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PRESS RELEASE

REGEnLIFE presents first results of pilot clinical trial evaluating photobiomodulation technology in the treatment of Alzheimer's disease

- **Within treated patient group, trends showed improved cognitive and executive functions, improved language comprehension and verbal memory, in comparison to placebo group**
- **REGEnLIFE's technology shown to be safe and well-tolerated by patients**
- **Initial results open up new possibilities for development of brain-gut stimulation device for prevention and treatment of neurodegenerative diseases**

Montpellier, France, March 17, 2021 – REGEnLIFE, a company specialized in the research and development of innovative photo-medical technologies for the prevention and treatment of neurodegenerative diseases, announces today the promising results of the pilot clinical trial[1] evaluating its technology in Alzheimer's disease (AD). The results were presented by Professor Jacques Touchon, scientific advisor on the trial, at the 15th International Conference on Alzheimer's and Parkinson's Diseases (AD/PD 2021), held online from March 9 to 14, 2021.

REGEnLIFE's innovative non-invasive technology, evaluated in a therapeutic trial, is based on photobiomodulation, targeting both the brain and gut via a helmet and abdominal device. This cutting-edge medical device, RGn530, stimulates cells in the brain and gut and regulates inflammation - to improve cognitive functions and behavior. It targets inflammation of the gut-brain axis, which is believed to be linked to the development of AD and other neurodegenerative diseases.

The trial enrolled adult volunteers aged 55 to 85, with mild to moderate Alzheimer's disease. They were equipped with a helmet and a photobiomodulation abdominal belt; the patients benefited from a total of 40 sessions; these lasted for 25 minutes and were spread over a two-month period. The volunteers were evaluated in a series of tests during the trial and up to one month after treatment ended. This double-blind, randomized, monocenter, placebo-controlled clinical trial began in 2018; it ended prematurely in 2020 due to the COVID-19 pandemic. Out of the 64 planned patients, 53 were randomized into two groups (treated and placebo) and 43 patients benefited from the full duration of the treatment.

The primary efficacy endpoint was measured by the evolution of the total ADAS-Cog score, (Alzheimer's Disease Assessment Scale), between inclusion and the end of the two-month period of treatment. The REGEnLIFE RGn530 device was shown to be safe; no major side effects were reported. Compliance with treatment sessions was very high for the vast majority of patients (92%). This level of compliance also confirms the good tolerance of the device. While the primary efficacy endpoint was not statistically met, there was a clear improvement trend in a set of cognitive functions. The results of this pilot study showed that REGEnLIFE's technology is safe and well-tolerated by patients. These very encouraging safety and efficacy results will now be confirmed in a pivotal or phase III clinical trial.

"The therapeutic strategy for AD should involve several targets. Drug treatments targeting the two characteristic proteins of the Alzheimer's process (beta-amyloid and tau proteins) must be supplemented by other therapies - targeting less specific but very important mechanisms in the pathophysiological AD cascade, such as inflammation and oxidative stress," said Professor Jacques Touchon, neurologist and psychiatrist, scientific advisor on the clinical trial. "REGEnLIFE's photobiomodulation technology acts at the early stages of this cascade, (mitochondria, inflammation, oxidative stress), and could be the non-drug

complement to the next-generation therapeutic strategy. This technology also makes it possible to act on both the brain and the gut, a significant advantage when we know the important role of the gut-brain axis and microbiota in neurodegenerative pathologies."

A unique photobiomodulation technology for the treatment of Alzheimer's disease

Photobiomodulation is based on photonic emissions in the near-infrared, it has already shown analgesic, anti-inflammatory and healing properties. One of the most reproducible effects is the overall reduction in inflammation, especially in the brain[2]. REGEnLIFE's technology could therefore be used on brain diseases and on pathologies linked to neuroinflammation. REGEnLIFE developed this device employing this scientific approach, using medical technology never before applied to neurology.

"There are increasing scientific data to endorse the hypothesis that the gut-brain axis is involved in the development of AD and other neurodegenerative disorders[3,4]; we also believe that some forms of electromagnetic emissions could prevent and treat this disease. Our initial clinical data, coupled with all our preclinical proof of concept studies, led us to pursue a pivotal clinical study in AD and to consider working on other neurological diseases," said Guillaume Blivet, co-founder and president of REGEnLIFE. "To accelerate this new phase in our development and to shortly gain early market access, we are preparing a new funding round before the end of 2021."

According to Alzheimer's Disease International, 35 million patients worldwide have AD. The annual cost of the disease worldwide is estimated at €850bn ($1.02tr). Currently, there are no treatments to cure Alzheimer's.

In order to address public health issues related to a disease that affects elderly and vulnerable people, REGEnLIFE chose to develop a non-invasive technology with low constraints for patients. The cost of this device is expected to be reasonable for patients and national healthcare systems.

About REGEnLIFE

REGEnLIFE specializes in the research and development of innovative photo-medicine technologies for the prevention and treatment of neurodegenerative diseases.
The company aims to provide a photo-medical technology targeting both the brain and the gut; in particular for the treatment of Alzheimer's disease. REGEnLIFE's innovative and non-invasive technology, currently in a clinical trial, is based on combined infrared waves emitted at the skull and abdomen levels, through a helmet and belt device.
REGEnLIFE brings together a team of multidisciplinary partners, including experts and researchers from many fields: engineering, optics, photonics, electronics, new technologies, physical sciences, public health, medicine, neurology and neurosciences.
The company is supported by private investors, the French investment bank Bpifrance and by the Occitania Region of France, in several R&D projects. REGEnLIFE raised €3M ($3.6M) in 2018 from business angels and family offices.
The REGEnLife team of eight is based at the BIC incubator in Montpellier, France.
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