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A contract signed with Cellgen Molecular Pathology Centre, Aurimed Private Healthcare Trust to execute part of the comparative study (referenced to the Real-Time RT-PCR method) validating the SARS-CoV-2 infection detection kit based on the saliva Direct-RT-LAMP technology.

The Management Board of Genomtec S.A. („Company", „Issuer") hereby informs that today, i.e. on 25th May 2021, it has signed an agreement with the Cellgen Molecular Pathology Centre, Aurimed Private Healthcare Trust to conduct a comparative study on the in-vitro genetic diagnosis kit for SARS-CoV-2 infection detection directly on saliva samples using Direct-RT-LAMP technology, against the reference Real-Time RT-PCR method.

Similarly to the information provided by the Issuer in the latest report 3/2021, this is an addition of a new clinical site with a purpose to perform a multi-cantered clinical effectiveness study of SARS-CoV-2 virus detection directly from the saliva samples using Issuer's technology (RT-LAMP). Furthermore, the kit trials a simple and streamlined saliva sample processing to the RNA-enriched supernatant being directly used for the amplification reaction set up, as opposed to the commonly used RT-PCR technology requiring laboratory RNA purification.

Cellgen's study Team will create a clinical report, in addition to the results being further disseminated in a form of a scientific publication or at scientific conferences; most importantly, it will provide the real-world date on the diagnostic performance of SARS-CoV-2 IVD device, improving statistical power of the already obtained results.

Achieved clinical performance data for the SARS-CoV-2 diagnostic kit will be incorporated in the larger clinical evidence report whose development is continued despite the positive results being supplied by the first clinical site, i.e. Hospital of the Ministry of the Interior and Administration, permitting market access for the product the in the European Union via CE-IVD registration. The greater number of patients and research centres participating in the study are extremely important from the perspective of the quality and quantity of scientific publications discussing the product development and also the technology itself.

Moreover, an additional study's goal is to compare the cost and time needed for SARS-CoV-2 diagnosis between the Genomtec kit operating in the Direct-RT-LAMP technique and the typical diagnostic procedure based on the Real-Time RT-PCR.

The obvious advantage developed by Genomtec saliva Direct-RT-LAMP method is elimination of the typical nucleic acid laboratory purification stage, thus reducing the time and cost of the entire procedure.

Firstly, the new type of test provides more comfortable solution for patients, as it uses non-invasive sampling - a simple saliva donation is enough to secure biological material being used for diagnosis. Secondly, the use of saliva sampling reduces medical personnel's exposure to SARS-CoV-2 infection.

A comprehensive technology validation developed by the Issuer, in the event of further confirmatory positive results, may propel sales of such an important for economic development diagnostic kit, generating increased revenue. For these reasons, in the opinion of the Management Board, this information meets the criteria of confidential information within the meaning of Art. 7 sec. 1 MAR.