CLINICAL STUDY DOCUMENT

STATISTICAL ANALYSIS PLAN (SAP)

Official Title: Removal the Uterine Fibroids

Brief Title: Composition for Treating Uterine Fibroid (SB-UF)

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STATISTICAL ANALYSIS PLAN (SAP)

1. Analysis Populations

* Safety Population: Given the study focus on safety in a vulnerable obstetric cohort, the primary population for safety monitoring will utilize the Safety Set, defined as all randomized pregnant women who received at least one dose of the assigned intervention (SB-UF or Placebo).

* Full Analysis Set (FAS) / Intent-to-Treat (ITT): Used as the primary population for efficacy evaluations, including all randomized subjects who have a valid baseline and at least one post-baseline ultrasound assessment.

* Per-Protocol (PP) Set: A subset of the ITT population who completed the 40-week protocol without major protocol deviations, used for sensitivity analyses of the primary outcome.

2. Primary Efficacy Analysis

The primary efficacy endpoint is the proportion of patients demonstrating complete disappearance of benign smooth muscle cell tumors at week 40. Based on empirical clinical study outputs indicating a 100% disappearance rate in the active SB-UF arm versus 0% progress in the placebo arm, the statistical significance of this binary categorical outcome will be evaluated using Fisher's Exact Test. This method provides exact p-values independent of sample distribution constraints.

3. Secondary Efficacy & Structural Analysis

* Longitudinal Volumetric Tracking: Serial measurements of fibroid dimensions from week 4 to week 40 will be analyzed using a Mixed Model for Repeated Measures (MMRM) or a Linear Mixed-Effects Model (LMM). This approach accounts for within-subject correlations over time and handles missing data under the Missing at Random (MAR) assumption.

* Myometrial Presentation: The continuous secondary outcome evaluating why the uterine muscle tissue image appears structurally thicker than normal post-dissolution will be evaluated using an Analysis of Covariance (ANCOVA) model, utilizing the baseline myometrial thickness as a covariate and the treatment group as a fixed effect.

4. Obstetric Safety & Complication Analysis

Maternal and fetal complication rates—specifically the incidence of spontaneous miscarriage, premature birth, placental abruption, labor dysfunction, and postpartum hemorrhage (PPH)—will be summarized using descriptive statistics (frequencies and percentages). Comparative evaluation between the experimental and control cohorts will be executed using the Chi-squared (χ 2) test or Relative Risk (RR) computation bounded by 95% Confidence Intervals (CI).

5. Subgroup Analysis

To determine whether therapeutic efficacy is modified by tumor topology, a stratified subgroup analysis will be implemented based on the baseline anatomical classification: Intramural, Submucosal, and Subserous fibroids. The primary dissolution rate at week 40 will be compared across these subgroups using Fisher's Exact Test.

6. Data Privacy, Integrity, and Handling

* IPD Sharing Statement: Plan to share IPD: No. In compliance with data protection policies, individual participant data will remain confidential. All statistical routines will be performed on aggregated, anonymized data matrices.

* Protocol Deviations: Candidates excluded during screening due to pedunculated subserosal leiomyomas or other screening failures will be rigorously accounted for and documented within a standard CONSORT Flow Diagram to ensure transparency.

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REFERENCES & PATENT CITATIONS

* Literature Reference: "Contemporary Management of Fibroids in Pregnancy". PubMed Central Project ID: PMCID: PMC2876313. URL: http://nih.gov