

Wroclaw, 8/12/2021

Press release for immediate release

# Genomtec's flagship solution enters critical development phase Company summarizes second quarter activities

Wroclaw, Poland - August 12, 2021. - Genomtec S.A., a NewConnect-listed company dedicated to the development of innovative medical technologies applied to genetic diagnostics at the point of care - POCT, has published a report for the second quarter of 2021 containing financial results and a summary of the most important activities during this period, including a description of the progress of the Company's flagship solution, which is a rapid mobile diagnostic platform - Genomtec ID. During the second quarter, the Company adapted the Genomtec ID prototype to pre-production and conducted EMC testing. The Company continued the development of the molecular diagnostic panels. Genomtec also received patent protection for a set of primers for duplicating the nucleotide sequence of Borrelia burgdorferi, the bacterium that causes Lyme disease, and filed another important patent application in the area of MRSA - infection of the body with methicillin-resistant Staphylococcus aureus. This is the third patent that the Company has obtained since commencing its operations.

In the second quarter of this year. Genomtec focused on advancing the Genomtec ID prototype to the pre-production version. Further modules of the device, such as actuators and the fluorescence detection module, were modified and verified. In addition, preliminary reliability tests were performed on prototype versions for selected modules. Genomtec also conducted electromagnetic compatibility tests. During this period, the method of heating the sample in the reaction card was also modified simplifying the design of this module. The design of the production reaction card was also modified taking into account mechanical and thermal aspects related to its handling by the analyzer.

Entering the final phase of Genomtec ID development is when the Company needs additional reinforcement. Charudutt Shah, an expert with global experience in building and growing biotech companies, focusing primarily on establishing distribution networks, has joined the Board. The newly appointed board member has numerous commercial successes with global medical device manufacturers and biotechnology suppliers. Charudutt Shah has assumed the position of Chief Business Officer.

- I am very pleased with our continued strong growth and planned entry into the key development phase of our mobile genetic testing platform, Genomtec ID. Once the final versions of Genomtec ID are produced, which will be in Q4 2021, we will enter the phase of benchmarking and clinical evaluation of our devices. These are essential steps prior to the registration filing. - said Miron Tokarski, co-founder and CEO of Genomtec. The second quarter was equally important for us from the perspective of our new laboratory tests. The results of comparative studies of Direct tests for COVID-19 directly from saliva, at the Central Clinical Hospital of the Ministry of Internal Affairs and Administration in Warsaw, allowed us to register for marketing in the European Union, the first test of this kind for SARS-CoV-2 in the world - added the CEO.



At the beginning of August this year, Genomtec received a certificate confirming compliance of the quality management system with the ISO 13485 standard based on audits conducted by TÜV Rheinland - a prestigious, independent certification body. The certificate was issued for the design and development of IVD devices for the detection of predefined biological pathogens. It confirms the highest level of quality management systems for medical devices developed by the Company. The certificate is valid until November 2023.

### Patent protection - a key competitive advantage

At the beginning of May this year the Company received patent protection from the Polish Patent Office (UPRP) for a set of primers to duplicate the nucleotide sequence of Borrelia burgdorferi - the bacterium that causes Lyme disease. The patent also covers a method of detecting Borrelia burgdorferi, a method of diagnosing Lyme disease and a kit for diagnosing Lyme disease developed by the Genomtec team. This is the second patent granted by the Polish Patent Office and the third patent received by the Company.

A month earlier Genomtec filed another important patent application with the Polish Patent Office concerning a proprietary primer set, diagnostic method and reaction mixture composition for the genetic diagnosis of MRSA (methicillin-resistant Staphylococcus aureus) using the LAMP technique. The diagnostic kit is part of a panel of systemic infections planned for detection by Genomtec ID. In addition to methicillin-resistant Staphylococcus aureus, the panel investigating systemic infections on the reaction card for the device will include Lyme disease and meningitis.

Already after the end of the second quarter (at the beginning of July this year), the Company filed a patent application with the Polish Patent Office concerning the technology developed by Genomtec, which concerned a proprietary set of primers, diagnostic method and composition of the reaction mixture for genetic diagnosis of Neisseria meningitidis (meningitis gland) in the LAMP technique.

## **Revolution in testing for SARS-CoV-2**

In the second quarter, Genomtec registered and marketed, within the European Union, the RT-LAMP Direct Kit diagnostic test, which enables testing for the identification of SARS-CoV-2 infection directly from patient saliva. The innovative test provides patients with greater comfort as they do not have to undergo a swabbing procedure such as nasopharyngeal swabbing. The ability to test directly from saliva, also reduces the risk of exposure to the virus for staff collecting the sample and does not require specialized skills. With the RT-LAMP Direct Kit, it takes just a few dozen minutes for the test result to be read from the moment the saliva sample is received by the laboratory.

Thanks to the cooperation with Dolnoslaskie Centrum Medyczne DOLMED S.A., the laboratory of this entity has become a reference center for Genomtec products. Genomtec provides its products and services to DCM Dolmed to perform RT-LAMP-based genetic diagnostic laboratory testing including SARS-CoV-2 testing for the Center's patients.

## Summary of Q2 2021 Financial Results

After the second quarter of this year. Genomtec generated PLN 171 thousand in sales revenue and PLN 1.60 million in other operating income (including PLN 1.55 million from grants), which, with operating expenses of PLN 4.74 million, meant an operating loss of PLN 3.00 million. In the



corresponding period of the previous year, the operating loss amounted to PLN 0.63 million. Due to the business model of Genomtec, at the current stage of development of the implemented projects, the Company does not generate net profit. The net loss was directly related to incurring significant operating expenses while generating no significant revenues from operations. The results achieved by the Company are influenced in particular by the expenditures incurred for the implementation of the next stages of project development and financing obtained by Genomtec.

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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<sup>®</sup> 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<sup>®</sup> SARS-CoV-2 EvaGreen<sup>®</sup> 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