Ausio Pharmaceuticals, LLC

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Ausio Pharmaceutical's ERβ Agonist AUS-131 is Well Tolerated in First Human Clinical Trials

Study Results Published in February *Menopause* Offer a Potentially Safer Option for the Treatment of Menopausal Symptoms

February 7, 2011 (Cincinnati, Ohio) –Results of two Phase 1 clinical trials of S-equol (AUS-131) were published in the February issue of *Menopause: The Journal of the North American Menopause Society*. This first-in-class, nonsteroidal, nonhormonal estrogen receptor β (ERβ) agonist offers a potentially safer alternative to estrogen for the treatment of menopausal symptoms. As part of a drug development program, these studies were the first to investigate AUS-131 in humans. Results demonstrated a favorable safety and pharmacokinetic profile for AUS-131, and have allowed the company to proceed to Phase 2 clinical trials, which will be completed in Q3 2011.

These studies evaluated the pharmacokinetics and tolerability of single and multiple oral doses of AUS-131 in healthy volunteers. These studies also established the doses for proof of concept Phase 2 studies investigating AUS-131 as a treatment for postmenopausal women with vasomotor symptoms (VMS), commonly referred to as hot flashes. Results also support Ausio's development of AUS-131 as a treatment option to inhibit prostate cell growth in men with benign prostatic hyperplasia (BPH).

The full paper is available at:

http://journals.lww.com/menopausejournal/Abstract/2011/02000/Single_dose_and_steady_state_pharmacokinetic.15.aspx

"One of the compelling reasons for developing S-equol as a pharmaceutical product is that women are reluctant to take estrogens for their menopausal symptoms" said Richard Jackson, PhD, Ausio Pharmaceuticals, LLC, President and CEO, and the study's lead author. "Based on the Phase 1 studies, AUS-131 offers an oral medication that safely delivers therapeutic levels of S-equol, which may benefit patients with a variety of diseases and conditions."

History of Treatment of Menopausal Symptoms and Significance of S-Equol

Whereas hormone therapy (HT) has been the therapy of choice for the management of menopausal symptoms in women, the Women's Health Initiative has shown that HT has been associated with increased risk of invasive breast cancer, coronary heart disease, stroke, and deep vein thrombosis. This increased risk is associated with the abundance and prominent role of the estrogen receptor α (ERα) in the breast, uterus, and endothelium in the cardiovascular system. Alternative treatments for VMS have included serotonin, norepinephrine, mixed reuptake inhibitors, and botanicals such as soy products and black cohosh, but these treatments have both efficacy and safety issues.

Beyond botanicals, purified, nonsteroidal isoflavones found in soy – genistein, daidzein and glycitien – have been studied for the treatment of chronic diseases in the aging population, including, among others, VMS in post-menopausal women, with limited success. Daidzein is further biotransformed to the isoflavan S-equol by the intestinal bacteria flora of certain individuals, particularly Asians. Published reports show that patients who demonstrate the health benefits of soy are those who are equol producers.

Cincinnati-based Ausio Pharmaceuticals, LLC has developed a patented chemical process for the synthesis of S-equol that allows for large-scale production of pure GMP-quality S-equol to conduct clinical trials.

About the Studies

Two randomized, double-blind, placebo-controlled clinical trials were performed in healthy volunteers: a single-rising dose study in 61 participants and a 14-day repeat-dose study in 40 participants. Safety, tolerability, and pharmacokinetics of AUS-131 were assessed in both men and women.

AUS-131 was well-tolerated by all participants with no significant drug-related adverse events at doses several-fold higher than the expected therapeutic range. Food decreased maximal plasma concentration but did not significantly affect overall exposure to the drug. AUS-131 was readily absorbed with a steady-state level of S-equol achieved after the first day of twice-daily dosing. The pharmacokinetics of the drug were linear with dose and showed that the drug was readily cleared from the body. Subjects receiving the lower doses of AUS-131 achieved plasma levels of S-equol equivalent to those that researchers have associated with the health benefits of ingestion of soy.

These studies in healthy participants also provided the first report of plasma and urine levels of unconjugated S-equol after oral dosing using a recently published highly sensitive method. Results from Phase 1 studies provided dosing information for the ongoing international, multicenter Phase 2a efficacy trials in patients with VMS and BPH.

About AUS-131

AUS-131 is a first-in-class, nonsteroidal, nonhormonal, selective ERβ agonist that has the potential to provide the therapeutic benefits that researchers have attributed to soy ingestion.

Importantly, results to date show that the compound has an excellent safety profile compared to estrogen. AUS-131 is pure, synthetic S-equol, which is a soy isoflavone that is naturally produced in a small percent of individuals after ingestion of soy. This molecule is being evaluated for a wide range of indications, including menopausal symptoms, BPH, osteoporosis, and topical applications.

About Vasomotor Symptoms

In the US, there are more than 40 million post-menopausal women. The major products available to these women for VMS are estrogens, which have current US sales of $1.8 billion, despite the risks associated with their use. The results of the Women's Health Initiative study showing increased risk of breast cancer, cardiovascular events, stroke and venous thrombosis with long-term estrogen-progestin therapy have dramatically decreased the use of estrogen therapy and increased the market opportunity for new VMS therapy with an ERβ agonist, such as the S-equol product, AUS-131.

About Ausio Pharmaceuticals

Ausio Pharmaceuticals, LLC, is a private biotechnology development company focused on the advancement of safe and effective medicines for the aging population. Ausio was founded in 2006 by Richard Jackson, PhD based on technologies licensed from the Australian Health and Nutrition Association Ltd, NSW, Australia, and Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio. The company has garnered a strong patent position for its lead compound, AUS-131. It has rapidly developed AUS-131 by working with excellent service providers. Ausio's strategic goal is to collaborate with international pharmaceutical partners for AUS-131 in the US and other markets worldwide. For further information on Ausio, please visit the Company's website: www.ausiopharma.com.