## LETTER



## Author's Response to: 'Letter to the Editor Regarding Efficacy and Safety of Diclofenac and Capsaicin Gel in Patients with Acute Back/Neck Pain: A Multicenter Randomized Controlled Study'

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We thank Drs. Schwartz, Urits and Viswanath for their comment, and we feel honored by their appraisal of our study. (Low) back pain treatment can be demanding, and we agree that systemic analgesics (including non-steroidal anti-inflammatory drugs [NSAIDs] and opioids) can play a role in the treatment of (low) back pain, but they do have their limitations in terms of efficacy, as well as tolerability and safety.

Topical NSAIDs might be treatment options; however, the database on efficacy for (low) back pain is rather limited. Neither the British National Institute for Health and Care Excellence (NICE) guideline [1] nor the US guideline [2] even mention topical NSAIDs, and the German guideline on diagnosis and treatment of non-specific low back pain [3] does not recommend these treatments due to the lack of clinical data.

The results of our study contribute to answering two questions. The first is: Is topical diclofenac more effective than placebo? In our

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T. W. Weiser · R. Lange (⊠) Consumer Health Care, Medical Affairs, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany e-mail: robert1.lange@sanofi.com study, the effect was similar to placebo, although an earlier study with another diclofenac formulation using the same methodology showed an effect on neck pain [4]. In this respect, Wiffen and Xia [5] recently highlighted the importance of the pharmaceutical formulation for effective pain relief. The second question is: Is topical capsaicin effective? The answer was yes, and—not surprisingly—the combination of both compounds did not exceed the efficacy of capsaicin alone. As one might imagine, our hope was that the combination treatment would exceed the efficacy of both single compound treatments.

Topical capsaicin (or the structurally similar nonivamide) has a long tradition of being used for the treatment of musculoskeletal pain, including (low) back pain. At least three state-of-the-art double-blind, placebo-controlled, randomized trials have been published in recent years (two of them on a fixed-dose combination of nonivamide with a nicotinic acid ester) showing that this pharmacological approach worked well for low back pain patients [6–8]. In two of these studies, efficacy outcomes approached or exceeded those described for several prescription-only treatments [9].

Thus, topical transient receptor potential vanilloid subunit 1 (TRPV1) receptor agonists like capsaicin can be considered to be a promising addition to the armamentarium of (low) back pain treatments.

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As the letter to the editor covers the topic of topical versus system analgesics in a much broader sense than the original full trial publication, this reply has been written by TWW and RL as medical representatives of the team.

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