Add-on Lupuzor Fails Primary Goal but Shows Some Positive Results in Phase 3 Trial for SLE

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Lupuzor (rigerimod, or IPP-201101) combined with standard therapy did not demonstrate a statistically significant response rate in systemic lupus erythematosus (SLE) patients over standard care alone, failing the primary goal of a Phase 3 clinical trial, according to top-line results.

Although not statistically significant, the investigational treatment did, however, show signs of promise in the trial, including a positive safety profile, with no serious adverse events reported.

“Lupuzor has demonstrated, in this study, a superior response rate over placebo and its exceptional safety, giving it, we believe, a compelling product profile,” Tim McCarthy, ImmuPharma’s chairman, said in a press release.

Systemic lupus erythematosus is a chronic, autoimmune, inflammatory disease, which is thought to affect 5 million people worldwide. Current standard therapy is focused on relieving symptoms of the disease, and most treatments are not disease-specific, have limited effectiveness, and cause several adverse effects.

Lupuzor, being developed by ImmuPharma, is a potentially revolutionary peptide-based therapy for SLE, because, contrary to other immunomodulating therapies, it suppresses the activation of auto-reactive T-cells — immune cells that attack the body’s own tissues — without affecting healthy immune cells.

Lupuzor’s aim is to potentially eliminate autoimmunity without the need for immunosuppression, allowing the occurrence of normal immune responses.

In June 2016, ImmuPharma began a Phase 3 clinical trial (NCT02504645) evaluating the safety and effectiveness of adding Lupuzor to standard treatment, compared with standard treatment alone. The study, completed in January 2018, enrolled 200 lupus patients and was conducted in 30 clinical centers around the world.

Participants were randomly assigned to receive 200 micrograms of either Lupuzor under the skin or a placebo in addition to standard therapy every four weeks for 48 weeks.

An analysis of all 202 participants showed that more patients had a reduction in disease activity with Lupuzor combined with standard therapy (52%) than with standard therapy alone (44.6%), but the difference was not statistically significant.

Among the 153 patients who completed the study, Lupuzor also showed a superior response rate compared with placebo (68.8% vs 59.2%), but the statistical significance of this result remains to be announced.

In patients with anti-dsDNA autoantibodies — a recognized biomarker for SLE — clinical response was achieved by a higher proportion of patients receiving Lupuzor (61.5%) than those receiving placebo (47.3%). Notably, 7.6% of these patients in the Lupuzor group went into full remission, compared with none in the placebo group.

Results also confirmed that the treatment is very safe, with no serious adverse events reported.

McCarthy said that although they are “disappointed” the response rates of patients receiving Lupuzor did not reach statistical significance compared with those of the placebo group, they believe Lupuzor “has the potential to bring a much needed safe treatment to the millions of Lupus sufferers around the world.”

ImmuPharma will review the trial’s full results and work with its regulatory advisers to decide their next steps.

Following requests from both patients and researchers, ImmuPharma launched an open-label extension study for all participants of the Phase 3 trial, allowing them to receive Lupuzor in combination with standard therapy for an additional six months. The company looks forward to providing updated results on the extension study.