We create chemistry

News Release

29 October 2018

BASF clinical trial reveals significant reduction in liver fat content in patients with non-alcoholic fatty liver disease

Oslo, Norway – October 29, 2018 – BASF AS completed a randomized, placebo-controlled clinical trial in the U.S., newly published in Nutrients, evaluating the use of high concentrate omega-3 to correct the nutritional deficiency of omega-3 fatty acid in patients with non-alcoholic fatty liver disease (NAFLD). Several studies have shown that NAFLD patients have lower levels of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)[i].

The study, covering 176 patients, demonstrates that intervention with high concentrate omega-3 for 24 weeks significantly raises the omega-3 index in adults with NAFLD compared to placebo, thereby correcting the patients' nutritional deficiency. Patients showed reductions of up to 44% in liver fat after placebo correction, providing evidence that clinical management of NAFLD with high concentrate omega-3 has a beneficial outcome on liver fat. This intervention study supports a recently published meta-analysis that concluded that omega-3 fatty acids are associated with significant improvements in liver fat and liver function tests with approximately 3g of EPA and DHA daily.

BASF launched Hepaxa™ in February 2018 in the U.S. as the first-to-market, dedicated product for the dietary management of patients with NAFLD. Hepaxa increases the levels of EPA and DHA in patients with NAFLD, which improves the liver´s ability to process fat in the liver. These data support the use of Hepaxa for

Media Relations
Raga Mahmoud
Phone: +49 621 60-48841
raga.mahmoud@basf.com

BASF SE
67056 Ludwigshafen
http://www.basf.com
presse.kontakt@basf.com

patients with NAFLD. Together with diet and exercise, Hepaxa offers a viable and dedicated option for managing NAFLD.

“Science has always been the backbone of all our development work and efforts in the area of liver health, and this study is further evidence that Hepaxa can significantly reduce liver fat content, which is crucial in managing NAFLD.” says Derek Tobin, Team Leader for Innovation, Advanced Health Solutions, BASF.

“We are excited about the growing and solid scientific basis for our product and its beneficial effects in the dietary management of NAFLD. Hepaxa can truly help millions of patients today with what has become a growing chronic disease.” adds Christoph Garbotz, Head of Commercial Management Advanced Health Solutions, BASF.

Hepaxa is manufactured using a patented purification technology, which removes persistent organic pollutants and other unwanted lipids, such as cholesterol, that are naturally found in many fish oil-based products. Research has shown that one specific pollutant, PCB 153, is particularly harmful in NAFLD[ii]. As the liver function of NAFLD patients is compromised, it is important to limit exposure to unwanted components that are present in many less-refined fish oils. Hepaxa has an excellent safety profile. It is GRAS (Generally Recognized As Safe) for use as a medical food for the dietary management of NAFLD at intakes of up to 3 g/day of EPA & DHA for both adults and pediatrics 10 years of age and older.

A poster presentation of the BASF study will be displayed at the “American Association for the study of Liver Diseases (AASLD)” conference in San Francisco, 9 – 13 November 2018. The poster from BASF has been awarded Poster of Distinction by the AASLD Scientific Program Committee. Posters of Distinction are considered by academics in the field to be particularly noteworthy and represent the top 10% of all accepted poster presentations. BASF invites physicians, healthcare professionals, commercial partners and other interested stakeholders to visit us at our poster, number 2348B, or booth number 143 of Diem Labs, BASF’s U.S. distributor for Hepaxa, to learn more about the study and engage in scientific and commercial discussions.

Hepaxa is available as a medical food product in the U.S. to patients 10 years and

older with NAFLD for use under physician supervision. Physicians, healthcare professionals and patients can gather more information at www.Hepaxa-USA.com.

About BASF's Nutrition & Health division
BASF Nutrition & Health provides a comprehensive product and service portfolio for the human and animal nutrition, pharmaceutical, ethanol and flavor & fragrance industries. With innovative solutions and modern technologies, we help our customers improve their business efficiency and the sustainability of their products. Our human nutrition solutions include vitamins and carotenoids, plant sterols, emulsifiers and omega-3 fatty acids. Vitamins and carotenoids also form an important part of our animal nutrition portfolio, as do other feed additives such as trace elements, enzymes and organic acids. We provide the pharmaceutical industry with a broad range of excipients and selected large-volume active pharmaceutical ingredients such as ibuprofen and omega-3 fatty acids. Leveraging our advanced technology, we create high performance industrial enzymes for different markets, such as ethanol production. Furthermore, we offer aroma ingredients such as citral, geraniol and L-menthol. BASF Nutrition & Health operates sites in Europe, North America, South America and in Asia-Pacific. For more information, go to www.basf.com.

About BASF
At BASF, we create chemistry for a sustainable future. We combine economic success with environmental protection and social responsibility. The more than 115,000 employees in the BASF Group work on contributing to the success of our customers in nearly all sectors and almost every country in the world. Our portfolio is organized into five segments: Chemicals, Performance Products, Functional Materials & Solutions, Agricultural Solutions and Oil & Gas. BASF generated sales of €64.5 billion in 2017. BASF shares are traded on the stock exchanges in Frankfurt (BAS), London (BFA) and Zurich (BAS). Further information at www.basf.com.

[i] Allard JP, Aghdassi E, Mohammed S, Raman M, Avand G, Arendt BM, et al. Nutritional assessment and hepatic fatty acid composition in non-alcoholic fatty liver disease (NAFLD): A cross-sectional study. J Hepatol 2008;48:300–7. doi:10.1016/j.jhep.2007.09.009.

Araya J, Rodrigo R, Videla L, Thielemann L, Orellana M, Pettinelli P, et al. Increase in long-chain polyunsaturated fatty acid n - 6/n - 3 ratio in relation to hepatic steatosis in patients with non-alcoholic fatty liver disease. Clin Sci 2004;106:635–43. doi:10.1042/CS20030326.

Pettinelli P, del Pozo T, Araya J, Rodrigo R, Araya AV, Smok G, et al. Enhancement in liver SREBP-1c/PPAR-α ratio and steatosis in obese patients: Correlations with insulin resistance and n-3 long-chain polyunsaturated fatty acid depletion. Biochim Biophys Acta - Mol Basis Dis 2009;1792:1080–6. doi:10.1016/j.bbadis.2009.08.015.

Elizondo A, Araya J, Rodrigo R, Poniachik J, Csendes A, Maluenda F, et al. Polyunsaturated fatty acid pattern in liver and erythrocyte phospholipids from obese patients. Obesity 2007;15:24–31. doi:10.1038/oby.2007.518.

Rose M, Veysey M, Lucock M, Niblett S, King K, Baines S, et al. Association between erythrocyte

omega-3 polyunsaturated fatty acid levels and fatty liver index in older people is sex dependent. J Nutr Intermed Metab 2016;5:78–85. doi:10.1016/j.jnim.2016.04.007.

[ii] Shi X, Wahlang B, Wei X, Yin X, Falkner KC., Prough RA, Kim SH., Mueller EG, McClain CJ, Cave M and Zhang X. Metabolomic Analysis of the Effects of Polychlorinated Biphenyls in Non-alcoholic Fatty Liver Disease. Proteome Res. 2012 July 6; 11(7): 3805–3815

Wahlang B, Falkner KC, Gregory B, Ansert D, Young D, Conklin DJ, Bhatnagar A, McClain CJ, Cave M, Polychlorinated Biphenyl 153 Is a Diet-dependent Obesogen Which Worsens Nonalcoholic Fatty Liver Disease In Male C57BL6/J Mice. J Nutr Biochem. 2013 September ; 24(9): 1587–1595