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Aptorum Group Announces Further Positive Interim Results of the Phase 1 Clinical Trial of ALS-4 Targeting Staphylococcus aureus

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

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) ("Aptorum Group" or "Aptorum"), a clinical-stage biopharmaceutical company, announces further positive results of its ongoing Phase 1 clinical trial for ALS-4 (a first in-class anti-virulence approach based small molecule targeting Staphylococcus aureus, including, but not limited to Methicillin Resistant Staphylococcus Aureus ("MRSA")). Specifically, two additional cohorts (Cohort C & D) of the single ascending dose (SAD) portion of the Phase 1 trial in healthy male and female adult subjects have been completed with no serious adverse events observed.[1]

ALS-4's first-in-human Phase 1 trial is a randomized, double-blinded, placebo-controlled, single (SAD) and multiple ascending dose (MAD) study designed to evaluate safety, tolerability, and pharmacokinetics of orally administered ALS-4 in healthy male and female adult volunteers. Dosing and safety reviews of Cohort C (100mg) and Cohort D (200mg) have been completed, with 8 subjects (6 received ALS-4 and 2 received placebo) were dosed in each cohort. We are pleased to announce that no human subjects were dropped out of the studies and no Serious Adverse Events (SAE) were observed. In addition, no clinically relevant changes in respect of vital signs, electrocardiogram (ECG), clinical laboratory test results and physical examinations were observed compared to baselines. Our SAD is still ongoing to gain additional insights as to the effect of food on bioavailability as well as pharmacokinetics. On this basis, we plan to proceed to MAD in Q3, 2021.[2]

About ALS-4

As part of Aptorum Group's Acticule infectious disease platform, ALS-4 is a novel first-in-class orally administered small molecule drug based on an anti-virulence approach targeting staphylococcus aureus including MRSA. ALS-4 targets the antimicrobial resistant properties of the bacteria and is believed to render the bacteria highly susceptible to the host's immune clearance. ALS-4 is targeted for potential administration on a standalone or on a combination basis with other existing antibiotics such as vancomycin.

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) and infectious diseases. 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 of a novel molecular-based rapid pathogen identification and detection diagnostics technology with Accelerate Technologies Pte Ltd, commercialization arm of the Singapore's Agency for Science, Technology and Research.

For more information about Aptorum Group, 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 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.

This press release is provided "as is" without any representation or warranty of any kind.

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[1] Dosing and safety reviews of Cohort A (25mg) and Cohort B (50mg) have been completed in May 2021 (see https://ir.aptorumgroup.com/news-releases/news-release-details/aptorum-group-announces-positive-interim-phase-i-clinical-trial).

[2] We plan to conduct 5 total cohorts (plus one optional cohort) for SAD and, thereafter, 3 cohorts for MAD (multiple ascending dose) in Phase 1. As of today, we have completed 4 of the 5 mandatory cohorts for SAD.

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