PLT Announces New Clinical Study on AprèsFlex® 5-Day Joint Support Ingredient that Demonstrates Longer-Term Overall Mobility Support and Cartilage Preservation and Protection

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Fourth Clinical on AprèsFlex breaks new ground on delivering joint space, and cartilage thickness benefits

MORRISTOWN, N.J., Sept. 6, 2023 /PRNewswire/ -- PLT Health Solutions, Inc announced the completion of a six-month clinical study on its AprèsFlex® 5-Day Joint Support ingredient in collaboration with PLT innovation partner Laila Nutraceuticals (Krishna, Andhra Pradesh, India). This study validates and extends the findings of three previous double-blind studies showing that AprèsFlex provides significant improvements in joint comfort at a low 100mg dose. The new study validates the improvements in joint comfort, stiffness and physical function at the 1- and 3-month marks, and shows that those benefits continue to increase, with no plateau effect through the end of the six-month study. The study also shows long-term improvements in functional capacity for walking and stair climbing, activities of daily

living most affected by those with joint comfort and mobility issues. Most impressively, these groundbreaking results demonstrate preservation of joint space and cartilage thickness compared with placebo, and significant reduction of biomarkers of inflammation and cartilage degradation.

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"Having previously shown that AprèsFlex was effective and fast-acting, this new study demonstrates that the improvements in comfort, stiffness and function experienced with AprèsFlex correlate with the preservation and long-term protection of cartilage," said Jen Murphy, Director of Innovation & Clinical Development at PLT Health Solutions.

This is the first study of a *Boswellia serrata* ingredient demonstrating support for cartilage preservation – a major concern for consumers and product formulators in the joint health/mobility space. This fourth double-blind, placebo-controlled human clinical study on AprèsFlex sets it apart from other ingredients in terms of its demonstrated efficacy across this broad range outcome measures. Previous studies of AprèsFlex have demonstrated improvements in joint comfort in as few as five days. All studies were completed with a low 100 mg/day dose.

According to Seth Flowerman, President & CEO of PLT Health Solutions, this study breaks new ground on the potential for the supplement industry to provide joint health and mobility support. "AprèsFlex is one of the world's most widely used joint comfort ingredients, powering major consumer brands – because it works – and now we know that it keeps

working for the long-term. Working with our innovation partner Laila Nutraceuticals, PLT designed a study that could evaluate both the long-term potential for this ingredient and its ability to address the unmet needs of joint space preservation and cartilage protection," he said. "When you see results like a 70% improvement in comfort, stiffness, and function, and 30% improvement in functional capacity in a longer-term setting, these are not just statistics, but tangible results that can meaningfully improve people's lives. The joint space and cartilage preservation data from this study is a game-changer for our industry," he added.

Patented formulation combats inflammation

AprèsFlex is a patented, synergistic *Boswellia serrata* gum resin extract. The oral bioavailability of acetyl-11-keto-beta-boswellic acid (AKBA) from AprèsFlex has been shown to be about 52% higher than other commercially available Boswellia extracts, allowing for a lower daily dose with enhanced efficacy.

Six-month study will power innovative mobility products

In the recently completed randomized, double-blind, placebo-controlled clinical trial, eighty normal-to-overweight women and men (age 40-75) received either 100 mg/day of AprèsFlex or a matching placebo for six months. Study endpoints included joint comfort (WOMAC, VAS, Lequesne Functional Index); functional capacity testing (six-minute walk, stair climb); MRI evaluation of the knee joints to assess joint space narrowing, cartilage thickness, and analysis of several biomarkers related to cartilage breakdown and inflammation.

Measurements were made at baseline, one, two, four, and six months.

Subjects taking AprèsFlex experienced steady improvement in joint comfort, with up to a 70% reduction in pain by the end of the study. Those same subjects experienced 25% less stiffness on Day 30 and up to a 72% reduction in stiffness at six months. AprèsFlex subjects showed a 71% improvement in physical function at six months.

Impressively, AprèsFlex subjects demonstrated substantial, significant improvements in their functional abilities including an increase in walking speed of nearly 27% and a reduction in time to ascend and descend stairs of 30%.

In first of its kind data for a low-dose joint health ingredient, MRI assessments of joint space in the knee showed AprèsFlex limited joint space narrowing, actually improving joint space, while subjects taking placebo experienced further narrowing of knee joint space. When joint space narrowing occurs, cartilage can no longer keep bones a normal distance apart, resulting in increased pressure and pain.

MRIs of femoral, patellar, lateral tibial, and medial tibial cartilage thickness showed decreases in the placebo group over six months, whereas cartilage thickness was maintained and even slightly improved in the AprèsFlex group at 180 days. Changes in biomarkers of cartilage degradation (C2C, uCTX-II, Fibulin-3) validated these protective effects of AprèsFlex against cartilage breakdown. Biomarkers of systemic and joint inflammation (hsCRP, MMP-3) were also significantly improved in the AprèsFlex group compared to placebo.

According to Jen Murphy, Director of Innovation & Clinical Development at PLT, the design of this study was developed in response to industry interest in three main indicators of joint health: fast-acting and long-lasting comfort, physical function, and cartilage protection, with the latter benefit being the most revelatory in terms of current results. "Currently, most ingredients that purport to support cartilage, like collagens, benefit from a story that relies on their compositional similarity to cartilage, but these ingredients lack human clinical data showing benefits to cartilage. The scientific evidence for structural benefits from consuming cartilage or any of its components is limited," Murphy said. "Having previously shown that AprèsFlex was effective and fast-acting, this new study demonstrates that the improvements in comfort, stiffness and function experienced with AprèsFlex correlate with the preservation and long-term protection of cartilage," she added.

To learn more about AprèsFlex, visit us at SupplySide West 2023 (Oct 23-27) in Las Vegas Booth #4655 or visit the PLT website at www.plthealth.com/apresflex.

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