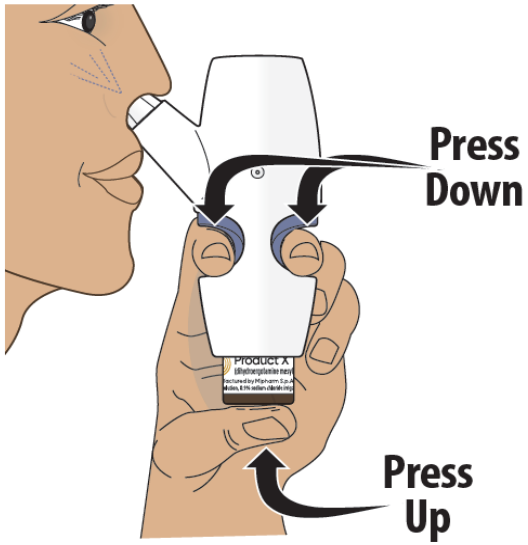
1. GBD 2016 Headache Collaborators. *Lancet Neurol.* 2018;17:954-976. 2. Leonardi M, Raggi A. *J Headache Pain*. 2019;20:41. 3. Ford JH, et al. *Headache*. 2017;57:1532-1544. 4. Blumenfeld AM, et al. *Cephalalgia*. 2011;31:301-315. 5. Silberstein SD. *Neurology*. 2000;55:754-762. 6. Lipton RB, et al. *Headache*. 2019;59:1310-1323. 7. Cooper W, et al. *Postgrad Med*. 2020;132:581-589. 8. Lipton RB, et al. *Cephalalgia*. 2020;40:437-447.

Impel PHARMACEUTICALS

Objective

- INP104 is drug-device combination product that delivers DHE to the upper nasal space using POD® technology[1] and has been approved for the acute treatment of migraine
- Previously reported data from the Phase 3 STOP 301 study showed that INP104 was well tolerated and associated with improvements in several outcomes of exploratory efficacy for the first INP104-treated MA as well as across multiple MAs over 24 and 52 weeks[1,2]





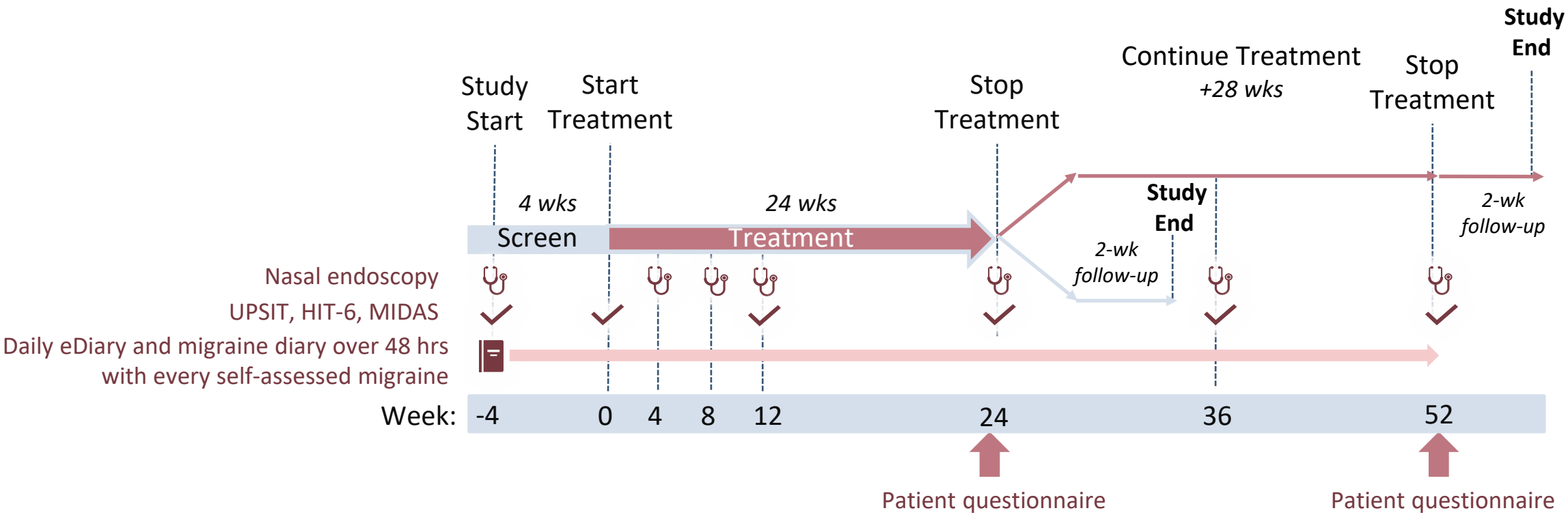
This post hoc analysis of data from the Phase 3, STOP 301 study aimed to determine if early treatment response to INP104 could predict response over consecutive MAs

DHE = dihydroergotamine mesylate; MA = migraine attack; POD = Precision Olfactory Delivery.

1. Smith TR, et al. *Headache*. 2021; 61:1214-1226. 2. Smith TR, et al. Presented at: Headache Update of the Diamond Headache Clinic; July 15-18, 2021. Lake Buena Vista, FL, USA.

Impel PHARMACEUTICALS

STOP 301: A Pivotal Phase 3, Interventional, Open-label, Single-group Assignment Study (NCT03557333)

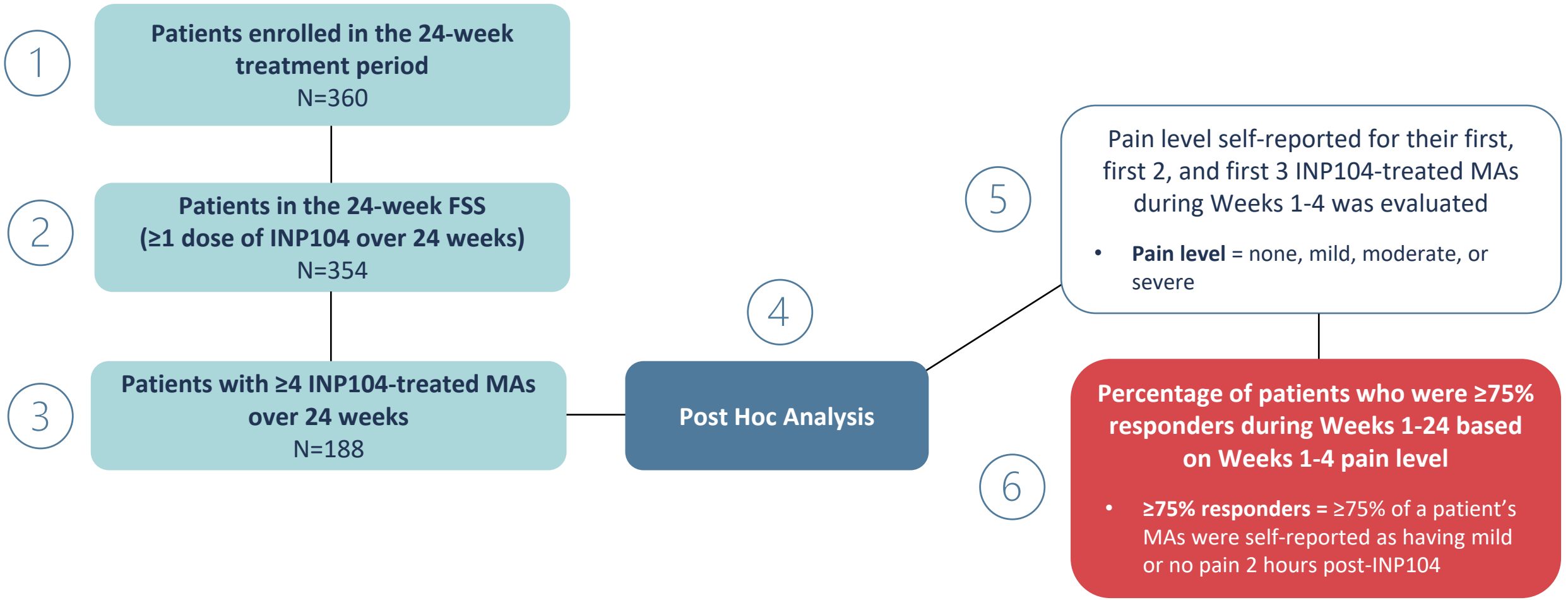


CV = cardiovascular; HIT-6 = Headache Impact Test-6; hr = hour; ICHD = *International Classification of Headache Disorders*; MA = migraine attack; MIDAS = Migraine Disability Assessment; UPSIT = University of Pennsylvania Smell Identification Test; w = with; w/o = without; wk = week.

Smith TR, et al. *Headache*. 2021;61:1214-1226.

Impel PHARMACEUTICALS

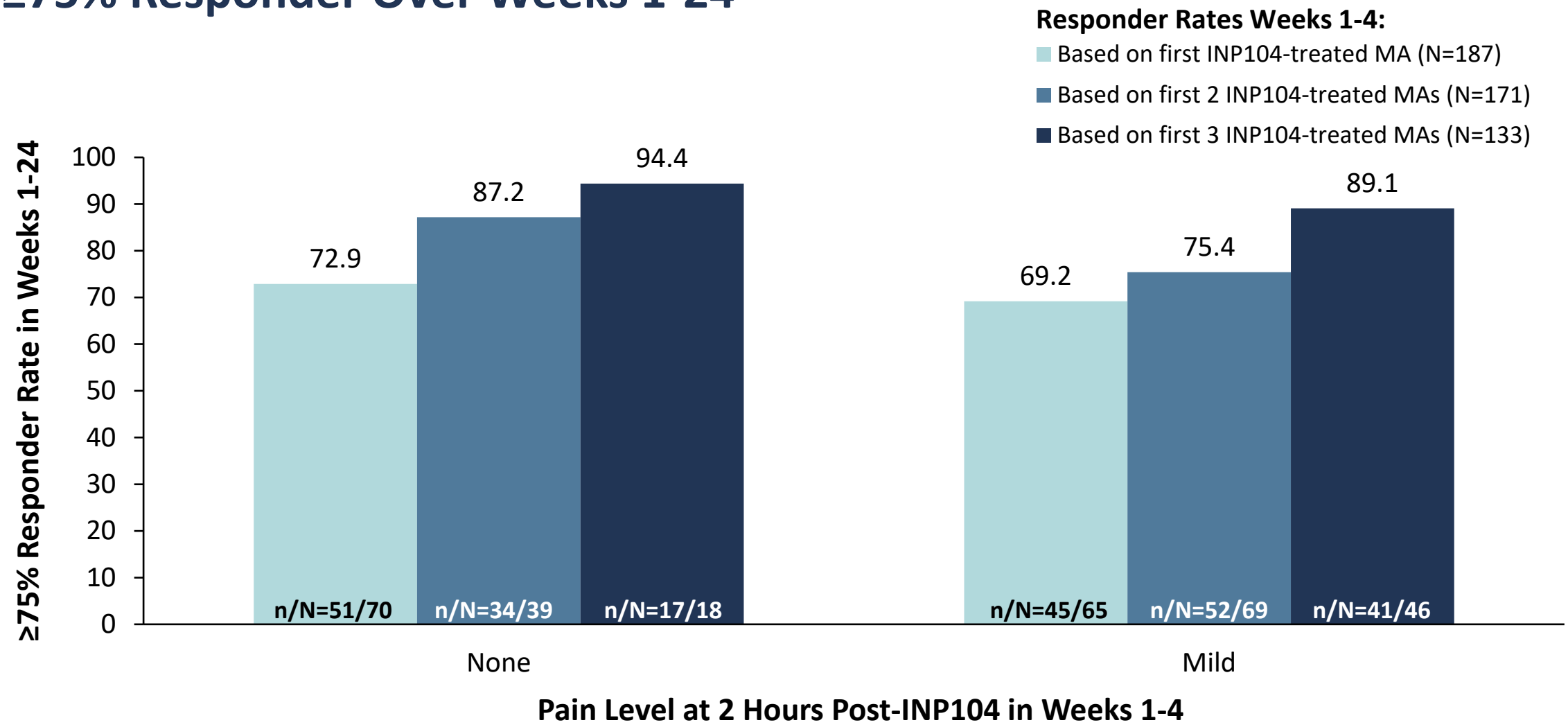
Post Hoc Analysis



FSS = full safety set; MA = migraine attack.

Impel PHARMACEUTICALS

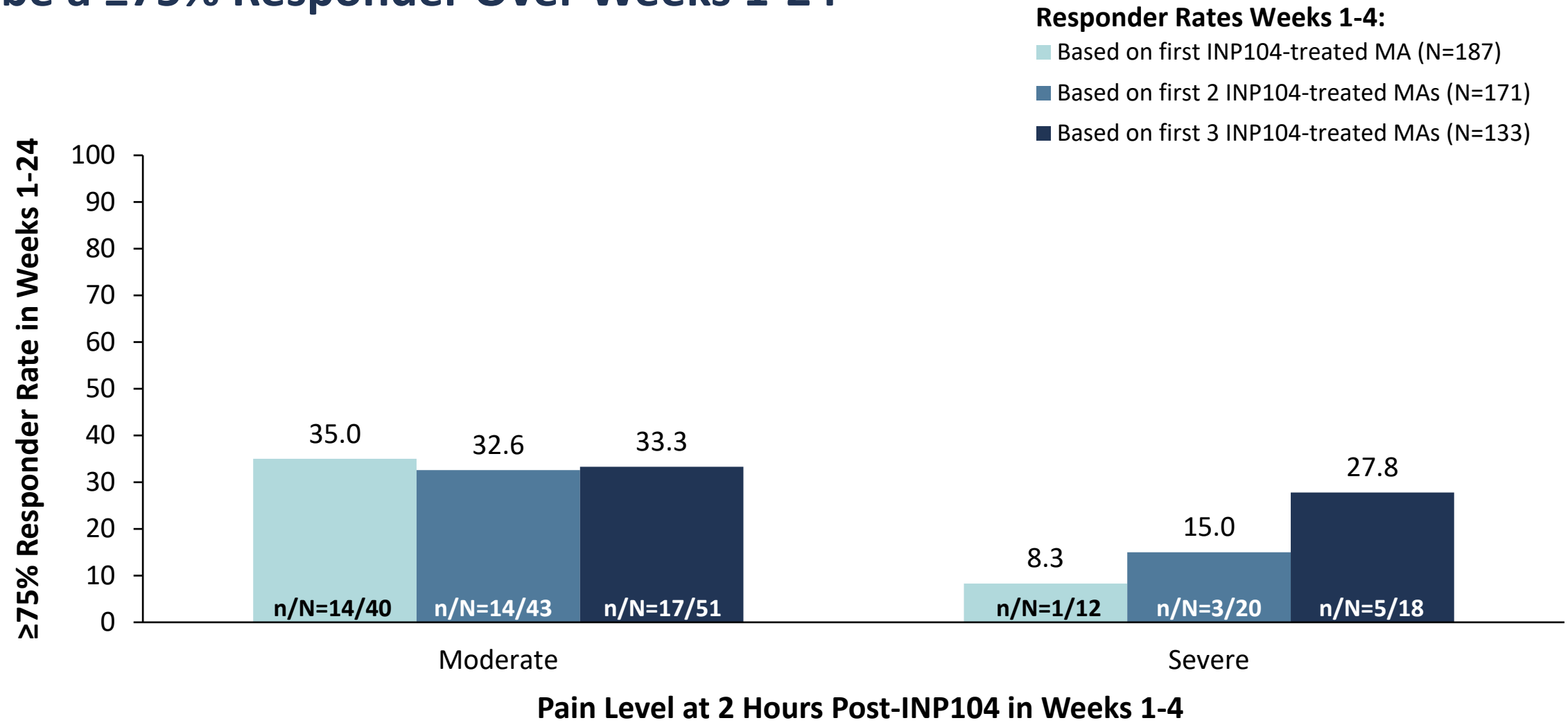
Patients Who Self-reported Mild or No Pain at 2 Hours After Treatment for Their First 3 INP104-treated MAs Are Extremely Likely (>89%) to Be a ≥75% Responder Over Weeks 1-24



Note: Data are self-reported.
FSS = full safety set; MA = migraine attack.

Impel PHARMACEUTICALS

Patients Who Self-reported Moderate or Severe Pain at 2 Hours After Treatment for Their First 3 INP104-treated MAs Are Less Likely (<34%) to be a ≥75% Responder Over Weeks 1-24



Note: Data are self-reported.
FSS = full safety set; MA = migraine attack.

Impel PHARMACEUTICALS

Conclusion

This post hoc analysis of data from the Phase 3, STOP 301 study aimed to determine if early treatment response to INP104 could predict response over consecutive MAs

- Patients who self-reported mild or no pain after treatment for their first 2 INP104-treated MAs are **likely** (>75%) to be a ≥75% responder over Weeks 1-24
- Patients who self-reported mild or no pain at 2 hours after treatment for their first 3 INP104-treated MAs are **extremely likely** (>89%) to be a ≥75% responder over Weeks 1-24
- Results from this post hoc analysis suggest that if INP104 provides pain relief (ie, mild or no pain) for the first 2-3 MAs, it is highly likely a patient will be an INP104 responder with long-term use, which is informative for clinical decision-making

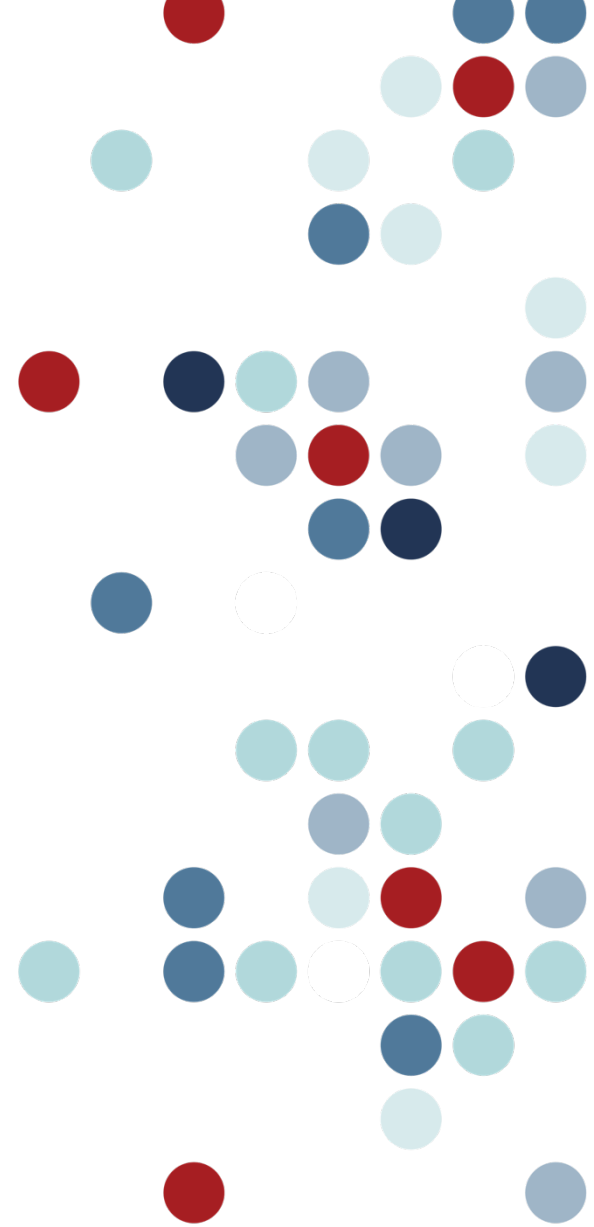
- Most patients do not have an optimal response to acute therapies for migraine,[1] highlighting the need for more reliable treatment options such as INP104
- Predictive models have the potential to individualize choice of acute medication class for MAs through a simple data-driven approach.[1] Future research needs to improve on predictive models and then prospectively explore if improvement in the selection of pharmacologic treatment gained from such treatment response predictors allows for patients or clinicians to confidently alter management plans[1]

MA = migraine attack.

1. Ezzati A, et al. *Headache*. 2022; [Epub ahead of print].

Impel PHARMACEUTICALS

THANK YOU!



Impel PHARMACEUTICALS

Q&A

Impel PHARMACEUTICALS