

New clinical trial analyses predict response to benralizumab by patients with COPD

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Gerard J. Criner, MD, FACP, FACCP, Chair and Professor of Thoracic Medicine and Surgery at the Lewis Katz School of Medicine at Temple University, Director of the Temple Lung Center and corresponding author on the new publication. Credit: Lewis Katz School of Medicine at Temple University

Chronic obstructive pulmonary disease, or COPD, is the third leading cause of death in the U.S., according to the American Lung Association.

More than 15.3 million people in this country suffer from it and they often experience potentially life-threatening exacerbations, which can include days-long flare-ups of symptoms including shortness of breath that occur when the airways narrow from muscle tightness, swelling and mucus.

Results from two Phase III, international clinical trials named GALATHEA and TERRANOVA that were published in May by the *New England Journal of Medicine*, presented at the American Thoracic Society International Conference 2019, and co-led by Temple's Gerard J. Criner, MD, FACP, FACCPC showed that the asthma drug benralizumab failed to decrease annual COPD [exacerbation](#) rates for patients with moderate to very severe COPD, a history of frequent moderate and/or severe exacerbations, and eosinophilic inflammation.

Eosinophilic inflammation occurs when a type of white blood cells known as eosinophils, which help fight off infections and play a role in the body's immune response, build up in one location. Eosinophilic inflammation is associated with an increased exacerbation risk. Benralizumab is a type of drug called an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody. Benralizumab depletes eosinophils by blocking the interleukin-5 receptor, and is approved by the FDA for the treatment of severe eosinophilic asthma.

Now, new hypothesis-generating analyses of GALATHEA and TERRANOVA published in *The Lancet Respiratory Medicine* and presented at the European Respiratory Society (ERS) International Congress 2019 in Madrid, Spain identified clinical and physiological characteristics of patients with COPD that could help to identify people who are likely to have the greatest treatment effect with benralizumab.

"Our goal was to identify patients with COPD who might benefit from biological therapies like benralizumab, said Dr. Criner, Chair and

Professor of Thoracic Medicine and Surgery at the Lewis Katz School of Medicine at Temple University, Director of the Temple Lung Center and corresponding author on the new publication. "This new study reports baseline clinical characteristics that were associated with reductions in annual rates of exacerbations in patients with COPD compared with placebo after benralizumab administration."

The researchers evaluated individual study and pooled results from GALATHEA and TERRANOVA as part of their hypothesis-generating analyses. They analyzed data for 3910 patients who received benralizumab (30 mg or 100 mg subcutaneously every 8 weeks; first three doses every 4 weeks) or placebo with dual or triple inhaled therapy. Benralizumab 30 mg every 8 weeks did not produce meaningful efficacy for any subgroups. However, the researchers found that for patients who received benralizumab 100 mg, elevated blood eosinophil count at baseline was a key factor for predicting the treatment effect of benralizumab, but that elevated blood eosinophil count alone was insufficient to identify treatment effect with anti-eosinophil therapy.

"We found that for patients with moderate to very severe COPD, a combination of elevated blood eosinophil counts and a history of frequent exacerbations during treatment with triple inhaled maintenance therapy seemed to predict exacerbation reduction with benralizumab 100 mg treatment," added Dr. Criner. "These hypothesis-generating analyses identified the potential efficacy of benralizumab 100 mg for this subpopulation and the findings support a prospective clinical trial of benralizumab 100 mg every 8 weeks for this patient subpopulation."

More information: Gerard J Criner et al, Predicting response to benralizumab in chronic obstructive pulmonary disease: analyses of GALATHEA and TERRANOVA studies, *The Lancet Respiratory Medicine* (2019). [DOI: 10.1016/S2213-2600\(19\)30338-8](https://doi.org/10.1016/S2213-2600(19)30338-8)

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