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Press release

For immediate release

Genomtec expands patient group in the additional comparative study of its COVID-19 test directly from saliva

Wroclaw, Poland – May 25, 2021 - **Genomtec SA, listed on the NewConnect market at Warsaw Stock Exchange, a company developing medical technology applicable in the segment of clinical diagnostics at the point of care testing – POCT, will conduct additional comparative study of its test detecting SARS-CoV-2 directly from saliva sample utilizing the Direct-RT-LAMP technology against the reference RT-PCR method, executed via the agreement signed with the Cellgen Molecular Pathology Center (NZOZ Aurimed). The comparative study will be performed in the Cellgen's laboratory. The acquired clinical data will enrich positive results obtained from currently running clinical validation research at the Central Clinical Hospital of the Ministry of Interior and Administration, which enabled market authorisation of the product in the European Union. The intentional effect of the Genomtec collaboration with Cellgen is obtaining analytical results from paired patients' samples, which will provide deeper clinical diagnostic insights and enlarge the study group required by the foreign regulatory bodies to conduct additional international registration of the revolutionary Genomtec® RT-LAMP Direct Kit operating directly on saliva.**

- Expanding the study number is extremely important from the perspective of distribution network development intended for innovative product adoption on international markets. It will help us to reach business partners and may accelerate product adoption on foreign markets. The greater number of participants enrolled in the comparative studies and the additional research centres partaking in the study may principally improve the quality and quantity of scientific publications on the product and the technology dissemination, said Miron Tokarski, Co-founder and the President of Genomtec.

The cooperative goal between Genomtec and Cellgen is execution of a comparative study informing SARS-CoV-2 virus detection effectiveness when conducted on the saliva samples employing Direct-RT-LAMP technology with a much-simplified process of saliva sample preparation for the amplification reaction compared to the commonly used RT-PCR technology requiring a laboratory RNA purification step.

- Since the beginning of the pandemic, as the diagnostic laboratory, we have been involved in the fight against SARS-CoV-2 virus, not only by performing the real-time PCR and antigen testing for our patients, but also by active participation in research projects. The collaboration with Genomtec provides patients with a new opportunitiy to eliminate nuisance associated biological material sampling. As a medical doctor with a diagnostic specialization, I am aware

how important comparative studies are, particularly allowing product validation and thus informing new methods' adoption into a routine medical diagnostic practice - emphasizes Łukasz Fuławka, the Founder of Cellgen and a Principal Investigator in the study.

In the last week Genomtec registered the world's first diagnostic test Genomtec® SARS-Cov-2 EvaGreen® Direct-RT-LAMP CE-IVD Kit (RT-LAMP Direct Kit), which allows for identification of SARS-CoV-2 infection directly from the patient's saliva. The innovative test will provide patients with a greater comfort, as they do not need to undergo the swabbing procedure, e.g. from the nasopharynx. The possibility of testing from saliva may also reduce the risk of virus' contraction by the personnel collecting the sample, additionally sampling does not require specialized skills. Deployment of the Direct-RT-LAMP Kit permits receiving test's results in just several minutes from the time the sample entered the laboratory. The registered test received market authorisation in the European Union. In Poland, will be performed it in the laboratory of the Dolnośląskie Centrum Medyczne DOLMED in Wroclaw, which is located at ul. Legnicka 40.

Genomtec tests are compatible with the devices already owned by laboratories utilizing Real-Time PCR technique, which may aid in releasing the diagnostic bottleneck without additional investment in the infrastructure and new personnel hires.

The innovative Genomtec® RT-LAMP Direct Kit test eliminates the step of nucleic acid purifying from the sample, significantly streamlining and accelerating the laboratory process, and frankly the amplification stage conducted in in a thermocycler can be slashed by almost 1.5 hour of device operation time.

Genomtec's flagship solution – the Genomtec ID is a mobile diagnostic system employing microfluidic system and the proprietary, patented SNAAT® technology. This innovative diagnostic platform will be able to execute multiplexed pathogens simultaneously testing on one biological sample, including causal determination of respiratory tract infections or sexually transmitted diseases, even in 15 minutes. Genomtec ID will be used for point of care diagnostics, i.e., in doctor's offices, emergency department, and even a pharmacy.

Additional information available at:

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About Genomtec S.A.

Genomtec is an innovative medical technology company dedicated to the development and commercialization of a mobile molecular diagnostics platform for detection of various infectious diseases, and also rapid laboratory diagnostic tests used, among others, in the detection of COVID-19 disease caused by the SARS-CoV-2 virus.

The company's flagship project is the Genomtec ID mobile IVD platform. The analyser is uniquely placed among Point-Of-Care (POC) products worldwide. It will allow for a quick and precise clinical molecular analysis outside the standard laboratory setting, without the need to involve qualified laboratory personnel. The system uses microfluidic technology and the proprietary, patent protected SNAAT® isothermal technology. Appropriate design of the system enables the process to be carried out in record time, i.e. even in 15 minutes, with the diagnostic parameters equal to, and in some cases exceeding, the quality of PCR laboratory tests.

The development and manufacturing process is executed in close cooperation with international CMO (Contract Manufacturing Organization) companies. According to the assumptions of the Genomtec Management Board, the commercialization of the flagship solution will take place in the first half of 2022.

Manufacturing of Genomtec® SARS-CoV-2 EvaGreen® laboratory tests in RT-LAMP technology is based in Poland, with current EU market authorisation (CE-IVD), and product registration started in other regulatory jurisdictions outside Europe.

Genomtec was founded in 2016. The seat of Genomtec SA is located in Wroclaw.

More information: genomtec.com

About Cellgen Molecular Pathology Center:

The Cellgen Molecular Pathology Centre is a specialist medical facility providing molecular biology and histopathology diagnostics.

Cellgen was the first centre in Wroclaw providing a full range of diagnostic services in onco-pathology, extending from histopathology and cytology assessments to molecular techniques. Until recently, our specialty was gynaecological pathology, in particular cervical cancer prophylactic screening and HPV infection detection.

In response to the pandemic, our activities additionally focused on the SARS-CoV-2 virus diagnosis.
Research and development is the second pillar of our activity, straight after diagnostic services. We cooperate with research institutes and companies in translational medicine and applied scientific projects.

Biobank Cellgen is part of the Polish Biobank Network, which in turn is embedded in the BBMRI-ERIC European Research Infrastructure Consortium (Biobanking and Biomolecular Resources Research Infrastructure - European Research Infrastructure Consortium).

More information: www.cellgen.pl