PRESS RELEASE FOR IMMEDIATE RELEASE

GenePOC announces FDA clearance for revogene™ instrument and its GBS LB test

GenePOC announces it received 510(k) clearance from the US Food and Drug Administration to market its first molecular assay to detect Group B Streptococcus and for the revogene molecular diagnostics instrument.

Québec, Canada and Lausanne, Switzerland – June 1st 2017 – GenePOC, Inc. (GenePOC) a member of the Debiopharm Group is pleased to announce that it has received FDA clearance for its GenePOC™ GBS LB assay and its revogene™ instrument. GenePOC considers this system as the most cost effective diagnostics solution in the molecular point of care market today. This is a key accomplishment in the evolution of GenePOC's commercial operations. This validation of revogene and GBS LB test will allow access to the US market, after its successful introduction in Europe in Q1 2017.

"The GenePOC GBS LB test will fulfill the increasing market need for cost-effective automated and easy-to-use testing for the identification of antepartum Group B *Streptococcus* colonization. This will lead to better control of the risk of transmission and infection of the newborn, potentially lowering mortality and morbidity", Patrice Allibert CEO of GenePOC commented. "The achievement of 510k clearance is a milestone for GenePOC, and the result of a collective team effort, giving us high confidence as we work towards our second assay submission to the FDA for the detection of Clostridium difficile in the near future", he continued.

"Our laboratory participated in the clinical validation of GenePOC group B Streptococcus assay. This was a parallel study which compared the GenePOC assay to the standard culture. The assay used vaginal and rectal swabs from pregnant women enriched in LIM broth for 18-24 hours prior to testing. GenePOC had high sensitivity and specificity during validation studies and clinical trials. The system was easy to use and provided the results up to 18 hours faster than standard culture", Dr Hossein Salimnia, Professor of Pathology and Chief of Microbiology Division, Wayne State University School of Medicine and Detroit Medical Center University Laboratories, Detroit commented.

About revogene instrument

The **revogene** is a compact, fully automated stand-alone instrument well suited to on the spot molecular diagnostic testing. The revogene offers unique flexibility, allowing the labs to run from 1 to 8 samples simultaneously, for an optimal testing workflow. Its user-friendly and innovative design has been recognized by the Red Dot with the best of the best 2017 award.

About GBS testing

Group B *Streptococcus* (GBS) remains the most common cause of neonatal sepsis and meningitis in the world[1]. The CDC recommends universal antepartum screening for GBS vaginal and rectal colonization for all woman at 35-37 weeks of gestation, along with intrapartum antibiotic prophylaxis[2,3]. While this has resulted in a decrease in early onset disease (EOD) rate, there is still an ongoing need for more precise GBS detection.

GenePOC GBS LB assay detects GBS colonization from Lim Broth samples using the real-time Polymerase Chain Reaction (PCR) technology. In clinical performances studies, the overall sensitivity and specificity of GenePOC GBS LB were 95,9% and 95,5% respectively, compared with standard culture.

About GenePOC
GenePOC is a company that specializes in the development of diagnostic devices which enable the prevention and detection of infectious diseases. A member of the Debiopharm Group, the company aims to become the market leader in the rapid microbial testing at the point of care (POC).
GenePOC's revogene™ instrument is available on the market also in Europe and the Middle East with a rapidly expanding test menu.
Further information: www.genepoc-diagnostics.com

About Debiopharm Group
Debiopharm Group™ is a Swiss-headquartered global biopharmaceutical group including five companies active in the life science areas of drug development, GMP manufacturing of proprietary drugs, diagnostic tools and investment management.
For more information, please see www.debiopharm.com

We are on Twitter. Follow @DebiopharmNews at http://twitter.com/DebiopharmNews

Contact at Debiopharm Group
Christelle Tur
Communications Coordinator
christelle.tur@debiopharm.com
Tel.: +41 (0)21 321 01 11

Contact at GenePOC
Patrice Allibert, Ph.D
CEO
patrice.allibert@genepoc.ca
Tel.: +1-418-650-3535

REFERENCES

1. Simonsen et al. (2014) Early-onset neonatal sepsis. Clinical microbiology reviews 27.1 pp 21-47.
2. CDC. (2010). Prevention of Perinatal Group B Streptococcal Disease, Revised Guidelines. Morbidity and Mortality Weekly Report, Vol.59.
3. ACOG, A.C. (2011). Prevention of Early-Onset Group B Streptococcal Disease in Newborns. Committee Opinion, 1.2