# a new **restorative** neurostimulation therapy for chronic low back pain


## ReActiv8-B Results

(clinicaltrials.gov ID: NCT02577354)

Data beyond primary endpoint is incomplete.

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MAINSTAY MEDICAL

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# ReActiv8-B – The First Sham-Controlled Neurostim Trial For CLBP

Prospective, randomized, sham-controlled, blinded trial

204 total patients

**Sham control with one way crossover after 120 days**

**Primary outcome: responder analysis**

"Responder" - ≥30% reduction from baseline in average low back pain VAS without any increase in pain medication or muscle relaxants

Primary efficacy endpoint is achieved if statistically significant difference in Responder rate between treatment and control

**Primary Endpoint assessed 120 days post randomization**

**Secondary Endpoints include EQ-5D Quality of Life Assessment and ODI**

Key patient demographics:
Mean age: 46
Mean duration of back pain: ~14 years
80% of patients on pain medication at baseline (37% on opioids)

# ReActiv8-B Primary Efficacy Endpoint Outcomes

- Primary Efficacy Endpoint: Responder Rate comparison between treatment and control groups:

| | **120 days** N=204 |
|---|---|
| **Responders ΔVAS ≥ 30%** | **56%** |
| **Control** | 47% |

**Results do not demonstrate statistically significant difference at 120 days**

# ReActiv8-B: Therapy Response Rises Steadily through One Year

- Responder Rate comparison between treatment and control groups:

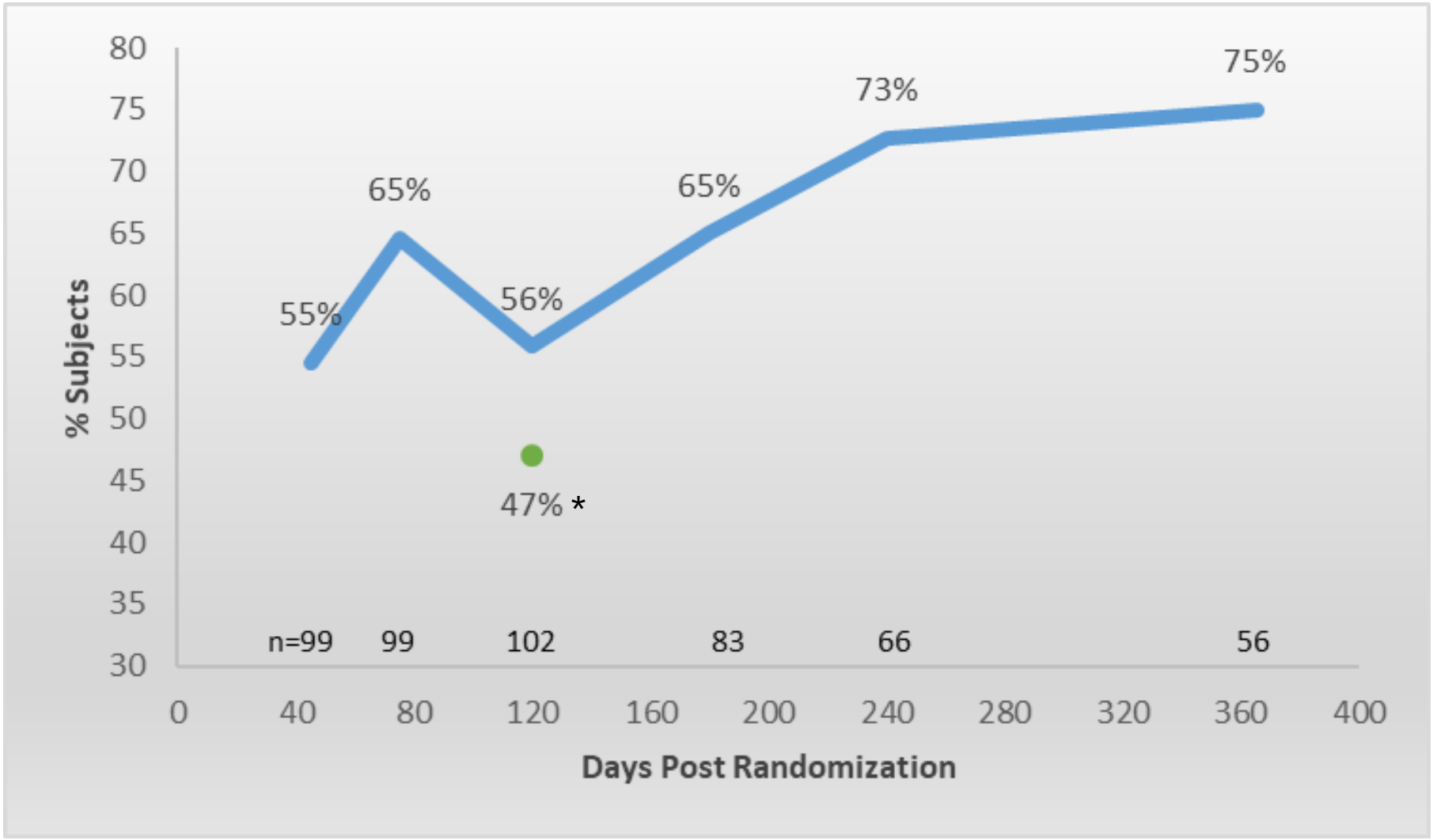
| | 120 days N=204 | 180 days N=160 | 1 Year N=116 |
|---|---|---|---|
| **Responders ΔVAS ≥ 30%** | **56%** | **63%** | **72%** |
| Control | 47% | NA | NA |
| ***Responders ΔVAS ≥ 50%** | **43%** | **53%** | **60%** |
| Control | 35% | NA | NA |
| ***Remitters (VAS ≤ 2.5)** | **33%** | **38%** | **48%** |
| Control | 28% | NA | NA |

✓ **44% of patients on opioids at baseline eliminated/reduced use at 1 year as follows:**

- ✓ **28% eliminated opioid use**
- ✓ **16% significantly reduced opioid use**

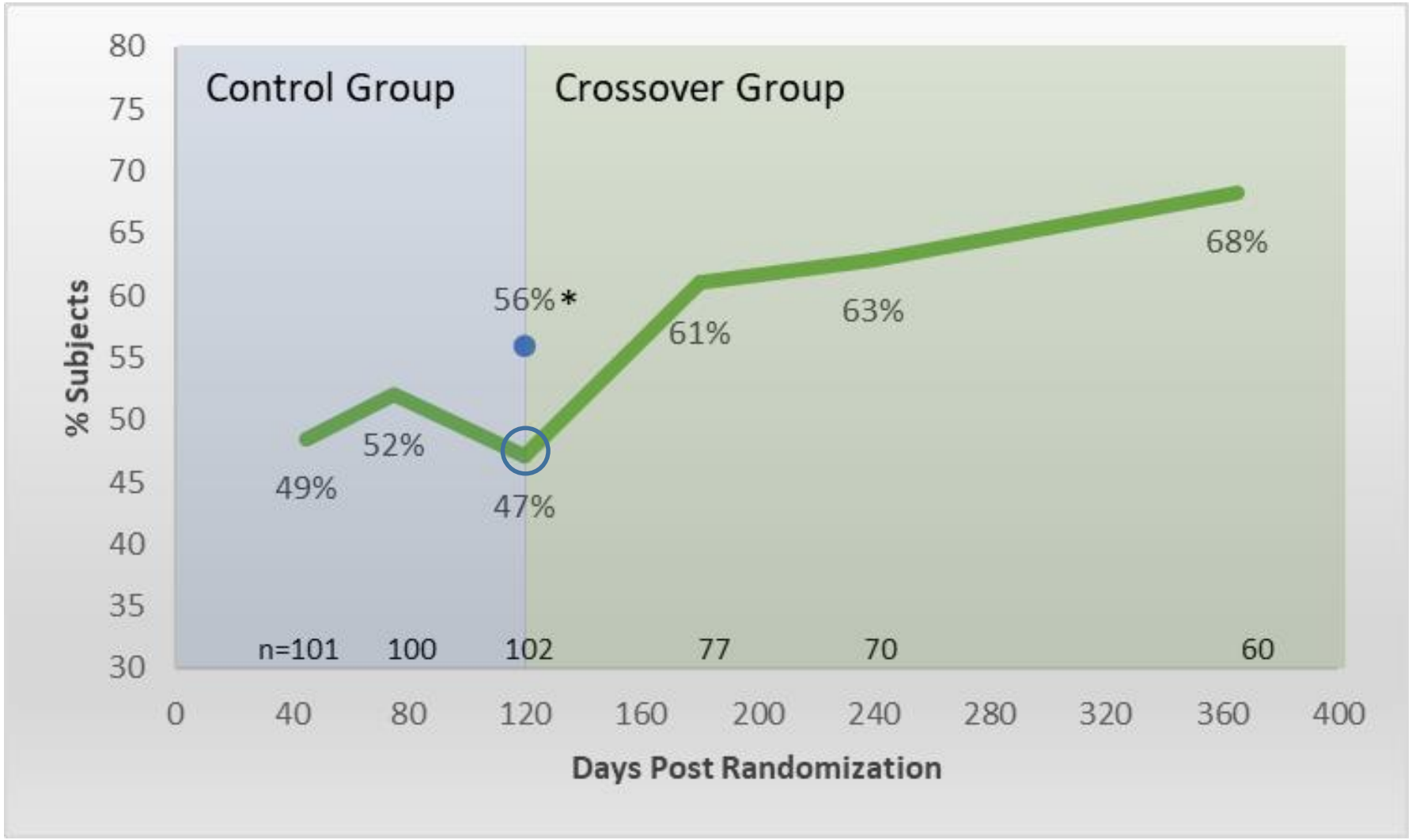
*Responder rate data for all time points exclude patients who have increased medication use. If those data points included all patients who experienced >30% VAS pain reduction regardless of medication increase (as it is typically calculated in neuromodulation trials), the response rates for Reactiv8 would be higher for all time points than the data shown. Data beyond 1 year is subject to change as additional patients complete further assessment visits.
*n=201 (3 patients lost to follow-up)

# Responder Rates – ReActiv8-B Treatment Group



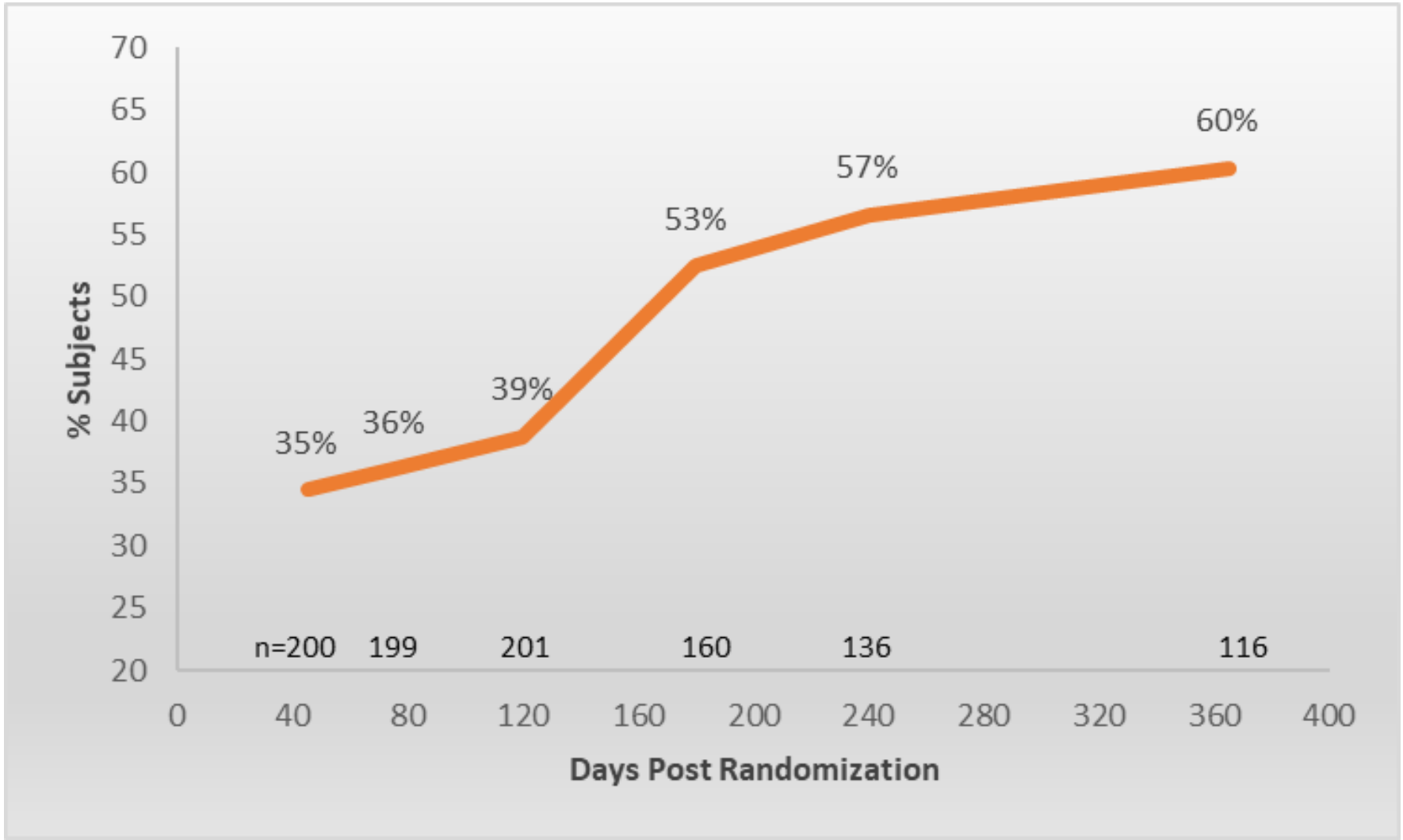

*Responder rate in Control Group

# Responder Rates – ReActiv8-B Control Group




*Responder rate in Treatment Group

# Responder Rates for Patients >50% VAS Pain Reduction*




*Same definition of Responder used as in primary endpoint, but applied only to patients showing >50% VAS pain reduction with no increase in medications

# Benchmarking ReActiv8 to Approved Therapies

- Most recent data from an open label trial comparing HF-10 to Traditional SCS.
- Although ReActiv8 targets a different patient population, both trials involve neurostimulation for types of chronic low back pain.

| | 6 Months | 1 Year |
|---|---|---|
| **Responders ΔVAS ≥ 30%** | | |
| ReActiv8* | **63%** | **72%** |
| **Responders ΔVAS ≥ 50%** | | |
| ReActiv8* | **53%** | **60%** |
| Traditional SCS[1] | 52% | 51% |
| HF10[1] | 76% | 79% |
| **Remitters (VAS < 2.5)** | | |
| ReActiv8* | **38%** | **48%** |
| Traditional SCS[1] | 37% | 43% |
| HF10[1] | 60% | 69% |

*For ReActiv8-B data points, n=160 patients at 6 months and n=116 patients at 1 year. ReActiv8-B Responder rates exclude patients who have increased medication use whereas the HF10 and Traditional SCS data does not exclude such patients. ReActiv8-B Responder rates would be higher if those patients were not excluded. Data subject to change as additional patients complete further assessments.

1. Kapural, L., Yu, C., Doust, M. W., Gliner, B. E., Vallejo, R., Sitzman, B. T., … Burgher, A. H. (2015). Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic and and Leg Pain. *Anesthesiology*, *123*(4).