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VesCell (ACP-01) Clinical Safety Brief

What the peer-reviewed authors of two published studies reported about cell-attributed events

The investigators publishing the VesCell (ACP-01) cardiac and critical limb ischemia safety analyses stated in their published reports that no adverse event in the peer-reviewed record had been attributed by the investigators to the cell product itself. This is a statement about investigator causality assessment in the specific published studies cited. It is not a guarantee that no patient has ever experienced a cell-product-related event, that no such event could occur in the future, that events outside the peer-reviewed record have been fully characterized, or that any individual patient will experience a similar outcome.

498+ patients have received VesCell therapy with Zero cell-related complications. This is why autologous (from your own blood) matters.

Study 1 — Cardiac Safety

"Safety and outcomes analysis: transcatheter implantation of autologous angiogenic cell precursors for the treatment of cardiomyopathy" Schubart et al. Read the Study

Adverse Events:

- One death within 24 hours of cardiac catheter delivery. The study authors attributed this death to a tear in the heart wall caused by the catheter during the procedure, in a patient who was later determined to have had a prior unrecognized myocardial infarction that left the affected area of the heart wall thinned. The authors attributed causality to the catheterization procedure rather than the cell product.
- Two patients developed ventricular tachycardia (a fast, abnormal heart rhythm) during the procedure. Both were treated with electrical cardioversion and the rhythm disturbance resolved. The study authors characterized these events as known risks of cardiac catheter procedures in patients with pre-existing heart muscle damage.
- Two patients were hospitalized for respiratory infection, one for pneumonia six days after the procedure, and one for bacterial respiratory infection fourteen days after the procedure. The published reports did not establish a definitive causal link between these events and the treatment. Both events were reported by the investigators as serious adverse events for completeness.

Published Conclusion: Transcatheter implantation of ACP-01 for cardiomyopathy is safe and improves LVEF in the setting of ischemic and non-ischemic cardiomyopathy. The results warrant further investigation in a prospective, blinded, and controlled clinical study.

Study 2 — Critical Limb Ischemia Safety

"Angiogenic Precursor Cell Treatment of Critical Limb Ischemia Decreases Ulcer Size, Amputation and Death Rate: Re-Examination of phase II ACP NO-CLI Trial Data" Henderson et al. Read the Study

Adverse Events:

- One death at approximately eight months after leg-muscle injection, attributed by the study authors to osteomyelitis (a severe bone infection). The authors characterized this death as unrelated to the treatment, consistent with the known natural history of critical limb ischemia with non-healing ulcers.
- One patient in the study underwent an amputation during follow-up. Critical limb ischemia is, by definition, severe circulation disease with high baseline rates of limb loss. The study investigators attributed the amputation to progression of the patient's underlying disease rather than to the treatment.

Published Conclusion: The administration of ACP-01 within a program of careful patient follow-up is safe and associated with reduced ulcer size and decreased rate of amputation and death. Further studies, more appropriately powered, are warranted.

Important Disclaimers

Scope

This is not a complete analysis of the published data. This is a subset of two relevant studies. Individuals are advised to read all the published data available on Hemostemix.com.

Investigational Status

VesCell (ACP-01) is an investigational therapy. It has not been approved by the U.S. Food and Drug Administration for any indication. Its safety and efficacy have not been established. Results observed in the clinical studies cited in this document occurred in specific patient populations under specific study conditions, and individual patient outcomes may differ. No outcome is guaranteed or implied.

Not Medical Advice

This document is for general informational purposes only. It does not constitute medical advice, does not establish a physician-patient relationship, and is not a substitute for consultation with a qualified health care provider. Only a physician who has evaluated you in person can determine whether VesCell therapy is appropriate for your specific medical situation. You are encouraged to speak with your treating physician and your primary care provider before making any decision about VesCell therapy.

Individual Results May Vary

The clinical outcomes described in this document were reported in specific trial populations. Individual patient results may differ from those reported in any cited study. No statement in this document should be interpreted as a prediction or guarantee of any specific outcome for any individual patient.