RNS Number : 1911P
OptiBiotix Health PLC
09 October 2019

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

LP_{LDL}® Pharmaceutical GMP process validation

Confirmation of GRAS letter received from FDA

OptiBiotix Health plc (AIM: OPTI), a life sciences business developing compounds to tackle obesity, cardiovascular disease and diabetes, announces that its fully-owned subsidiary ProBiotix Health Ltd. ("ProBiotix"), has completed process validation under Pharmaceutical Good Manufacturing Practices ("GMP") for LP_{LDL}® as a drug substance and received a letter from the United States Food and Drug Administration (FDA) affirming LP_{LDL}®'s Generally Recognized As Safe ("GRAS") status. Obtaining GMP certification is linked to a milestone payment under the pharmaceutical deal in the US (RNS: 4 September 2018, http://www.optibiotix-ir.com/content/news/archive/2018/04-09-18.asp).

Completing process validation under Pharmaceutical GMP's proves that a drug substance (LP_{LDL}®) is produced consistently with pharmaceutical grade quality. GMP process validation is required by customers and health authorities around the globe to commercialise active ingredients as drugs. The validation of LP_{LDL}® Pharmaceutical GMP manufacture is a significant step in the development of LP_{LDL}® as a pharmaceutical drug product.

GRAS is an FDA designation that a substance added to food is considered safe. ProBiotix had obtained a positive opinion from an independent panel of experts earlier this year (RNS: 21 February 2019, http://optibiotix-ir.com/content/news/archive/2019/21-02-19.asp), and has now received a letter from the FDA affirming LP_{LDL}®'s status as GRAS. This is the highest level of safety certification for a food ingredient in the US and ends an almost three year scientific and regulatory process. LP_{LDL}® (referred to as *Lactobacillus plantarum* ECGC 13110402, its scientific name) has been assigned the code GRN 000847 in the FDA register.

Steve Prescott, Chief Executive Officer of ProBiotix, commented: *"Completing Pharmaceutical GMP process validation and receiving the GRAS notification letter from the US FDA is a significant achievement for ProBiotix and LP_{LDL}®. Few marketed*

probiotics have achieved this level of proven safety and efficacy and it has triggered another milestone payment in the US Pharmaceutical agreement we announced last year. GMP manufacturing is required to commercialise a probiotic as a drug and is a de facto requirement of many companies to include ingredients in their food supplement formulations. Both GMP manufacturing and full GRAS status increases LP_{LDL}®'s market attractiveness and shows ProBiotix's commitment to commercialising the highest quality products. I would like to especially thank Dr. Luis Gosalbez who led both processes internally."

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 / Ludovico Lazzaretti — Tel: 020 7213 0880

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

Goetz Partner Securities Limited
Ulrich Kinzel — Tel: 020 3859 7725

Walbrook PR Ltd
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

REACKFDDPBDDQKK