RNS Number : 6638Q
OptiBiotix Health PLC
21 February 2019

OptiBiotix Health plc
("OptiBiotix" or the "Company")

LP_{LDL}® determined GRAS by an Expert Panel in the United States

OptiBiotix Health plc (AIM: OPTI), a life sciences business developing compounds to tackle obesity, cardiovascular disease and diabetes, announces that ProBiotix Health Ltd, its fully-owned subsidiary, has had its cholesterol and blood pressure reducing *Lactobacillus plantarum* LP_{LDL}® probiotic strain determined as Generally Recognized As Safe ("GRAS") by an independent Expert GRAS Panel in the United States.

GRAS is a United States Food and Drug Administration (FDA) designation that any substance added to food is considered safe by experts. GRAS status is therefore required for the use of these substances in foods. In the case of probiotics, it is a strain-specific process in which all strains not described before 1958 - as is the case of LP_{LDL}® - must be categorised as GRAS if they are to be added to foods. GRAS assessment involves submitting an extensive technical dossier for evaluation by an independent panel of experts. They confirm if the ingredient is safe, under what conditions it can be used, and for which applications.

The Expert GRAS Panel that reviewed the LP_{LDL}® dossier was formed by international experts in toxicology, pharmacology and regulatory affairs. After evaluating information on LP_{LDL}®'s science, genetic composition, lack of antibiotic resistance, human clinical study results and market feedback, the Panel members concluded that the evidence was sufficient to determine that LP_{LDL}® is safe for use in food and beverage categories at a concentration of up to 10 billion colony forming units (CFU) per serving. This is more than double the dose found to significantly reduce cholesterol and blood pressure in the human trial conducted by Reading University (Costabile et al., 2017).

The process of GRAS determination has taken over two years of work, led by OptiBiotix's Business Development Director, Dr. Luis Gosalbez. Compiling the GRAS dossier has involved the generation of large amounts of laboratory data, genetic analyses, and an extensive review of the scientific literature. Whilst a costly and time-consuming process, it extends the potential applications of LP_{LDL}®

to use as a functional ingredient in food, dairy, and beverage products across the USA.

This is a strategic step by OptiBiotix to extend the market opportunity within the US probiotic market to food, dairy, and beverage products. The USA is one of the largest and fastest growing probiotic markets in the world with sales in 2016 of supplements accounting for $2.06 billion, and food and beverage products $5bn per annum*.

(**Market data from 'TRENDS, INNOVATIONS AND OPPORTUNITIES DRIVING THE GLOBAL PROBIOTICS MARKET' (Euromonitor International June 2017)*

Stephen O'Hara, CEO of OptiBiotix, commented: "*We are pleased to announce that the independent Expert Panel has ruled in favour of LP_{LDL}®'s GRAS status. This is a significant achievement and a major commercial milestone as it expands the potential applications of LP_{LDL}® from use as a supplement to use as a functional ingredient in a wide range of food, dairy, beverage, and high value medical food applications, across the USA. In addition, obtaining GRAS status is increasingly being seen by large US corporates as a key requirement to independently validate the safety of commercial probiotic strains in supplements and as such, is a major point of differentiation from other probiotics, as very few strains currently have this status.*

This acknowledgement provides international, independent endorsement from experts for the science behind LP_{LDL}® and for OptiBiotix's approach to novel probiotic strain development."

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.
For further information, please contact:

OptiBiotix Health plc — www.optibiotix.com
Stephen O'Hara, Chief Executive — *Contact via Walbrook below*

Cairn Financial Advisers LLP (NOMAD)
Liam Murray / Jo Turner — Tel: 020 7213 0880

finnCap (Broker)
Geoff Nash/ Scott Mathieson / Kate Bannatyne (Corporate Finance)
Camille Gochez (Corporate Broking) — Tel: 020 7220 0500

Walbrook PR Ltd — Tel: 020 7933 8780 or optibiotix@walbrookpr.com
Anna Dunphy — Mob: 07876 741 001

About OptiBiotix - www.optibiotix.com

OptiBiotix Health plc (AIM: OPTI), which was formed in March 2012, brings science to the development of compounds which modify the human microbiome - the collective genome of the microbes in the body - in order to prevent and manage human disease and promote wellness.

OptiBiotix has an extensive R&D program working with leading academics in the development of microbial strains, compounds, and formulations which are used as active ingredients and supplements. More than twenty international food and healthcare supplement companies have signed agreements with OptiBiotix to incorporate their human microbiome modulators into a wide range of food products and drinks.

OptiBiotix is also developing its own range of consumer supplements and health products. The Company's current areas of focus include obesity, cardiovascular health, and diabetes.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

END

MSCLLFLDFSIIFIA