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Shilpa Medicare completes Phase 1 trial for Recombinant Human Albumin (rHA) 20%

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Plans to initiate Phase 3 clinical trials for rHA by Q4 FY25



In a major breakthrough, Bengaluru-based Shilpa Medicare has announced the successful completion of its Phase 1 clinical trial for its flagship product, sRbumin - recombinant human albumin 20% (rHA), becoming the first Indian company to achieve this milestone. The positive results underscore rHA's potential as a viable alternative to plasma-derived human serum albumin, addressing a critical gap in global healthcare.

The Phase 1 clinical study was a randomised, dose-escalating, comparative trial against European-sourced human-derived serum albumin, involving 62 healthy volunteers. It aimed to evaluate the safety, efficacy, and pharmacokinetics of rHA at different dose levels.

rHA demonstrated clinical benefits comparable to human-derived albumin in surrogate endpoints such as colloidal osmotic pressure and hematocrit ratio. rHA was generally well-tolerated, with no serious adverse events reported. No significant difference was observed in the incidence of anti-drug antibodies compared to human-derived albumin, and rHA showed bioavailability comparable to human albumin.

Human serum albumin is essential for various medical treatments, such as volume replacement therapy for accidents, burns, and surgeries. However, the current supply is heavily dependent on blood donations, leading to potential shortages. Shilpa's rHA, produced using yeast fermentation, offers a highly purified, structurally and functionally equivalent alternative.

Building on this success, Shilpa Medicare plans to initiate Phase 3 clinical trials for rHA by Q4 FY25. These trials are expected to be completed within a year, followed by product approval filings in FY26.