

**FDA fully endorses the GRAS dossier submitted by Caelus on *A. soehngeni* (*E. hallii*) as the first next-generation microbe**

**Amsterdam – Caelus Health, a European company developing innovative products based on next generation microbiota for the prevention and treatment of cardio-metabolic diseases with an initial focus on Type 2 diabetes and related liver disorders, has recently received a “No Questions Letter” from the US Food and Drug Administration (FDA) regarding their Generally Recognized As Safe (GRAS) Notice for *A. soehngeni* (formerly known as *E. hallii*). *A. soehngeni* CBS 145175 is an anaerobic butyrate-producing strain that promotes cardio-metabolic health among others in individuals at risk of developing Type 2 diabetes.**

**The FDA established the GRAS procedure to ensure that companies performed the necessary research and testing, demonstrating their food ingredients are safe for the public at the intended levels and use specified within the application. In practice this may be based on the self-assessment of the GRAS status by a panel. However, the ultimate step is submission of the dossier to the FDA and applying for a No Objections Letter. Such a letter is FDA’s communication showing that an ingredient is safe and permitted for use.**

**On April 14<sup>th</sup> the FDA has issued the “No Questions Letter” to Caelus regarding the strain of *A. soehngeni*. This is the first GRAS endorsement by the FDA of a next-generation microbe.**

In the past months, 2 clinical trials of a product based on *A. soehngeni* in pre-diabetes and in Type 2 diabetes were completed successfully. The clinical development was performed in close cooperation with team of prof. Max Nieuwdorp at the Amsterdam University Medical Center (AUMC). The availability of significant positive clinical results and the No Objections Letter of FDA mark the transition to next phase of commercialization of *A. soehngeni* as next-generation microbe, which enhances cardio-metabolic health.

Prof Willem M de Vos who together with Prof Max Nieuwdorp co-founded Caelus Health stated: *“A. soehngeni (E. hallii) CBS 145175 is capable of converting sugars as well as lactate and acetate into butyrate and hence is involved in important trophic chains in the human gut. This strain is the first next-generation beneficial microbe isolated from the human gut that has received this No Objections Letter from the FDA, opening the way for broader access to the product.”*

In addition, Luc Sterkman, MD, CEO of Caelus commented: *“The endorsement by the FDA of the safety of the *A. soehngeni* strain as an ingredient marks the completion of the development of the product. This enables the global commercialization of products based on the patent-protected strain of *A. soehngeni* with an imminent start in the US.”*

-----

***AUMC**, the Amsterdam University Medical Center (AUMC), location AMC, is one of the foremost research institutions in the Netherlands, as well as one of its largest hospitals. Over 7000 people work at AMC to provide integrated patient care, fundamental and clinical scientific research, and teaching. The AMC complex houses among others the university hospital and the faculty of medicine of UvA as well as the Emma Children's Hospital and the Netherlands Institute for Neuroscience. A number of biotech companies (some of which are AMC spin-offs) are also located on the premises. This concentration of expertise makes the centre a breeding ground for fruitful scientific collaboration.*

***Caelus Health** is an Amsterdam-based biotech company. Caelus is dedicated to the commercialisation of functional food, food supplements and pharmaceutical products for the prevention and early treatment of cardio-metabolic diseases. Based on the strong correlation between the intestinal microbiome and health, the company is developing an entirely new class of microbiota-based therapeutics for the reduction of insulin resistance and prevention of Type 2 Diabetes mellitus (T2D) in people with metabolic syndrome (MetS). In addition, the company has built an extensive range of patents based on the gut microbiome and Fecal Microbiota Transplants (FMT) - studies In Type 1 Diabetes, cancer cachexia and liver disorders.*

**For more information, please contact:**

Luc Sterkman, CEO Caelus Health: [l.sterkman@caelushealth.com](mailto:l.sterkman@caelushealth.com) tel.: +31-6-22979249