Subject: Clinical Study Inquiry – Alomac® (Aloe macroclada)

Company Introduction

Alomac US, LLC is the exclusive global supplier of Alomac®, a standardized dried leaf gel of *Aloe macroclada* sourced from Madagascar.

Alomac is currently used as a key ingredient in commercially available dietary supplements and has demonstrated biological activity in preliminary human and in-vitro studies.

Study Objective

We are seeking a CRO or academic partner to conduct a **randomized, double-blind, placebo-controlled human study** to:

- validate previously observed increases in circulating stem/progenitor-cell markers (e.g., CD34+)
- characterize the types of circulating cell populations affected
- explore short-term mechanistic biomarkers associated with mobilization

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Background

A prior placebo-controlled human crossover study (n=4) demonstrated statistically significant transient increases in circulating CD45dim CD34+ and CD34+ CD133+ cells within 2–3 hours following oral ingestion.

Additional in-vitro work suggests immune-modulating and cytokine-associated activity.

We are now seeking to **replicate and expand these findings in a larger, more rigorous study**.

Proposed Study Design

- Randomized
- Double-blind
- Placebo-controlled
- **Crossover design preferred** (parallel acceptable with justification)

Population

- Healthy adults (ages 30–65)
- Target sample size: **24–36 subjects (30 preferred)**

Intervention

- Single oral dose of Alomac® (capsule format)
- Matched placebo

Primary Endpoint

- Change from baseline in **circulating CD34+ cells** vs placebo over acute timepoints

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Secondary Endpoints

- CD34+ CD133+ cells
- Expanded marker panel (e.g., CD45, CD90, CD73, CD105 – open to CRO input)
- Selected serum biomarkers (e.g., G-CSF, CRP, IL-6)

Sampling Timepoints

- Baseline
- 1 hour
- 2 hours
- 3 hours post-dose
- (Optional: 4 hours)

Laboratory Requirements

- Flow cytometry capability with standardized gating
- Ability to define and lock analysis plan in advance
- Experience with stem/progenitor-cell markers preferred

Quality Requirements

We are particularly interested in partners who can support:

- Pre-specified statistical analysis plan
- Blinded sample handling
- Raw data retention (FCS files)
- Endotoxin/product quality integration if needed
- Optional: study preregistration support

Deliverables Requested

Please provide:

1. Proposed study design (including any modifications)
2. Estimated cost range
3. Timeline (start → final report)
4. Relevant prior experience (especially flow cytometry / immune studies)
5. Any recommendations to improve robustness

Timeline

Target study start: within 2–4 months
Target completion: within 6 months of initiation

Next Steps

We are currently evaluating partners and would welcome an initial discussion.
Please respond with availability for a call and preliminary thoughts.