

Aptorum Group Announces Positive Interim Phase I Clinical Trial Progress for ALS-4 Targeting *Staphylococcus aureus* and Positive Pre-IND Progress for SACT-1 Targeting Neuroblastoma

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 positive progress in respect of: (i) its ongoing Phase I 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”)), under which two initial cohorts of the single dose ascending dose (SAD) portion of the trial in healthy male and female adult subjects have been completed with no serious adverse events observed (with in total 6 cohorts for SAD and 3 cohorts for multiple ascending dose (MAD) have been planned); and (ii) its ongoing Pre-IND preparation for SACT-1, a repurposed small molecule targeting neuroblastoma, under which the Pre-IND meeting with the US FDA has been completed.

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 safety reviews of Cohort A (25mg) and Cohort B (50mg) have been completed and eight 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 there were no Serious Adverse Events (SAE) observed. In addition, no relevant clinical changes in respect of vital signs, ECG, clinical laboratory test results and physical examinations were observed compared to the relevant baseline. On this basis, the remaining ALS-4 Phase I study will continue to progress and as of this date, Cohort C (100mg) studies have been initiated.

SACT-1, a repurposed drug candidate for the treatment of neuroblastoma, has completed its Pre-IND meeting with the US FDA. With the guidance provided by the US FDA, SACT-1 is on track to open an IND to commence clinical studies in quarter 3 of 2021.

About ALS-4

As part of Aptorum Group’s Acticle 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

As part of Aptorum Group’s SMART-ACT® platform, SACT-1 was discovered from our SMART-ACT® platform focused on orphan and unmet diseases. SACT-1 is a repurposed small molecule drug targeted for the treatment of neuroblastoma especially in combination with standard of care based chemotherapies. Our internal in vitro studies demonstrated that SACT-1’s mechanism has enhanced DNA damage and tumor cell death.

About Aptorum Group

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) is a clinical stage biopharmaceutical company dedicated to the discovery, development and commercializing 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.

Contacts

Aptorum Group Limited
Investor Relations Department:
investor.relations@aptorumgroup.com
+44 20 80929299

Redchip – Financial Communications United States
Investor relations
Dave Gentry
dave@redchip.com
+1 407 491 4498

Actifin – Financial Communications Europe
Investor relations
Ghislaine Gasparetto
ggasparetto@actifin.fr
+33 1 56 88 11 22

Source: Aptorum Group Limited