Study Finds Extended Release Niacin, but not IHN, Effective in Lowering Cholesterol Levels

Allendale, New Jersey, 6 February 2013 – Evidence from a study published in the January issue of Journal of Clinical Lipidology, Volume 7, Issue 1, Pages 14 – 23 reports inositol hexanicotinate (IHN) ineffective in managing high cholesterol. The study, which published clinical results comparing an extended-release form of niacin to IHN and a placebo, simultaneously confirms a wax-matrix form of extended release niacin can help lower cholesterol.

Conducted by Joseph M. Keenan, MD, and a team of researchers from the University of Minnesota, the study examined 120 subjects with high cholesterol at the University’s Clinical Research Center. Subjects received instruction for a heart-healthy diet, and were monitored for diet, medication side effects, blood chemistries, blood lipids and dosing compliance throughout the study. Five subjects from each group were randomly selected for a pharmaco-kinetic sub-study in the research center. Blood tests over eight hours were used to measure the absorption rate and metabolism of the subjects’ first 500 mg dose of wax-matrix, extended release niacin in the form of Niamax™ (also known by the brand name Endur-Acin®) and IHN.

Results showed IHN and placebo produced no significant improvement in blood lipids. Conversely, wax-matrix niacin, demonstrated positive lipid benefits, reducing total cholesterol 11 percent, LDL cholesterol 18 percent, non-HDL cholesterol 15 percent and triglycerides nine percent. It also promoted an increase in HDL cholesterol by 12 percent.

“IHN has been a popular choice for niacin therapy, especially by alternative health providers because of its ‘no flush’ claim. However, there has never been a controlled study of IHN conducted on a United States population, and several European studies using IHN were combination interventions making it difficult to measure the contribution of IHN to lipid benefits,” said principal investigator Joseph Keenan, MD. “This clinical trial was a six-week placebo controlled comparison of 1500 mg/day of the two niacin products, which also included a pharmaco-kinetic sub-study designed to give health professionals a scientific basis for making their choice in niacin therapy.”

Previous studies with wax-matrix niacin have shown that about 15 percent of subjects are especially sensitive to niacin, and instead utilize a lower than typical therapeutic dose. Six subjects in the wax-matrix niacin arm of this study completed the study on a reduced dose (500 to 1000 mg/day) and had comparable lipid benefits to the full dose subjects. Blood chemistry monitoring showed a modest rise in liver enzymes within the range of normal, which was not considered clinically significant.
"IHN was well tolerated, and subjects were compliant with dosing and study protocols, but there were essentially no lipid benefits at all and the IHN results were the same as placebo," said Dr. Keenan. "The pharmaco-kinetic sub-study was helpful in explaining these results since the blood assays showed no evidence of nicotinic acid rise after a 500 mg dose nor any nicotinic acid metabolites." (See Fig 1-3)

"This study concluded that the nicotinic acid in IHN is not bio-available, and there’s no evidence that it reaches the therapeutic levels needed to alter lipids. Therefore it has no place in the management of high cholesterol," continued Dr. Keenan. "In fact this study raises the ethical issue of whether IHN has any benefit at all even as a vitamin supplement."

For over 40 years, Lonza has been the global leader in niacin production. Niacin is used as a dietary supplement and maintains good cholesterol within the normal range.

About Lonza
Lonza is one of the world’s leading suppliers to the pharmaceutical, healthcare and life science industries. Products and services span its customers’ needs from research to final product manufacture. It is the global leader in the production and support of chemical and biological active pharmaceutical ingredients. Biopharmaceuticals are one of the key growth drivers of the pharmaceutical and biotechnology industries. Lonza has strong capabilities in large and small molecules, peptides, amino acids and niche bioproducts which play an important role in the development of novel medicines and healthcare products. Lonza is also the world leader in microbial control providing innovative, chemistry-based and related solutions to destroy or to selectively inhibit the growth of harmful microorganisms. Its activities encompass the areas of water treatment, personal care, health and hygiene, industrial preservation, materials protection, and wood treatment. In addition, Lonza is a leader in cell-based research, endotoxin detection and cell therapy manufacturing. Furthermore, the company is a leading provider of value chemical and biotech ingredients to the nutrition and agro markets.

Lonza is headquartered in Basel, Switzerland and is listed on the SIX Swiss Exchange and secondary listed on the Singapore Exchange Securities Trading Limited (“SGX-ST”). Lonza is not subject to the SGX-ST’s continuing listing requirements. Lonza is subject to the listing rules of the SIX Swiss Exchange, which do not have specific requirements equivalent to the listing rules of the SGX-ST in respect of interested person transactions, acquisition and realizations, and delisting. In 2012, the company had sales of CHF 3.925 billion. Further information can be found at www.lonza.com.
Figure 1. Mean serum levels of nicotinic acid after 500 mg dose of Niamax™/Endur-Acin® (WMER) or IHN
Figure 2. Mean serum levels of nicotinuric acid after 500mg dose of Niamax™/Endur-Acin® (WMER) or IHN

Figure 3. Mean serum levels of nicotinamide after 500mg dose of Niamax™/Endur-Acin® (WMER) or IHN