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GSKâ??s Nucala reduces flares of Hypereosinophilic Syndrome (HES) patients

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Positive data from a pivotal study supports new regulatory filing in HES



GlaxoSmithKline plc (GSK) has announced positive results from the pivotal study of Nucala (mepolizumab) in the treatment of patients living with Hypereosinophilic Syndrome (HES), making it the first treatment to demonstrate a reduction in flares for this rare disease.

The phase 3 study met its primary endpoint, demonstrating a statistically significant result with 50% fewer patients experiencing a HES flare (worsening of symptoms or eosinophil threshold requiring an escalation in therapy) when treated with mepolizumab, compared to placebo, when added to standard of care treatment over the 32-week study period (56% vs 28%; p=0.002).

Dr Hal Barron, Chief Scientific Officer and President, R&D, GSK, said: “Mepolizumab has the potential to change the treatment landscape for patients with HES which is a complex and debilitating disease with limited therapeutic options today.”

Secondary endpoints from the study were also statistically significant and supported the primary endpoint, showing:

- Risk of first HES flare over the study period was 66% lower for patients treated with mepolizumab compared to placebo (hazard ratio 0.34; 95% CI 0.18, 0.67).
- There was a 66% reduction in the annualised rate of HES flares versus placebo (rate ratio 0.34; 95% CI 0.19, 0.63).
- Fatigue scores improved in mepolizumab compared to placebo (p=0.036).
- The safety results in the study were consistent with the known profile of mepolizumab.

Dr Gerald Gleich, MD, allergist, immunologist and HES expert, University of Utah, said: “Mepolizumab is thought to work by reducing blood eosinophil levels and evidence suggests it has potential as a targeted treatment option for a range of inflammatory diseases driven by raised eosinophils. These data are very promising and should provide hope for patients affected by this rare, life-threatening condition caused by eosinophilic inflammation”.

Based on these data, GSK plans to progress regulatory submissions in 2020.