

Press release for immediate release

Genomtec®ID Respiratory Panel 5-Plex (RP5-PLEX) for the detection of respiratory tract infections has received CE-IVD certification as the only solution of its kind in Europe

Wroclaw, Poland - June 8, 2022. - Genomtec S.A. "GMT", a NewConnect-listed MedTech company specializing in the development of advanced technology in the field of point-of-care (POCT) genetic diagnostics, has obtained the CE-IVD mark for its flagship solution, the Genomtec®ID Respiratory Panel 5-Plex (RP5-PLEX) diagnostic panel for the detection of pathogens causing respiratory diseases. This is the only diagnostic panel of its kind that simultaneously tests for the presence of as many as 5 viruses and bacteria in the same test and which, thanks to CE-IVD certification, will be available for sale in 27 European Union countries as well as in Iceland, Norway and Liechtenstein. Thus, Genomtec has realized the most important stage in the Company's development so far, fulfilling the promises made to investors.

CE-marking is required for all *in vitro* diagnostic (IVD) devices to be placed on the market in countries of the European Economic Area (EEA) and Iceland, Norway and Liechtenstein, and means that the device can be legally sold in these areas and that its standard is in accordance with the directive on *in vitro* diagnostics (98/79/EC).

The Genomtec®ID RP5-PLEX diagnostic panel simultaneously detects the presence of Influenza A and B viruses, RSV (Respiratory Syncytial Virus), SARS-CoV-2 and the atypical bacteria *Mycoplasma pneumoniae* and *Chlamydomphila pneumoniae*. The Genomtec® ID Analyzer, with which a reaction card (panel) is used along with a sample from a patient to perform a genetic test, is one of the smallest portable genetic laboratories in the world.

- I am very proud to register and assign CE-IVD mark for our first POCT product that enables rapid genetic testing targeting respiratory tract infections . Genomtec was founded in 2016 and we have worked hard to realize our plans. I would like to thank my team for their tireless work, brilliant ideas and commitment as well as investors that since 2016 are continuously trust that the pathway we are heading is the right one. We are excited to move to the main part of the commercialisation stage focused expanding the network of distributors , validating our invention with early customers and preparing to start scalable production - said Miron Tokarski, co-founder and CEO of Genomtec.

The company will now work to acquire as many distributors in Europe as possible, optimize the cost of manufacturing of the analyser and reaction cards, and prepare for scalable production of its flagship solution.

- We have just signed a distribution agreement in Greece and are working on further commercial agreements. By the end of the year, we hope to have early feedback on the device by our partners, which will be very valuable. We will also optimize the cost of manufacturing the solution by working with new, larger partners. We will consider what new solutions we should work on in the next stages of the Company's development. I am very pleased that we have reached such an important regulatory



milestone as registration in the European Union and obtaining CE-IVD Certification. Now, an exciting new chapter begins for us – said Charudutt Shah, Chief Business Officer with Genomtec.

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Additional information at: :

Genomtec S.A.
Magdalena Kicińska
+48 604 201 230
m.kicinska@genomtec.com

InnerValue Investor Relations
Michał Stępniewski
+48 603 159 739
m.stepniewski@innervalue.pl

O firmie 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, 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.

Genomtec was founded in 2016 and it headquartered in Wrocław.

More information at: www.genomtec.com