



Microphyt's PhaeoSOL receives New Dietary Ingredient (NDI) Status from the FDA

- **PhaeoSOL is a natural microalgae-based nutritional ingredient aiming at improving the well-being of the elderly and preventing certain metabolic disorders**
- **Backed by proprietary efficacy data, PhaeoSOL key benefits will be presented at the 2019 Supply Side West show in Las Vegas (USA)**
- **Microphyt is the first European microalgae company which has received NDI Status from the FDA**

Baillargues (France), October 15th, 2019 – Microphyt, a leading company in microalgae-based natural solutions for nutrition and well-being, announced that it has received New Dietary Ingredient (NDI) status from the Food and Drug Administration (FDA) for its patented PhaeoSOL ingredient. Microphyt received the FDA's Acknowledgement Without Objection letter within its 75-day evaluation period to respond. The recommended conditions of use of 215 mg daily with no time limit (equivalent of 5mg fucoxanthin) or 430mg daily for a maximum of 30 days (equivalent of 10mg fucoxanthin), allow a safe and high-dose of this ingredient in the dietary supplements.

Proprietary preclinical data on PhaeoSOL have demonstrated significant nutritional benefits in the prevention of age-related cognitive decline. Compared to standard natural ingredients, the superior efficacy of PhaeoSOL was demonstrated and was associated with the synergy of unique bioactive compounds, enhancing fucoxanthin biological role in the body. In addition, numerous scientific studies have reported that fucoxanthin has many physiological functions and biological properties, opening the door to several other applications of PhaeoSOL in the nutrition and well-being markets.

PhaeoSOL will first be presented at the SupplySide West show in Las Vegas, the largest gathering of health & nutrition professionals. Taking place October 15-19, 2019, SupplySide West will welcome over 17,000 industry professionals. In health & nutrition, consumer demand for natural, effective, safe and sustainably produced solutions is booming. The world market for ingredients for these markets, represents more than US\$ 70 billion with a share of natural ingredients (US\$ 5 billion) that shows the strongest growth (8% per year). Among the natural ingredients, microalgae best meet consumer expectations thanks to their natural diversity, offering richness of molecules that can be produced in a close-controlled and sustainable way.

PhaeoSOL is produced in Microphyt's proprietary production technology. This patented process, developed in-house, solves the usual drawbacks of microalgae production. It is based on 5,000-litre tubular photobioreactors, which offer both high differentiation potential (access to a new diversity of species) and the ability to supply natural active ingredients in an industrial and standardized way. This technology, operated within an industrial production platform, has already made it possible to establish several commercial partnerships with key players in the sector.

Virginie Wasiolek, Regulatory Affairs Manager at Microphyt expressed her enthusiasm at obtaining NDI status for PhaeoSOL *"Thanks to the dedication of the whole Microphyt team, we have been able to place on the market our first flagship ingredient PhaeoSOL which is backed by a strong body of science and intellectual property. The FDA's acknowledgement of our NDI notification demonstrates not only the safety of PhaeoSOL but also Microphyt's commitment to regulatory compliance"*.

“This NDI notification is a significant milestone in our development” said Vincent Usache, Microphyt’s CEO. *“NDI status opens the door to the commercialization of PhaeoSOL in the US, which is the world-leading market for dietary supplements”*.

In addition of PhaeoSOL, and following its latest funding of €28.5 million, Microphyt is pursuing the development of its portfolio of microalgae-based natural solutions for nutrition and well-being with 10 nutritional active ingredients and 20 cosmetic active and functional ingredients being developed.

About Microphyt

Microphyt is a leading company in the production and marketing of microalgae-based natural active ingredients. With more than 10 years of expertise in this field, Microphyt draws from the untapped microalgae diversity to provide unique solutions for Nutrition and Wellness. Microphyt’s technologies, developed in-house and patented, allow the controlled production of a wide variety of microalgae on an industrial scale and in a sustainable way. The company has 20 employees and has filed 5 patent families.

More information : www.microphyt.eu – Follow us on LinkedIn and Twitter: @Microphyt

About NDI notification

The Federal Food, Drug and Cosmetic Act (FD&C Act) requires that manufacturers and distributors who wish to market dietary supplements that contain “new dietary ingredients” notify the FDA about these ingredients. Generally, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling.

(See Section 413(d) of the FD&C Act, 21 U.S.C 350b(d))