Aptorum Group Updates on the Clinical Validation of RPIDD Infectious Disease Liquid Biopsy Molecular Diagnostics

NEW YORK & LONDON & PARIS--(BUSINESS WIRE)-- Regulatory News:

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) a clinical stage biopharmaceutical company dedicated to tackling unmet medical needs in oncology, autoimmune diseases and infectious diseases, is pleased to announce further updates on the analytical and both the retrospective and prospective clinical validation of the RPIDD technology in patient samples, employed under both Illumina iSeq 100 and MiniSeq sequencing platforms[1].

RPIDD, using its proprietary developed depletion and enrichment technologies, has been clinically validated in over 100 patient samples so far. In the completed retrospective clinical validation, both iSeq 100 and MiniSeq employing the RPIDD workflow demonstrated a 100% agreement with positive clinical data in identifying the causative pathogen (by employing standard of care (SOC) diagnostics when the Ct value of the samples is <30). In addition, under both iSeq 100 and MiniSeq platforms, RPIDD also showed a 100% agreement with the negative clinical molecular diagnosis data on the relevant clinical samples. In our prospective clinical validation of RPIDD, patients have been enrolled with febrile neutropenia and sepsis conditions and that over 50 samples have been collected and analyzed. The trial is still ongoing but so far general agreement has been observed compared with standard of care diagnostics results such as blood culture technology and/or PCR. Various bacteria and both DNA and RNA viruses have been detected in these patient samples, including (but not limited to) Hepatitis B and C virus, Cytomegalovirus, Epstein-Barr virus, Human Immunodeficiency virus, Dengue, Escherichia coli, Klebsiella pneumoniae and Herpesviridae, etc. In the analytical validations of RPIDD, it has also been demonstrated that (a) analytical sensitivity of 100% in MiniSeq and 92.5% in iSeq 100 in the low-depth low-cost sequencing assay, and (b) analytical specificity of more than 95.0% in MiniSeq.

Mr. Darren Lui, CEO and Executive Director of Aptorum Group Limited comments “We are extremely excited with the clinical and analytical validation results of RPIDD conducted so far in 2022. The results so far have been extremely encouraging and support the capability and potentials of the RPIDD technology to overcome some of the highly unmet shortcomings of the existing standard of care diagnostics such as blood culture and PCR currently deployed by clinics and hospitals around the world. We believe the patented RPIDD technology has promisingly tackled the historical industry challenges of depleting hosts’ and enriching pathogenic genetic materials, respectively, for the purposes of NGS sequencing for detection of pathogens in an untargeted manner (without the need for a prior guess of what pathogens are present in the samples). Through the demonstrated clinical results so far, RPIDD has significant potential to disrupt the existing frontline diagnostics industry and hence in due course to significantly contribute towards the reduction of infected patient’s mortality and morbidity. With the encouraging results, we are continuing to expand our clinical validation efforts, in addition to the current site in Singapore, to involve multiple clinical sites and countries targeting to commercialize this technology as soon as possible in conjunction with regional hospitals and clinics. As part of this effort, this year we have commenced steps to establish a clinical laboratory site in the state of California, subject to the relevant Clinical Laboratory Improvement Amendment (CLIA) certification, with the dual aims of continuing expansion of (i) clinical validation collaboration targeting US based regional healthcare and academic institutions and (ii) the eventual commercialisation of the RPIDD technology in the United States through proprietary laboratories and healthcare partner collaborations. In addition to iSeq 100 and MiniSeq, we strongly believe the RPIDD technology is compatible with other NGS sequencing platforms and will continue to broaden its adaptation to both different NGS sequencing platforms and sampling methods as well.”

About Aptorum’s Rapid Pathogen Identification and Detection Molecular Diagnostics Technology

RPIDD is an innovative liquid biopsy-driven rapid pathogen molecular diagnostics technology. RPIDD, through proprietary and patented technologies, is developed with the aim to, cost effectively through patient blood samples, enrich pathogenic DNA and RNA for pathogenic genome sequencing analysis through harnessing the power of Next-Generation Sequencing platforms and proprietary artificial intelligence-based software analytics with the goal to rapidly identify and detect any foreign pathogens (virus, bacteria, fungus, parasites) without bias through its genome composition and to identify other unknown pathogens and novel mutated pathogens. RPIDD is comprised of two proprietary metagenomics next-generation sequencing (mNGS) components: (i) HostEL for depletion of human background under selective lysis to enrich both pathogen DNA and RNA; (ii) AmpRE for one pot DNA/RNA library preparation for overall cost reduction. RPIDD has been and continues to be validated in human clinical samples and so far, such testing has been able to detect pathogens – ranging from bacteria, fungi and viruses in an unbiased manner.

1 https://emea.illumina.com/systems/sequencing-platforms.html

About Aptorum Group

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) is a clinical stage biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutic assets to treat diseases with unmet medical needs, particularly in oncology (including orphan oncology indications), autoimmune and infectious diseases. Aptorum has completed two phase I clinical trials for its ALS-4 (MRSA) and orphan drug designated SACT-1 (Neuroblastoma) small molecule drugs and commercializing its NLS-2 NativusWell® nutraceutical (menopause). The pipeline of Aptorum is also enriched through (i) the establishment of drug discovery platforms that enable the discovery of new therapeutics assets through, e.g. systematic screening of existing approved drug molecules, and microbiome-based research platform for treatments of metabolic diseases; and (ii) the co-development and ongoing clinical validation of its novel molecular-based rapid pathogen identification and detection diagnostics technology with Singapore's Agency for Science, Technology and Research.

For more information about the Company, please visit www.aptorumgroup.com.

Disclaimer and Forward-Looking Statements

This press release does not constitute an offer to sell or a solicitation of offers to buy any securities of Aptorum Group.

This press release includes statements concerning Aptorum Group Limited and its future expectations, plans and prospects that constitute "forward-looking statements" within the meaning of the US Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," or "continue," or the negative of these terms or other similar expressions. Aptorum Group has based these forward-looking statements, which include statements regarding projected timelines for application submissions and trials, largely on its current expectations and projections about future events and trends that it believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions including, without limitation, risks related to its announced management and organizational changes, the continued service and availability of key personnel, its ability to expand its product assortments by offering additional products for additional consumer segments, development results, the company's anticipated growth strategies, anticipated trends and challenges in its business, and its expectations regarding, and the stability of, its supply chain, and the risks more fully described in Aptorum Group's Form 20-F and other filings that Aptorum Group may make with the SEC in the future, as well as the prospectus that received the French Autorité des Marchés Financiers visa n°20-352 on 16 July 2020. As a result, the projections included in such forward-looking statements are subject to change and actual results may differ materially from those described herein.

Aptorum Group assumes no obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

This announcement is not a prospectus within the meaning of the Regulation (EU) n°2017/1129 of 14 June 2017 as amended by Regulations Delegated (EU) n°2019/980 of 14 March 2019 and n°2019/979 of 14 March 2019.

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Source: Aptorum Group Limited