This is Proton Rahman, Rheumatologist and Professor of Medicine at Memorial University in St. John’s, Newfoundland. I am summarizing the manuscript, “Pooled Safety Results Through 1 Year of 2 Phase III Trials of Guselkumab in Patients with Psoriatic Arthritis.”

I am presenting on behalf of my coauthors and I’d like to thank them for their meaningful contributions.

As you know psoriatic arthritis, or PsA, is a chronic inflammatory disorder primarily affecting the skin and joints.

Two phase 3 trials, DISCOVER-1 and DISCOVER-2, investigated the efficacy and safety of guselkumab in patients with active psoriatic arthritis.

Guselkumab is a human monoclonal antibody that selectively targets the p19 subunit of interleukin-23 in adult patients with active PsA, and is the first IL-23 inhibitor approved in psoriatic arthritis.

Selective IL-23 inhibition with guselkumab is an efficacious treatment option for patients with active PsA and the safety profile of guselkumab has been established for up to 5 years in patients with psoriasis.

Most patients with PsA who receive biologics require continual therapy; thus, understanding the safety of long-term treatment is critical.

This manuscript reports the safety of guselkumab in patients with PsA through 1 year from the pooled DISCOVER-1 and DISCOVER-2 studies.

The DISCOVER-1 and -2 studies were randomized, double-blind, placebo-controlled, phase 3 trials of guselkumab in adults with active PsA.

As you’re aware, patients were randomized equally to receive subcutaneous injections of guselkumab 100 mg every 4 weeks; guselkumab 100 mg at Weeks 0 and 4, and then every 8 weeks; or placebo with crossover to guselkumab 100 mg every 4 weeks at Week 24. Safety was assessed through Week 60 in DISCOVER-1 and Week 52 in DISCOVER-2. Adverse event incidence rates are reported as patients and events per 100 patient-years of follow-up.

Regarding the results, a total of 1,120 patients were randomized and treated in DISCOVER-1 and -2. Most patients completed 24 weeks and 1 year of follow-up. Baseline characteristics were generally similar between the DISCOVER-1 and DISCOVER-2 studies.

The rates of discontinuation were higher with placebo than guselkumab through Week 24, remained low with guselkumab through 1 year, and were similar between the guselkumab dosing regimens.

Regarding safety, adverse events were similar between placebo- and guselkumab-treated patients from Week 0 to Week 24. No increase was seen with continued guselkumab treatment through 1 year. Rates of adverse events were similar between guselkumab dosing regimens at both timepoints, which is shown in the manuscript.
The most common class of adverse events through 1 year in patients treated with guselkumab were infections, which were generally nonserious and included nasopharyngitis, upper respiratory infections, and bronchitis.

Rates of infections and serious infections were similar with guselkumab and placebo and did not increase over time through 1 year.

Rates of serious adverse events and adverse events leading to discontinuation of study agent were comparable in the guselkumab and placebo groups from Week 0 to 24, and the rates remained low among guselkumab-treated patients at 1 year. The results were consistent when assessed by numbers of patients per 100 patient-years and number of events per 100 patient-years.

No patients treated with guselkumab died through 1 year; two patients receiving placebo died prior to Week 24. Through 1 year, no cases of active tuberculosis, opportunistic infections, or inflammatory bowel disease were seen in patients treated with guselkumab. Also, through 1 year, low rates of malignancy, major adverse cardiovascular events, and injection-site reactions were observed.

Serum hepatic transaminase elevations and decreased neutrophil counts were generally mild, transient, and did not result in treatment discontinuation.

Antibodies to guselkumab were uncommon, and the vast majority were non-neutralizing.

So, in conclusion, the safety events with guselkumab 100 mg every 4 weeks or every 8 weeks through Week 24 were consistent with those seen in the placebo group, with no new safety concerns through 1 year of guselkumab treatment.

These findings in PsA patients are consistent with the long-term safety results of the VOYAGE-1 and VOYAGE-2 trials of patients with psoriasis.

For more information, please see the full manuscript. Thank you for listening.