Flaxseed Lignan-Enriched Complex Products in Chronic Disease

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Technology description

History of Industry Engagement:
In 2007 Archer Daniels Midland (ADM) began marketing a flaxseed lignan enriched complex (38% SDG) called BeneFlax® with both FDA and Health Canada approval. Later, ADM stopped production of BeneFlax® to focus on soy isoflavanoids. However there has been a growing body of science to support the value of lignan supplementation in management of chronic diseases. Bioactive enriched products like BeneFlax® are likely to show meaningful therapeutic or chemopreventative properties.
Collaborators:

Dr. Alcorn has built a strong collaborative network of researchers and clinician researchers including Dr. Ed Krol (Pharmacy and Nutrition, Dr. Phil Chilibeck (Kinesiology), Dr. Susan Whiting (Pharmacy and Nutrition), Dr. Sharyle Fowler (Medicine), and Dr. Thomas Hadjistavropoulos (U. of Regina), as well as with one of the original inventors of the technology for BeneFlax, Dr. Alister Muir, to create an integrated package of safety, efficacy, and mechanism of action data for the lignans of flaxseed.

Pre clinical Data:

In Dr. Alcorn’ s laboratory, animal model studies demonstrate clear anticholesterolemic effects and in vitro analyses may have identified lignan mode of action (a novel mechanism) in the hypercholesterolemic effect of lignans (results pending). Furthermore, in vitro analyses are demonstrating important effects in inflammatory conditions of the gastrointestinal tract. (Fig 2) As well, in in vitro evaluations we have we demonstrated synergism between the lignans and important chemotherapeutic agents used in treatment of breast or prostate cancer (Table 1).

Clinical Data:

Recently completed Phase IIa human clinical trials in healthy and frail older adults indicate good safety and tolerability of BeneFlax®. Current human clinical trials are underway to examine efficacy of BeneFlax® oral supplementation in patients with 1) mild-to-moderate ulcerative colitis and 2) elderly patients with high normal to stage I hypertension. Furthermore, a validated pharmaceutical analytical method has allowed for important pharmacokinetic (PK) characterizations of the flaxseed lignans (e.g. intestinal permeability in Caco-2, phase II metabolism in intestinal and hepatic microsomes, cytochrome P450 inhibition potential (DDI potential), PK of individual flaxseed lignans in animal models, PK of single oral dose and multiple oral dose administration of BeneFlax® in healthy adults (Fig. 3)). The combination of our biomedical studies on safety, efficacy, and mechanism of action, and clinical trials to confirm the biomedical studies, has compiled important information to begin to establish a scientific basis for possible health claims for the flaxseed lignans.

Fig. 3

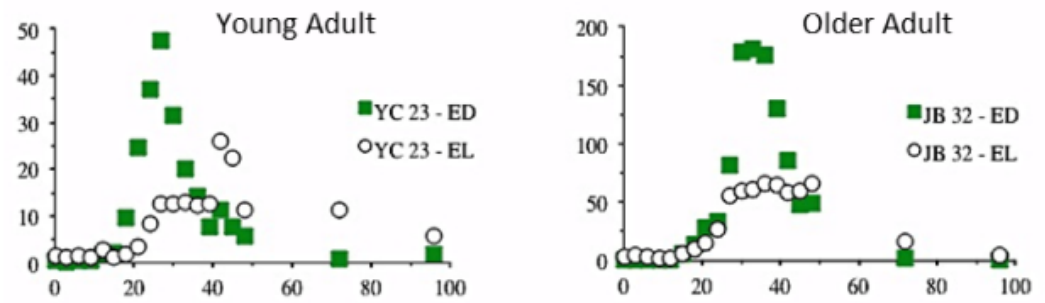

Figure 3. Single oral dose administration of BeneFlax® (equivalent to 300 mg secoisolariciresinol diglucoside) to young and elderly healthy adults. Age-dependent differences in lignan pharmacokinetics were noted.

Advantages

Lignans are naturally occurring biologically active polyphenolic compounds present in flaxseed. The major lignan in flaxseed is SDG (Secoisolariciresinol diglucoside) and flaxseed is the richest known source of this compound (Fig.1). Cell models, animal studies, epidemiological studies, and randomized human clinical trials have all demonstrated significant potential for flaxseed lignan supplementation in

management of or risk reduction for a number of chronic diseases including cancer, heart disease, BPH, hypertension, and inflammatory bowel disease.

Institution

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