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A contract signed with specialist clinical center based in Gliwice 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 21th June 2021, it has signed an agreement with specialist clinical center based in Gliwice to conduct part of the comparative study on the invitro genetic diagnostic kit for SARS-CoV-2 infection detection directly from saliva samples using Direct-RT-LAMP technology, against the reference Real-Time RT-PCR method.

Similarly to the information provided by the Issuer in reports 3/2021 and 11/2021, 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.

The clinical data gathered for Genomtec®Direct-RT-LAMP test in this study will me majorly used towards filling with the Regulator(s) requiring a minimal sample size to obtain sale authorisation for SARS-CoV-2 diagnostic product in various markets. The date will be reported by the Team from specialist clinical center, in addition to results' further dissemination in a form of a scientific publication or at scientific conferences.

Achieved clinical performance data for the SARS-CoV-2 diagnostic kit will be incorporated in the larger clinical evidence report encompassing already obtained positive results from the Hospital of the Ministry of the Interior and Administration (CSK MSWiA) that permitted market access for the product in the European Union via CE-IVD registration.

The research project goal is mostly focused on further diversification of the patients' population. The profile of the specialist clinical center, where majority of the patients' historical test results came negative, whereas the positive patients were presented either with the asymptomatic disease or with very low viral load infection, creates an opportunity to investigate effectiveness of Issuer's Direct-RT-LAMP test in the diagnosis of patients creating potential risk of infection outbreak occurrence, confirming its adequate diagnostic parameters in identification of the asymptomatic cases (with low-viral load that means little amount of virus in patients' body).

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.

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. Furthermore, 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 the diagnostic kit, causing increase in Issuer's economic development and generated 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.