



Aptorum Group Announces Completion of Phase I Clinical Trials for ALS-4 and SACT-1, Small Molecule Drugs Targeted for Infections Caused by Staphylococcus Aureus and Neuroblastoma

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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 completion of the Phase I clinical trial for ALS-4 (a first in-class anti-virulence based small molecule drug targeting infections caused by Staphylococcus aureus, including, but not limited to Methicillin Resistant Staphylococcus Aureus ("MRSA")) and the Phase I clinical trial for assessing relative bioavailability and food effect of SACT-1 (a repurposed small molecule drug targeting Neuroblastoma and potentially other cancer types).

ALS-4's first-in-human Phase I trial is a randomized, double-blinded, placebo-controlled, single and multiple ascending dose study designed to evaluate safety, tolerability, and pharmacokinetics of orally administered ALS-4 in healthy male and female adult volunteers. Dosing and clinical evaluations of the Single Ascending Dose studies ("SAD") and Multiple Ascending Dose studies ("MAD") have now been completed for a total of 72 healthy subjects and Aptorum is pleased to announce that no subjects were dropped from the studies. There were no Serious Adverse Events ("SAE") observed and no relevant clinical changes in respect of vital signs; ECG, clinical laboratory test results and physical examinations were observed compared to the relevant baseline in both SAD (25-200mg) and MAD (50-100mg). The safety data of the last SAD cohort (300mg) and MAD cohort (200mg twice a day for 14 days) are pending. With the encouraging safety data in our Phase 1 trial, we are on track to submit an IND application to the US FDA this year seeking to initiate a Phase 2 clinical study to assess the efficacy of ALS-4 in patients.

SACT-1's first in-human clinical trial is a Phase 1, Open-label Randomized, Single Cross Over Bioavailability and Food Effect Study of SACT-1 in healthy adult volunteers. Aptorum is pleased to announce the successful completion of the trial, during which no SAE were observed. With the encouraging data in our trial so far, we are on track to submit an IND application to the US FDA this year seeking to initiate our planned Phase 1b/2a trial for SACT-1.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: "Further to our previous announcements, we are pleased to announce the completion of the above clinical trials for ALS-4 and SACT-1. This represents another key milestone for the company and one of the targeted strategic goals we had for 2021. This milestone supports the focus of Aptorum Group to embark on the exciting Phase II clinical trials for ALS-4 and planned Phase 1b/2a clinical trials for SACT-1, subject to IND clearance. The World Health Organization deems MRSA a high priority due to its significant mortality risks¹. Neuroblastoma is a highly unmet solid tumor arising in the nervous system outside of the brain predominantly in pediatric patients. We believe that both ALS-4 and SACT-1 have the potential to effectively target these diseases, respectively and address the unmet needs in this area."

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 SACT-1

SACT-1 is an orally administered repurposed small molecule drug to target neuroblastoma. SACT-1's mechanism has been investigated in our preclinical studies to enhance tumor cell death and suppress MYCN expression (a common clinical diagnosis in high-risk or relapsed neuroblastoma patients where an amplification of MYCN is usually observed). SACT-1 is designed to be used especially in combination with standard-of-care chemotherapy.

About Aptorum Group Limited

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 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.

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

¹ <https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed>

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