Horizon Discovery Enters into Agreement with a Leading Global Molecular Diagnostics Provider for Reference Standards for Non-Invasive Prenatal Testing

- Agreement to develop and manufacture reference standards to support assay development for three commonly tested for genetic disorders
- Initial project to provide a minimum of £0.8 million in Product revenue over a 12-month period, with the option to expand to additional projects
- Establishes Horizon as a leader in the provision of reference standards for non-invasive prenatal testing

Cambridge, UK, 14 March 2017: Horizon Discovery Group plc (LSE: HZD) ("Horizon or "the Company"), the world-leader in the application of gene editing technologies, today announces it has entered into an agreement with a global leader in the development and provision of innovative molecular diagnostic testing solutions ("Client"). The agreement includes the development and manufacture of reference standards for three common forms of non-invasive prenatal testing (NIPT). The initial project, anticipated to be completed within 12 months, will provide Horizon with a minimum of £0.8 million in Product revenue.

Under the terms of the agreement, an extension of a previously established Master Service Agreement entered into in November 2015, Horizon will use its world-leading gene editing capabilities to develop reference standards to be used by the Client for in-house assay development and to support the Client's clinical trials for regulatory approval through the FDA. The reference standards for this project will be designed to model real clinical samples and will be used as a whole-process control, from extracting DNA from a patient sample to final determination of the genotype.

Horizon will retain full commercialisation rights for the reference standards delivered under this agreement, which will be made available to the market either directly by Horizon or, through an OEM agreement, included in diagnostic assays sold by the Client following the successful completion of the project.

Future programmes of work may be requested by the Client to develop and manufacture additional reference standards for prenatal testing at any time during or after the initial project has been completed, generating further Product revenue for the Company.

Dr. Darrin M Disley, Chief Executive Officer, Horizon Discovery Group commented: *"Through this agreement, Horizon continues to show leadership in the provision of reference standards to help identify and control the sources of variability across many assay formats and applications. NIPT testing is an area of high unmet need, and we are excited to be supporting our Client, a global industrial leader in molecular diagnostics, as they seek to advance their programmes internally and through the FDA.*

"As with previously announced agreements, this is a demonstration of the success of our model of working with major assay developers early in their process, helping to drive their assay development and validation efforts with the goal of establishing reliable, long-term product revenue streams for Horizon."

- ENDS -

Notes

About HDx™ Reference Standards

There are many potential sources of variability that can lead to molecular diagnostic tests providing erroneous results. HDx Reference Standards offer a source of genetically defined, quantitative, sustainable and independent third party reference material, critical to the validation and routine performance monitoring of assays, providing an unprecedented level of control. Horizon reference standards are available in broad range of formats including Formalin-Fixed Paraffin-Embedded (FFPE) cell line sections and purified genomic DNA (gDNA).

About Non-Invasive Prenatal Testing

NIPT testing is an attractive alternative to invasive diagnostic procedures, allowing women at an elevated risk of having children with genetic disorders to determine the status of their foetus through a non-invasive test. This is possible because during gestation blood exchange between mother and child can occur, and so the genetic status of the foetus has the potential to be detected directly from the mother. Driven by advancing diagnostic testing options and increasing maternal age, the global NIPT market is estimated to be worth approximately £1.2 billion by 2020[1]. Although NIPT testing is increasingly common, incidence of real positives can be low, and so the risk of a false positive or negative result is significant and can have a major clinical impact[2], and so approaches to control for these errors is a high need area.

About Horizon's NIPT Reference Standards

Each Reference Standard generated through this project will consist of DNA blended at up to three ratios from two cell lines, one from a healthy mother and the second from her biological foetus displaying the genetic disorder. Separate reference standards will be generated for each of three commonly tested-for genetic disorders, all of which will be made available in up to three formats according to customer requirements, along with a normal maternal control. The DNA in each standard will be fragmented to reflect the condition cell-free DNA is normally found in a liquid biopsy sample, and will be provided as extracted DNA or in synthetic plasma.

References

1. https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf
2. Non-Invasive Prenatal Testing (NIPT) Market Size, Share, Development, Growth and Demand Forecast to 2020, P&S Market Research, 2015

Glossary:

- Assay – an analysis performed to determine the presence of a substance and the amount of that substance
- Genotype – The genetic makeup of an organism, it can refer to the status of a single gene or to the arrangement and number of chromosomes
- OEM – Original Equipment Manufacturer, a firm that manufactures components or parts included in the finished product made by another

- Reference standard – a highly characterized, standardised and validated material that enables the measurement of the sensitivity, specificity and accuracy of assays and workflows.

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About Horizon Discovery Group plc www.horizondiscovery.com
Horizon Discovery Group plc (LSE: HZD) ("Horizon"), is a world-leading gene editing company that designs and engineers genetically-modified cells and then applies them in research and clinical applications that advance human health.

Horizon's core capabilities are built around its proprietary translational genomics platform, a highly precise and flexible suite of gene editing tools (rAAV, ZFN and CRISPR) able to alter almost any gene sequence in human or mammalian cell-lines.

Horizon offers over 23,000 catalogue products and related research services, almost all of which are based on the generation and application of cell and animal models that accurately recapitulate the disease-causing genetic anomalies found in diseases like cancer. Horizon's commercial offering has been adopted by c. 1,600 unique research organisations in over 50 countries as well as in the Company's own R&D pipeline to support a greater understanding of the genetic drivers of disease and the development of molecular, cell and gene therapies that can be prescribed on a personalised basis.

Horizon is headquartered in Cambridge, UK, and is listed on the London Stock Exchange's AIM market under the ticker "HZD".