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Press release for immediate release

Genomtec begins comparative testing phase of Genomtec®ID

Wroclaw, Poland - February 14, 2022. - Genomtec S.A. "GMT", a NewConnect-listed medical technology company, has started the comparative testing phase of Genomtec®ID, a mobile platform for genetic diagnostics and the Respiratory Panel (RP) 5-plex assay. The results obtained in this clinical study will be the basis for the CE-IVD registration of Genomtec®ID in the European Union planned for the middle of this year. This multi-center study will be conducted in Poland and France across a network of medical clinics, clinical diagnostic laboratories, and hospitals. Genomtec's Respiratory Panel test will rapidly identify whether a patient is sick with influenza, infected with RSV and/ or SARS-CoV-2 viruses or *Mycoplasma pneumoniae* and *Chlamydophila pneumoniae* atypical bacteria.

The primary goal of the clinical studies that commenced today, is to evaluate the performance of the diagnostic platform and the test for 5 pathogens, so called 5-plex, causing respiratory infections described above compared to laboratory diagnosis of the same pathogens by RT-PCR from samples from the same patients.

To carry out the trial, Genomtec has signed agreements with a Contract Research Organization (CRO) and healthcare facilities based in Europe which helps medical devices and in-vitro diagnostics manufacturers in the various steps of sample collection from patients, testing, product validation, statistical analysis, and report submission within the regulatory framework of CE marking.

"The signing of our agreements with the healthcare facilities and the CRO is the first stage of the external research phase for Genomtec®ID. In the phase launched, we will collect samples from patients in Poland and France, which we will be tested on our Genomtec®ID mobile platform directly in the clinic, hospital environment and in the clinical laboratory and compared with RT-PCR methods. Comparison of the results of these tests will allow us to determine the so-called: confidence level of our solution and to prepare the data necessary for registration of Genomtec®ID as a medical device for in-vitro diagnostics, according to the Directive 98/79/EC (IVD) in the European Union in the first half of this year." - said Miron Tokarski, co-founder and CEO of Genomtec SA.

"This is a very important milestone for us to confirm the effectiveness of the technology invented by Genomtec and the culmination of many years of work by our entire team and the trust placed in us by investors and institutions that have provided funding for our daily efforts." – CEO adds.

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About Genomtec:

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.

Genomtec SA is headquartered in Wroclaw.
More information at: www.genomtec.com