

PRESS RELEASE

Sagentia partners with Premaitha Health to develop first to market non-invasive diagnostic for prenatal screening

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[Sagentia](#), a leading global science, technology & product development company, is working with [Premaitha Health, a molecular diagnostics company based in Manchester UK](#), to develop Premaitha's IONA[®] test. It will be the first complete non-invasive *in vitro* diagnostic product for prenatal screening to determine the likelihood of a trisomy affected pregnancy such as Down's Syndrome. Sagentia will develop the custom clinical bioinformatics analysis application that performs the test analysis, computes test results and generates test reports.

As the first product of its type available to clinical laboratories who wish to offer their own Non-Invasive Prenatal Test (NIPT), the IONA[®] test accurately estimates the risk that a fetus is affected with Down's syndrome and other serious genetic conditions based on analysis of cell-free fetal DNA isolated from a sample of maternal blood. Compared to existing screening methods the IONA[®] test has both a higher detection rate and a lower false positive rate, leading to improved confidence in the screening result for both pregnant women and their doctors. The IONA[®] test will see a reduction in the number of unnecessary invasive procedures such as amniocentesis, making the IONA[®] test safer for women and their pregnancy.

As an experienced leader in the development of new technologies and products, including complex diagnostic systems and medical-grade software, Sagentia is partnering with Premaitha to develop a custom, dedicated bioinformatics analysis package. The software is part of the IONA[®] test clinical workflow, employing highly efficient, multi-core analysis algorithms that automatically process sequenced DNA fragments and clinical data, and interprets them to produce a self-contained storable or printable report.

The software is being developed to IEC62304 and ISO13485 medical device development standards and is suitable for verification and validation for CE marking, FDA submissions and other regulatory approval processes. Completion of clinical performance and commercialisation testing of the IONA[®] test is expected by the end of 2014 and CE marking and commercial launch are anticipated for Q1 2015.

Dr Stephen Little, CEO at Premaitha, comments: "The information generated by the IONA[®] test will be used to guide significant medical decisions so it is important that every stage of

the test is as accurate as possible. We chose to work with Sagentia because they were able to offer development of the IONA[®] software within a quality management system which ensured that performance of the product was assured at every step of the development process.”

Paul Wilkins, SVP Medical at Sagentia, adds: “DNA sequencing is an exciting and growing area of activity for us and we’re very excited to be working with Premaitha on bringing this groundbreaking technology to market. The IONA[®] test harnesses the potential of next generation sequencing, providing a clinical utility that will be very beneficial to patients. There is huge potential for Premaitha’s technology in other clinical applications and we look forward to helping bring those to market in the future.”

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About Sagentia

Sagentia is a global science, product and technology development company. Our scientists and engineers redefine what’s possible and help R&D groups achieve commercial return from their most complex technology projects. We have over 27 years’ experience and have successfully completed over 10,000 projects for start-up and global market leader clients alike, across the medical, industrial, oil & gas and consumer sectors. Our services span the full product development lifecycle, from new concept generation and technology validation, through prototyping and full product development, to transfer to manufacture and sustainability. Sagentia employs over 150 scientists, engineers and market experts and is part of the Sagentia Group, with headquarters in Cambridge, UK and offices in London, Guildford, Boston, Houston and Dubai. Further information can be found at

www.sagentia.com or email info@sagentia.com

About Premaitha Health

Premaitha Health is a new molecular diagnostics company employing next generation DNA analysis technology to develop, manufacture and commercialise molecular diagnostic products intended to have a major beneficial impact on human health. The IONA® test is Premaitha's lead product and will be the first complete CE marked IVD product available to clinical laboratories who wish to offer their own Non-Invasive Prenatal Test (NIPT). The IONA® test estimates the likelihood that a fetus is affected with Down's syndrome (Trisomy 21) and other genetic conditions. The IONA® test reduces the number of unnecessary invasive tests such as amniocentesis. Premaitha Health was established in 2013 and is located on Manchester Science Park, UK. The Company joined the London Stock Exchange's AIM on 4 July 2014 and trades as NIPT.