Gmail

**eric ehlenberger <ehlenberger@gmail.com>**

# Fwd: Proposed study collaboration regarding Rimegepant and Central Sensitivity

**Jack Hammer** <noahsalowitz@gmail.com> Fri, Jul 16, 2021 at 10:19 AM
To: eric ehlenberger md <doctor@ehlenberger.com>

---------- Forwarded message ---------
From: **Jack Hammer** <noahsalowitz@gmail.com>
Date: Fri, Jul 16, 2021, 9:07 AM
Subject: Proposed study collaboration regarding Rimegepant and Central Sensitivity
To: <Kelly.temple@biohavenpharma.com>

To: Medical Liaison and Director of Research at Nurtec (Rimegepant)
Re: Proposed study collaboration regarding Rimegepant and Central Sensitivity

We are clinicians providing chronic pain management to over 400 patients with a wide range of chronic pain syndromes, including migraine headache. Our experience managing our chronic migraine patients has been encouraging so for using Nurtec both as an abortive and as a preventative. Because many of our patients suffer from peripheral and central sensitivity, we have developed an interest in identifying those of our patients with these conditions as well as attempting to reduce the impact of sensitization.

Sensitization is the process by which nerves become hyper-responsive to stimulation, both painful and non-painful. Sensitization takes place both in the peripheral nervous system as well as in the central nervous system and is thought to play a role in the transformation of acute pain to chronic pain, including the evolution of episodic headaches to chronic daily migraine headaches. Central Sensitization is also thought to play an important role in
fibromyalgia, osteoarthritis, TMJ, and dental pain, as well as visceral pain hypersensitivity disorders like interstitial cystitis, IBS, pancreatitis, and post-surgical pain (paraphrased from Accurateclinic.com).

According to Iyengar, et al (Pain, Apr 2017 158(4):543-559) “There is growing evidence that Calcitonin Gene Related Peptide plays a key role in the development of peripheral sensitization and the associated enhanced pain.” CGRP is also “up-regulated in conditions of inflammatory and neuropathic pain” and “contributes to the development and maintenance of a sensitized, hyper-responsive state” both in the peripheral and central nervous system.

Based on our understanding of the proposed mechanisms of action of Nurtec in the context of our understanding of the mechanisms involved with the evolution of sensitization, we believe nurtec has the potential to suppress or even reverse the process of sensitization not only in chronic migraine patients but others suffering from sensitization related to fibromyalgia, chronic neck and low back pain, and other conditions.

We therefore propose a study in which patients in our pain management practice who are thought to have Central Sensitivity or are at risk for it, be treated with Rimegepant. The evolution and trends of their pain symptoms would then be tracked using subjective survey tools such as the Central Sensitization Inventory, and Pain Disability Index (see attachments). Assuming a positive preliminary response, the study could be expanded and analyzed into subgroups such as acute pain, chronic pain, fibromyalgia, dental pain, IBS, etc.

If successful, this research could lead to new indications for Rimegepant, as well as focus much-needed attention on a wide variety of conditions that are often very difficult for patients to experience and for clinicians to treat. Given that Rimegepant is already an FDA-approved medication and is comparatively safe with few adverse side effects

or
contraindications, we believe that conducting this study would pose minimal risk of complications or adverse outcomes in our patients.
We would like to ask for your assistance in obtaining an adequate number of samples of Nurtec to conduct this study, and we would also like to ask for the assistance of your experience and expertise in designing, implementing, analyzing, and if indicated, publishing the study.

Sincerely,
Eric Reed Ehlenberger, MD
Noah Salowitz, Physician Assistant

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**2 attachments**

**Scan2021-07-15_172421_000.jpg**
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**Scan2021-07-15_172421_001.jpg**
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