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| **Fractional exhaled nitric oxide (FeNO) biomarker in uncontrolled asthma** |
| Jana Moody1\*, Joy Lee2,3\*, William W. Busse4, Ian D Pavord5, Michael E. Wechsler6, Ignacio J. Davila7, Arman Altincatal8, Xavier Soler9, Megan Hardin8 |
| *1Sanofi, New South Wales, Australia*  *2Allergy, Asthma and Clinical Immunology and Respiratory medicine, Alfred Health, Melbourne, Victoria, Australia 3School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia 4University of Wisconsin School of Medicine and Public Health, Madison, WI, USA 5NIHR Oxford Biomedical Research Centre, University of Oxford, Oxford, UK 6National Jewish Health, Denver, CO, USA 7University of Salamanca, Salamanca, Spain 8Sanofi, Cambridge, MA, USA 9Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA* |
| **Introduction/Aim:** Dupilumab reduces asthma exacerbation rates and improves lung function in children (VOYAGE, NCT02948959) and adults/adolescents (QUEST, NCT02414854) with uncontrolled, moderate-to-severe asthma. Previous data have demonstrated that FeNO is a valid prognostic biomarker, a predictor of response to dupilumab.The aim of this post hoc analysis was to evaluate the stability of FeNO over time following the American Thoracic Society (ATS) and European Respiratory Society (ERS) FeNO guidelines, in placebo patients from the QUEST and VOYAGE studies.  **Methods:** FeNO levels were collected in placebo patients from QUEST (≥12 years) and VOYAGE (6–11 years), in non-exacerbating (0 exacerbations) and frequent exacerbator (≥3 exacerbations) subpopulations. Asthma exacerbation was defined as a worsening of asthma that led to hospitalization, emergency medical care, or treatment with systemic corticosteroids.  **Results:** For combined placebo patients, median (95% CI) baseline FeNO in non-exacerbators and frequent exacerbators was 25.0 ppb (22.0, 27.0) and 34.0 ppb (27.0, 40.0) in QUEST, and 18.0 ppb (14.0, 21.0) and 48.5 ppb (9.0, 100.0) in VOYAGE, respectively. At Week 24, fold change in FeNO from the previous visit (week 20) was 0.97 (0.91, 1.00) and 1.08 (0.96, 1.16) in non-exacerbators and frequent exacerbators in QUEST, and 1.05 (0.96, 1.25) and 0.66 (0.48, 2.09) in VOYAGE, respectively. At Week 52, fold change in FeNO from the previous visit was 1.00 ppb (0.96, 1.05) and 1.03 (0.87, 1.25) in non-exacerbators and frequent exacerbators in QUEST, and 0.98 (0.89, 1.09) and 0.74 (0.22, 0.92) in VOYAGE, respectively.  **Conclusion:** In QUEST and VOYAGE, FeNO measurements for patients on placebo were stable, with low variability, in between visits among exacerbators and non-exacerbators.  **Grant Support:** \*Presenting on behalf of authors. Data first presented at the American College of Allergy, Asthma & Immunology (ACAAI) annual scientific meeting; Anaheim, CA, USA; November 9-13, 2023. Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT02948959, NCT02414854. The authors would like to thank Michelle Choi for the contributions to the original abstract. Medical writing/editorial assistance was provided by Maya Chergova, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the [Good Publication Practice guideline](https://www.acpjournals.org/doi/10.7326/M22-1460) |

**Key words:** Fractional exhaled nitric oxide, biomarker, asthma, exacerbations

**Conflicts of interest: J Lee:** has received speaker fees from Boehringer Ingelheim, GlaxoSmithKline, AstraZeneca and Sanofi. **Busse WW:** GSK, Novartis, Sanofi, – consultant, speaker fees. **Pavord ID:** AstraZeneca, Boehringer Ingelheim, Chiesi, Circassia, Dey Pharma, Genentech, GSK, Knopp Biosciences, Merck, Merck Sharp & Dohme, Napp Pharmaceuticals, Novartis, Regeneron Pharmaceuticals Inc., RespiVert, Sanofi, Schering-Plough, Teva – consultant fees; AstraZeneca, Boehringer Ingelheim, Chiesi, GSK, Napp Pharmaceuticals, Teva – international scientific meeting sponsorship; Chiesi – research grant. **Wechsler ME:** AstraZeneca, Boehringer Ingelheim, Equillium, Gala Therapeutics, Genentech, Mylan, Novartis, Pulmatrix, Regeneron Pharmaceuticals Inc., resTORbio, Sentien Biotechnologies, Teva – personal fees; GSK, Sanofi – grants and personal fees**. Davila IJ:** Allergy Therapeutics, AstraZeneca, Chiesi, Diater, GSK, Leti, Novartis, Sanofi – speaker fees; Allergy Therapeutics, ALK-Abello, AstraZeneca, GSK, Merck, MSD, Novartis, Sanofi – consultant fees; Thermo Fisher Diagnostics, ISCIII, Junta de Castilla y León – grants. **Altincatal A, Moody J**, **Hardin M**: Sanofi − employees, may hold stock and/or stock options in the company. **Soler X:** Regeneron Pharmaceuticals Inc. − employee and shareholder.