

# **CLINICAL STUDY DOCUMENT**

## **STUDY PROTOCOL**

**Official Title: Removal the Uterine Fibroids**

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

**NCT Number: NCT04762316**

**Document Date: June 3, 2026**

## 1. ADMINISTRATIVE INFORMATION & TRIAL IDENTIFICATION

- \* Unique Protocol ID: Removal of the Uterine Fibroids
- \* Brief Title: Composition for Treating Uterine Fibroid (SB-UF)
- \* Official Title: Uterine Fibroids Are a Prevalent Finding in Women of Reproductive Age. Ready Safety Study Extracts of Plants Pregnenolone, Pyridoxal Phosphate, and Dydrogesterone for Treating Uterine Fibroids in Women's Pregnancy.
- \* Study Phase: Phase 4
- \* Primary Purpose: Treatment
- \* Study Type: Interventional (Clinical Trial)
- \* Interventional Model: Parallel Assignment (Two-arm, randomized study)
- \* Masking: Double-Blind (Participant, Investigator)
- \* Allocation: Randomized
- \* Target Enrollment: 66 subjects [Actual]
- \* Study Timeline:
  - Study Start Date: January 1, 2019 [Actual]
  - Primary & Study Completion Date: December 31, 2025 [Actual]
  - Overall Status: Completed
- \* Regulatory Status:
  - U.S. FDA-regulated Drug/Device: No
  - U.S. FDA IND/IDE: No
  - Human Subjects Review Board Status: Exempt
  - Data Monitoring: No
- \* Study Site & Facility: Saigon Biopharma Company Limited, Ho Chi Minh City, Vietnam (Postal Code: 700000)
- \* Study Officials & Investigators:
  - Principal Investigator: Thi Trieu Nguyen, M.D.
  - Central Contact Person: Minh Duc Tran, Dr. (Email: ductranminh61@gmail.com | Tel: 0938307835 Ext. 84)
  - Central Contact Backup: Minh Cam Tu Tran, Dr. (Email: seasun2012@gmail.com | Tel: 0789839942)

## 2. CLINICAL STUDY PROTOCOL

### 2.1 Background & Pathogenesis Rationale

Pregnenolone is synthesized from cholesterol and serves as the precursor for Progesterone, Estrogen, and Dehydroepiandrosterone (DHEA). A physiological decline or hormonal imbalance in Pregnenolone levels disrupts the progesterone-to-estrogen ratio, triggering the abnormal proliferation of uterine smooth muscle cells (myometrial cells) and subsequent development of multiple leiomyomas. Uterine fibroids are a highly prevalent finding during pregnancy in women of reproductive age, exhibiting rapid expansion during the first trimester under intense gestational hormonal influence. Supplementation with the investigational formulation SB-UF is proposed to restore hormonal equilibrium, stabilize estrogen levels, inhibit rapid fibroid growth, and induce fibroid tissue dissolution.

### 2.2 Mechanism of Action (MOA)

The investigational compound SB-UF features a synergistic combination of plant-derived active ingredients: Pregnenolone (extracted from *Dioscorea villosa* / *Dioscorea permisilis* prain & burkill), Coenzyme Pyridoxal Phosphate, and Dydrogesterone. This unique composition targets the uterine smooth muscle fibers within the leiomyomas. The formulation acts to soften, diffuse, and dissolve the fibroid tissues, thereby curbing hyper-proliferation, maintaining baseline uterine muscle integrity, and allowing normal uterine involution alongside uncompromised fetal development.

### 2.3 Study Objectives

\* Primary Objective: To evaluate the therapeutic efficacy of the investigational drug SB-UF in achieving complete uterine fibroid dissolution or significant volumetric regression after a standardized 40-week intervention period in pregnant women.

\* Secondary Objectives: To assess the reduction of fibroid-associated maternal and obstetric complications, including spontaneous miscarriage, premature birth, placental abruption, labor dysfunction, cesarean section rates, and postpartum hemorrhage (PPH), while evaluating future fertility preservation.

### 2.4 Eligibility Criteria

\* Inclusion Criteria:

1. Women aged 18 to 40 years presenting with an active pregnancy.
2. Documented diagnosis of uterine fibroids presenting in the following specific anatomical phenotypes: Intramural fibroids, Submucosal fibroids, or Subserous fibroids.

3. Subjects must be precisely in their 8th week of pregnancy at the time of screening and enrollment.

4. Subjects undergoing medical procedures/interventions for the management of fibroids during pregnancy who strictly desire future fertility preservation.

\* Exclusion Criteria:

1. Presence of pedunculated subserosal fibroids hanging from a stalk, located either inside or outside the uterine cavity (due to risk of acute adnexal torsion).

2. Healthy volunteers without active uterine fibroids affecting pregnancy (Accepts Healthy Volunteers: No).

## 2.5 Treatment Arms and Intervention Regimens

\* Experimental Arm: SB-UF Drug Group (n = 33)

- Assigned Intervention: Active oral drug formulation.

- Active Ingredients per Tablet: Pregnenolone (60 mg), Pyridoxal Phosphate (20 mg), Dydrogesterone (10 mg), and Impatiens balsamina extract (100 mg).

- Dosing Regimen: Take 1 tablet, 2 times daily (BID) orally, administered continuously throughout the duration of pregnancy.

\* Control Arm: Placebo Comparator Group (n = 33)

- Assigned Intervention: Inactive oral device/formulation matching the appearance, taste, and packaging of the active drug.

- Composition per Tablet: Pregnenolone & Pyridoxal Phosphate Placebo matrices without therapeutic active components.

- Dosing Regimen: Take 1 tablet, 2 times daily (BID) orally, administered continuously throughout the duration of pregnancy.

## 2.6 Outcome Measures

\* Primary Outcome Measure: Regression and complete disappearance of benign smooth muscle cell tumors of the uterus (uterine leiomyomas), monitored longitudinally via serial ultrasound examinations assessing tumor diameter and myometrial wall presentation.

- Time Frame: 40 weeks (sequential tracking from week 4 to week 40 through study completion).