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

Scientific and commercial development
Update on LP_{LDL}®

OptiBiotix Health plc (AIM: OPTI), a life sciences business developing compounds to tackle obesity, high cholesterol, diabetes and skin care, provides the following scientific and commercial update on its cholesterol and blood pressure reducing probiotic, LP_{LDL}®.

Scientific update
The Company differentiates LP_{LDL}® from other probiotic products by its scientific studies into LP_{LDL}® mechanisms of action, human studies demonstrating the strains safety and efficacy and its regulatory approvals (FDA GRAS and GMP pharma manufacture).

Scientific and human studies
The Company has published six studies on LP_{LDL}® in peer reviewed journals or as abstracts at international scientific conferences. These cover the safety and performance of LP_{LDL}® in human studies, the three mechanisms of action by which LP_{LDL}® reduces blood lipids, and LP_{LDL}®'s antimicrobial activity against a wide range of clinically important human and/or animal pathogens including *Campylobacter*, *Shigella*, *Salmonella*, *E.coli* O157, and *Clostridium difficile.*

The results of two published independent human studies in different countries show significant reductions in both blood pressure and cholesterol and the product to be safe and well tolerated. The first study (see https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0187964), in volunteers taking LP_{LDL}® with normal to mild cholesterol showed statistically significant reductions in total cholesterol (36.7%), LDL cholesterol (13.9%) and blood pressure (5.1%). A second study, on a food supplement formulation containing LP_{LDL}® (see http://article.foodnutritionresearch.com/pdf/jfnr-8-6-5.pdf), showed statistically significant reductions in both systolic, diastolic blood pressure and total and LDL cholesterol. A recent study (awaiting publication) in volunteers taking LP_{LDL}®, in a high cholesterol patient group, showed reductions of total cholesterol (>40%) and LDL cholesterol (>30%) after six weeks compared to a

placebo control. The study also showed significant reductions (>25%) in Apolipoprotein B (ApoB), a biomarker increasingly linked to atherogenic risk. The results of these studies, customer surveys, and feedback from the use of LP_{LDL}® in over 60 countries show that LP_{LDL}® is safe and well tolerated, with an ability to significantly lower a range of cardiovascular risk factors.

Publications and presentations help differentiate LP_{LDL}® from products which are sold solely on marketing and reduce the risk of commoditisation and price erosion.

Regulatory

LP_{LDL}® was 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 and expands potential applications from supplements to use as a functional ingredient in a wide range of food, dairy, beverage and high value medical food applications. GRAS, and pharmaceutical GMP manufacture validation, creates the potential for LP_{LDL}® to be commercialised as a pharmaceutical drug product, and are major points of differentiation from other probiotics. They increase the market attractiveness of LP_{LDL}® to pharmaceutical partners either used by itself, or as combination treatment to help lower the dose and potential side effects of statins. This extends the opportunity outside the traditional supplement market into broader therapeutic opportunities.

Commercial update

ProBiotix Health has developed the science, carried out human studies to confirm product safety and efficacy, protected its commercial interests with a broad IP portfolio (~30 patents), and built a supply chain of licensed partners to manufacture, formulate, and distribute product around the world. The company now has partners commercialising LP_{LDL}® in over 60 countries including the world's largest probiotic market (USA: Seed Health) and second largest (Italy: AlfaSigma). The next stage of its strategy is to grow sales with existing partners, extend territories and applications, and continue to sign up new partners. In addition to growing sales, the company is renegotiating contracts as volumes increase to reduce the cost of goods. The renegotiation of our contract with Sacco S.r.l.,(RNS: March 2020) from a profit sharing to a manufacture supply agreement where we buy from Sacco and then sell product to partners significantly improved margins.

Of particular note is the growing list of pharmaceutical partners (AlfaSigma, Actial Pharma Akums Pharma) who recognise the value of a natural product with a known mechanism of action, human studies and a portfolio of trademarks and patents which protect their commercial interests. LP_{LDL}® is now building a global brand presence and industry credibility with pharmaceutical companies who sell into the high value hospital, GP, and pharmacy network which typically require a greater level of science and clinical evidence than consumer markets. This takes longer but once established creates a high barrier to entry for other probiotic products which often have little science, no IP and no clinical studies.

Outlook

The Company is extending the use of LP_{LDL}® into a wider range of applications. These include dairy (RNS: 12 February 2020), anti-aging products, and the development of a cardiovascular health portfolio including a blood pressure

(CholBiome$_{BP}$) and vascular health product (CholBiome$_{VH}$). This will complete a suite of cardiovascular applications of different formulations which should meet the regulatory and market needs of most countries around the world.

The Company is also exploring:-

i. The potential of LP$_{LDL}$® for immune health properties after a number of customers have reported reduction in allergies, particularly hay fever
ii. The use of LP$_{LDL}$® in combination with existing treatments such a statins, to help lower dose and reduce side effects, whilst maintaining efficacy
iii. The Company has sequenced LP$_{LDL}$®'s genome and is exploring the genetic predisposition of the strain to impact on a range of health areas
iv. The Company has been awarded (subject to contract) a grant to explore the effect of LP$_{LDL}$® on stress, anxiety, and sleep disorders with Universities in the UK and Europe

Mikkel Hvid-Hansen, Commercial Director of ProBiotix Health commented: *"The identification, and development of LP$_{LDL}$® from over 4,000 candidate bacterial strains has followed a systematic discovery programme more akin to pharmaceutical products than probiotics. This has led to a strain with a fully sequenced genome, full GRAS status, pharmaceutical GMP manufacture validation, and published studies on its mechanisms of action and clinical effectiveness. We believe these features are key differentiating factors in today's probiotic market. As the gap between drugs and probiotics developed using these approaches narrows, these so called next-generation probiotics, become closer to the emerging concept of live drug biotherapeutic products."*

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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 programme 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 snacks and food products. The Company's current areas of focus include obesity, digestive health, cardiovascular health, and diabetes.

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