Long-Term Outcomes of Treatment with Responsive Brain Stimulation in Adults with Refractory Partial Seizures

**SUMMARY**

- Patients treated with the RNS® System experience substantial seizure reductions that continue to improve over time.
- At 7 years, patients achieved a 72% reduction in seizures and reported sustained improvements in quality of life.
- The risk of infection was 3.7% per neurostimulator procedure.
- 25% of subjects had a greater than or equal to 93% reduction in seizures during year 7 post-implant.

**METHODS**

**Study Design:** Data from the open label period of a randomized, controlled, double-blinded pivotal trial* and a long-term treatment (LTT) trial† with median follow up of 6.8 years.

**Population:** 256 patients† representing 1716.1 patient implant years.‡

**Effectiveness Outcomes:** Seizure reduction and quality of life

**Safety Outcomes:** Serious adverse event (SAE) rates

**KEY RESULTS**

**Long-Term Efficacy:**
- **72% median seizure reduction** at 7 years
- **66% responder rate** at 7 years
- At least one seizure-free period lasting
  - ≥3 months = 39% of patients
  - ≥6 months = 29% of patients
  - ≥1 year = 16% of patients

**Median Seizure Reduction**

![Graph showing median seizure reduction over years](chart.png)
Long-term Safety\(^1,6\)
- **SUDEP rate**\(^5\) (probable or definite) was 2.0 per 1,000 patient stimulation years (CI 0.7–5.2).
- **3.7% infection rate**\(^6\) per neurostimulator procedure. All infections except one were superficial soft tissue infections. There were no meningitis or parenchymal infections, and no chronic neurologic or medical consequences.
- **2.7% intracranial hemorrhage rate**\(^7\) with no persistent, clinically significant neurologic sequelae.

**PATIENT CHARACTERISTICS\(^1\)**

- **Region of Seizure Onset**\(^1\)
  - Neocortical 49.2%
  - Mesial Temporal 43.4%
  - Both 7.4%

Among mesial temporal patients:
- 28% unilateral
- 72% bilateral

Among neocortical patients:
- 45% temporal (non-mesial)
- 38% frontal
- 13% parietal
- 4% occipital

- **History**
  - 32% had prior treatment with vagus nerve stimulation (VNS)
  - 34% had prior treatment with epilepsy surgery
  - 65% had prior localization with intracranial monitoring

- **97% of patients chose to continue treatment by enrolling in the LTT Study.**\(^1\)
- **Efficacy results were not due to patient drop-out: the responder rate was 60% using a last observation carried forward analysis.**\(^1\)
- **There was no relationship between adjustments in AEDs and seizure outcomes.**\(^1\)

**ADDITIONAL OBSERVATIONS**

- 18 yrs. or older, refractory to 2 or more AEDs and with no more than 2 foci localized by diagnostic testing
- Interim results as of 11/01/2015
- Data represents number of patients who had reached that time point as of Nov 01, 2015.
- Data at 7 years were presented at the 2016 American Epilepsy Society meeting and are from a more recent data cut-off than those published by Bergey et al. As a result, more patients had completed 7 years of post-implant follow-up.
- Data on file, as of 05/05/2016. Presented at American Epilepsy Society Meeting. December 2016. Houston, TX.
- Device related serious adverse events not due to seizure-related head trauma
- Serious adverse events, not seizure related

See important prescribing and safety information in the RNS\(^5\) System labeling. This is intended as supplementary information and should be used in conjunction with the labeling. Refer to the labeling for a description of the RNS\(^5\) System and its components, indications for use, contraindications, warnings, cautions, adverse events and instructions for use. The manuals are available at www.NeuroPace.com. ©2017 NeuroPace, Inc. All rights reserved. NeuroPace\(^5\) and RNS\(^5\) are registered trademarks of NeuroPace, Inc. NP 150061 Rev 3 / Rev. date: 2017-02