Patients use keywords such as “burning” to describe neuropathic pain (NP). However, little has been reported on the correlation between patient descriptions and quantitative measures of pain. DTCL100 was a proof of concept study to evaluate the effects of KRN5500 in reducing NP.

The purpose of this exploratory analysis was: (1) to compare frequency of patient pain descriptors (keywords) to Neuropathic Pain Questionnaire (NPQ) symptom scores; and (2) to ascertain the correlation between pre and post-treatment symptom scores and Numeric Rating Scale (NRS) scores.

Methods

During each study visit in this multicenter, placebo-controlled, randomized study in patients with neuropathic pain and end-stage cancer, patients rated their pain on a 0-10 point NRS and on the 0-100 point NPQ items. They also described their pain in their own words. NRS and NPQ symptom scores were summarized for the best overall response. A Wilcoxon Rank Sum test was used to assess treatment differences in NRS. NRS scores and symptoms were correlated at baseline and post-treatment.

Introduction

Patient keyword descriptions were consistent with NPQ symptoms.

KRN5500 Best NRS Weekly Response was statistically significant compared to placebo.

NPQ scores appeared to be positively correlated with NRS.

Symptom scoring methods were not sensitive enough to detect efficacy demonstrated in NRS scores.

SUMMARY & CONCLUSIONS

KRN5500 NRS Best Response Significantly Better Than Placebo

Twelve (12) of 19 patients received KRN5500. Baseline characteristics were consistent between the KRN5500 and Placebo treatment groups. The correlation between baseline NRS and NPQ symptoms was significant for burning (r=0.56) and freezing (r=0.58). The correlation between post-treatment NRS and NPQ symptoms was significant for electric (r=0.50), sensitive to touch (r=0.58), shooting (r=0.56), and tingling (r=0.55). However, no treatment differences in symptoms were observed. KRN5500 treated patients showed a median decrease of 29.3% in best pain intensity NRS response, while placebo treated patients showed no decrease (p=0.02).

KRN5500 NRS Best Response Significantly Better Than Placebo

Baseline Patient Characteristics

Demographics

<table>
<thead>
<tr>
<th>Description</th>
<th>KRN5500 (N=12)</th>
<th>Placebo (N=7)</th>
<th>Total (N=19)</th>
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<tr>
<td>Age, years: Mean (SD)</td>
<td>62.1 (11.1)</td>
<td>61.5 (11.9)</td>
<td>61.7 (11.7)</td>
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<td>Gender: Male / Female</td>
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<td>6 / 1</td>
<td>12 / 7</td>
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<tr>
<td>Race: Caucasian / Black / Hispanic</td>
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<td>5 / 1 / 1</td>
<td>12 / 2 / 2</td>
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<tr>
<td>Study Bureau Area: Mean (SD)</td>
<td>180 (60)</td>
<td>180 (90)</td>
<td>180 (75)</td>
</tr>
<tr>
<td>Numeric Rating Scale for Pain: Mean (SD)</td>
<td>7.4 (1.8)</td>
<td>8.4 (1.8)</td>
<td>8.4 (1.8)</td>
</tr>
</tbody>
</table>

References


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DARA BioSciences

1 DARA BioSciences, Raleigh, NC, USA; 2Applied Statistics & Consulting, Spruce Pine, NC, USA; 3Isadore Pike MD Consulting, Fairhope, AL, USA

Incorporate the following references into the text:
