RESEARCH SUMMARY

High Triterpene Shea Nut Extract (HTSNE)

ACTIVE INGREDIENT:
Shea Nut,
Butyrospermum parkii

STUDY MATERIAL:
BSP-201

CLINICAL PROBLEM:
chronic inflammation, including elevated or imbalanced cytokines, affecting IL-6, TNF-α and other markers of inflammation

Inflammation is a pervasive health problem, causing serious local and systemic illness when left uncorrected. Bodily systems adversely affected by inflammation include the musculoskeletal, cardiac, respiratory, dermatological and other systems. The active ingredient in BSP-201, a high triterpene Shea nut extract, HTSNE, provides substantial anti-inflammatory support without any known adverse side effects or toxicity reactions. This extract demonstrated significant anti-inflammatory properties in a number of clinical studies. These studies showed effectiveness for both systemic and specific inflammation.

MEDICATION	DESIRED EFFECT	CYTOKINE ACTION	SIDE EFFECTS
HTSNE	Anti-inflammatory	Yes	None
NSAIDs (e.g. ibuprofen)	Anti-inflammatory	No	GI lesions, ulcers, bleeding, renal failure, etc.
Cox 2 inhibitors	Anti-inflammatory	No	Renal impairment, edema, hypertension, cardiac stress, myocardial infarction
Steroids (e.g. dexamethasone)	Anti-inflammatory	Yes	Hypertension, thromboembolism, heart failure, immuno-suppression, bone destruction

PROVEN SAFETY

As a result of proven safety, the HTSNE was one of only 7 new products in 2004 allowed into the US by the FDA and designated a new dietary ingredient by the US government. The raw material, shea nuts, has been used in cosmetics and food in Europe and Africa, for centuries.

STUDIES SHOWED THE FOLLOWING CLINICAL BENEFITS OF HTSNE

- Improved function of Type II collagen, which compromises 70% of cartilage. This type of collagen forms the structural meshwork that holds the proteoglycans in place in cartilage.
- Retention of collagen, the primary building block of all connective tissue.
- Inflammation reduction in osteoarthritis
- Modulating effect on cytokines TNF-α and IL-6
- Reduction of hs-CRP, inflammatory marker
- Reduction of destruction of cartilage and bone, including in the highest risk groups
- Reduction of pain in affected joints
- Improved circulatory flow of needed nutrients to the joint matrix and capillary membranes affected by osteoarthritis

BIOMARKER IMPROVEMENTS IN OSTEOARTHRITIS PATIENTS

A randomized placebo controlled trial focused on the safety and efficacy of HTSNE in osteoarthritis used radiologic and clinical evidence methods for assessment. COAT (Comprehensive Osteoarthritis Test) Scores were used as part of the assessment measures during the trial. Overall results were:

- TNF-α: reduction was 17.9% overall, and in the group with elevated levels the reduction was 23.9%.
- IL-6: 30.9% reduction
- hs-CRP: 20.6% reduction
- CTX-II: this cartilage marker fell 28.7% in the group with elevated levels vs. the placebo group, where this marker increased by 17.6%, for a total of 46.3% reduction in cartilage destruction.
- Osteocalcin: 9.2% reduction in the group with elevated levels, and no reduction in the group with lower levels. The significance of this is the HTSNE provides a protective effect for the highest risk group by reducing the factors that cause bone repair to occur in response to the unabated inflammatory processes that are part of osteoarthritis.

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As part of this same study, the following results were observed for those participants who were in the highest risk inflammation subset:

- TNF-α: 24% reduction.
- IL-6: 22% reduction
- hs-CRP: 22% reduction
- CTX-II: 39% reduction in this marker for cartilage destruction in subjects with elevated levels, vs. placebo which had a 31% increase in this marker. This represents a total of 70% reduction in cartilage destruction.
- Osteocalcin: 7.75% reduction in the group with elevated osteocalcin.
- Significant improvement in circulation: 6.3 mmHg reduction in diastolic blood pressure in the group with elevated blood pressure.

EXERCISE INDUCED PAIN SIGNIFICANTLY REDUCED

A human trial on post-exercise pain was designed to have the participants start at reported levels of no muscle pain at the beginning of the trial. An exercise was performed to cause pain in a specific muscle. This trial showed that for the group who used the HTSNE, muscle tenderness was significantly reduced right after exercise, 1 day after exercise, 2 days after exercise (expected maximal pain and discomfort) and 8 days after exercise, as compared to the group who did not take HTSNE. No adverse events were reported by the group who used HTSNE. The Visual Analog Scale (VAS) showed a statistically significant reduction of pain in the group that used the HTSNE.

EFFICACY WITHOUT SIDE EFFECTS
DIRECT COMPARISON OF HTSNE AND IBUPROFEN (NSAID)

In another study, performed on animal subjects, a comparison was made between the anti-inflammatory effects of ibuprofen and HTSNE. The HTSNE, dosed at 1000 mg/kg equaled the anti-inflammatory, anti-edema effects of ibuprofen at 150 mg/kg. An added benefit is that the use of HTSNE does not cause gastrointestinal lesions, such as ulcers and other GI damage, which are key side effects with the use of NSAIDs, including ibuprofen.

DIRECT COMPARISON OF HTSNE AND DEXAMETHASONE (STEROID)

Animal studies on inflammation have compared the effects of HTSNE and a steroid medication, dexamethasone. HTSNE at 1000 mg/kg equaled the anti-inflammatory effects of dexamethasone at 0.025 mg/kg. Additionally, an adverse impact on body weight was only noted in the dexamethasone group. When compared to a steroid, HTSNE does provide a strong anti-inflammatory benefit and it does not cause the adverse side effects commonly noted with steroid use.

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