Aptorum Group Announces Publication of a Co-authored Paper on its Paths^{Dx} Technology - a Rapid-Turnaround Low-Depth Unbiased Metagenomics Sequencing Workflow for Liquid Biopsy based Diagnosis of Infectious Diseases on Illumina Platforms

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 and infectious diseases, is pleased to announce the recent publication of a joint effort for assessing a rapid-turnaround low-depth unbiased metagenomics sequencing workflow on Illumina platforms. This technology, Paths^{Dx} Test, was shown to be robust, rapid and sensitive for the diagnosis of infectious diseases.

The paper is titled, “Towards a rapid-turnaround low-depth unbiased metagenomics sequencing workflow on the Illumina platforms” has been published online in Medrxiv, which can be downloaded at the following website address: https://medrxiv.org/cgi/content/short/2023.01.02.22283504v1.

Dr Clark Cheng, Chief Medical Officer of Aptorum Group Limited commented, “We are pleased to announce the exceptional performance of Paths^{Dx} for the diagnosis of infectious diseases. The Paths^{Dx} Test has achieved so far over 95% for both sensitivity and specificity. Our clinical validation also shows that at least 93% of plasma samples agreed with the standard of care clinical diagnostic test results (compared to reported industry liquid biopsy test of 92.9%[1]). These results are remarkable as an initial stage of clinical validation. The remaining 7% are viruses with very small genome (5kb), which is a common challenge across the genomic industry, we have a workflow development plan currently to strive towards detecting these small genome viruses, eventually targeting close to full agreement. The trend of our validation results so far also suggests further improvement of our validation statistics (including the comparison of agreement with standard of case diagnostics) based on increases in further clinical validation samples. The effect of different sequencing times was evaluated with the 19-hour iSeq 100 paired end run, a more clinically palatable simulated iSeq 100 truncated run and the rapid 7-hour MiniSeq platform. Significantly, our results demonstrate the ability to detect both DNA and RNA pathogens with low-depth sequencing. In conclusion, it was demonstrated that iSeq 100 and MiniSeq platforms are compatible with unbiased low-depth metagenomics identification with the Paths^{Dx} Test workflow and its library preparation kits and can be chosen based on required turnaround times. We are also pleased to now have built up a pathogen genomic database of close to 20,000 species to support our software analytics in identifying, on an unbiased metagenomic basis, the pathogenic composition in the patient sample. With these remarkable results, we are actively expanding our validation sites in Singapore, Hong Kong and United States. We would also like to express our heartfelt appreciation of Illumina for supporting this project via intellectual, mechanical and technical input.”

References

1. https://kariusdx.com/karius-test/clinical-and-analytical-validation

About Aptorum’s Paths^{Dx} Program

Paths^{Dx} Test (formerly known as “RPIDD”) is an innovative liquid biopsy-driven rapid pathogen molecular diagnostics technology. Paths^{Dx} Test, 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. Paths^{Dx} Test is comprised of two proprietary metagenomics next-generation sequencing (mNGS) components: (i) HostEL for depletion of human background to enrich both pathogen DNA and RNA; (ii) AmpRE for one pot DNA/RNA library preparation for overall cost effective amplification. Paths^{Dx} Test 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 both DNA and RNA based viruses in an unbiased manner.

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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