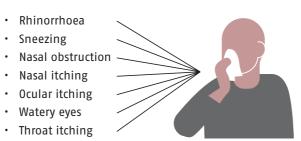


# Allergic Rhinitis and air pollution: New clinical evidence with fexofenadine hydrochloride 180 mg

Worldwide **prevalence** of allergic rhinitis (AR)

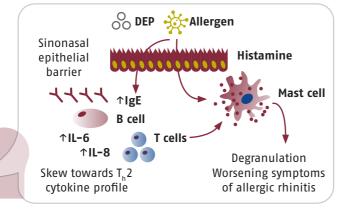


### Main allergic rhinitis symptoms



# Diesel exhaust particles (DEP) aggravate allergen-induced allergic response

- AR is a **type I hypersensitivity** reaction to airborne allergens, such as pollen (or house dust mites)
- Exposure to air pollutants and climate change has been linked to AR symptom exacerbation
- DEP, an air pollutant, when combined with airborne allergen is able to enhance allergen-induced degranulation, leading to worsening AR symptoms



FEXPOLSAR was a phase III, single-centre, sequential, parallel-group, double-blind, randomized study conducted in an environmental exposure unit

## Inclusion criteria:

- 2-year history of seasonal allergic rhinitis (SAR) with positive skin prick test to ragweed
- Self-reported history of SAR symptoms aggravated by pollen or air pollutants exposure
- Total Nasal Symptom Score (TNSS) ≥3 in Period 1 (V2)















Ragweed + DEP Ragweed challenge challenge

Ragweed + DEP challenge + single dose fexofenadine HCl or placebo (R 1:1) Safety follow-up and analysis

			·· p······	
Day -90 to -7	Day 1	Day 15	Day 29	Day 35
<u>V1</u>	<u>V2</u> Wa		shout <u>V4</u>	<u>V5</u>
Screening N = 375	Evaluable population N = 257	eriod Modified <sup>p</sup> i intention-to-treat population N = 251	eriod Modified intention-to-treat population N = 251	Modified intention-to-treat population N = 251

Adapted from Margarita Murrieta-Aguttes, MD, Sanofi, Paris, France, and Marina Volonte, DVM, Sanofi, Milano, Italy, Evid Self Med 2021;1:210332 | https://doi.org/10.52778/efsm.21.0332. Publication date: 29.11.2021

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## **Primary endpoints**

Participants graded their Total Nasal Symptom Score (TNSS) on a 0-3-point scale over 12-hours from baseline for each Period. TNSS was calculated as the sum of rhinorrhoea, sneezing, and nasal itching scores.

### First primary objective:

to demonstrate the aggravation of the SAR symptoms caused by DEP exposure



Period 2 vs Period 1

**Change in TNSS AUC from** baseline to hour 12 (TNSS AUC. ...)

### Second primary objective:

to evaluate the efficacy of fexofenadine HCl in alleviating symptoms aggravated by DEP presence



Period 3

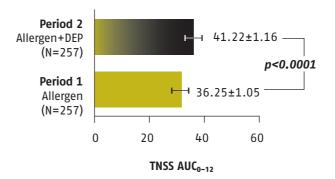
Change in TNSS AUC from hour 2 to 12 (TNSS AUC, a)

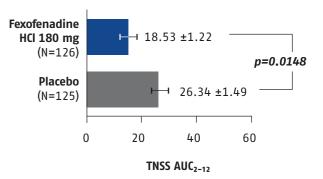
## TNSS $AUC_{0-12}$ in Period 1 and 2

A significant increase in SAR symptoms from Period 1 to Period 2 was observed

## TNSS AUC<sub>2-12</sub> in Period 3

A significant decrease in DEP-aggravated, SAR symptoms was observed with fexofenadine HCI compared with placebo







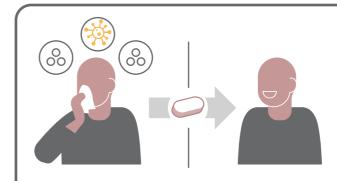
The proportion of subjects reporting treatment-emergent adverse events was higher in the placebo group



Placebo group



Fexofenadine HCI group



- · DEP, a common constituent of air pollution, significantly aggravates pollen induced allergic rhinitis symptoms
- Fexofenadine HCl 180 mg significantly improves pollutant-aggravated pollen induced SAR symptoms vs placebo

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