PRESS RELEASE
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Devyser Compact achieves Class III approval in China

Devyser has achieved a significant regulatory milestone with its first market registration from China's National Medical Products Administration (NMPA) for Devyser Compact, an IVDR-certified genetic test for detecting fetal chromosomal abnormalities. Rapid prenatal aneuploidy detection kits fall under Class III IVD as part of the NMPA product registration process. This approval enables Devyser to market Devyser Compact as an in vitro diagnostic in China and paves the way for future regulatory approvals in the region for its simple, fast, and accurate genetic testing solutions.

"Devyser has been engaged in extensive efforts to obtain regulatory approval for its products, and it's therefore great to see that after several years of hard work, we have successfully obtained market registration in China. Based on this regulatory approval, we are optimistic about the potential of this product in China. This first product approval by the NMPA gives us confidence that several more products will be approved in the future in China. I am very proud of the team who made this happen," says Devyser's CEO, Fredrik Alpsten.

Devyser Compact is IVDR-certified and measures the most common chromosomal abnormalities, such as Down syndrome, and also includes patented technology for safe detection of Turner syndrome. Devyser's single-tube kit is easy to use, requires minimal manual handling, provides fast results and reduces the risk of mixing samples. Utilizing a single-tube PCR process minimizes hands-on time, reduces the risk of sample mix-up, and allows laboratories to efficiently analyze chromosomes 13, 18, 21, and XY with 26 highly informative genetic markers. This patented technology enables accurate, reliable diagnoses, including a dedicated method for Turner syndrome detection. Its streamlined, low-DNA-requirement workflow is fully validated under IVDR, offering labs a fast, standardized solution for critical prenatal insights. Devyser Compact is now the leading standard for prenatal diagnosis in several European countries.

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About Devyser
Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 65 countries. Our products are used for advanced genetic testing in the hereditary disease, oncology and transplant fields, to enable targeted cancer treatment, the diagnosis of a large number of genetic diseases, and transplant patient follow-up. Devyser's products, and unique, patented solution requiring only one test tube, simplify genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. Our goal is for every patient to receive a correct diagnosis in the shortest possible time. Sustainability is a central part of our business and an important prerequisite for long term value creation.

Devyser was founded in 2004 and is based in Stockholm, Sweden with eight in-house sales offices in Europe and the US. The company also runs Devyser Genomic Laboratories, a CLIA certified laboratory in Atlanta, US. In 2022, Devyser's quality management system was certified according to the IVDR and a number of the company's products have since been certified according to the IVDR.

Devyser's shares are listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company's Certified Adviser is Redeye AB.

For more information, visit **www.devyser.com**.