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# Aptorum Group Updates on Data from the Completed Phase 1 Clinical Trial of SACT-1, targeting 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, is pleased to announce the finalized data from the Phase 1 clinical trial of SACT-1, a repurposed small molecule drug targeting Neuroblastoma and potentially other cancer types.

Following the announcement of the Phase 1 clinical trial of SACT-1 in January 2022, Aptorum is pleased to announce further data updates from the trial conducted by an independent clinical contract research organization. The Phase 1 clinical trial of SACT-1 was an open-label, randomized, 3-period, 3-sequence, single-dose crossover bioavailability and food effect study of SACT-1 (oral suspension) in healthy adult volunteers. The primary objective of this study was to assess the relative bioavailability of 150 mg of SACT-1 (oral suspension) under fasted and fed conditions. The secondary objectives were to evaluate the safety, tolerability and any potential QT prolongation after a single oral administration of 150mg of the studied drug under fasted and fed conditions in healthy adult subjects. The study treatments were well tolerated and no subjects were discontinued from study participation because of adverse events. No serious adverse events were reported during the study. The phase 1 clinical data also suggested that any QT interval after oral administration of SACT-1 at 150mg was well within clinically acceptable limits. Regarding the relative bioavailability under the Fed vs Fasted condition, the $AUC_{0\text{-}tlast}$, $AUC_{0\text{-}\infty}$ and $C_{max}$ ratio of SACT-1 were determined to be 189.87%, 189.43%, and 205.25% respectively.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: "Further to our previous announcements, we are very encouraged by the impressive safety data even at a relatively high dosage. The relative bioavailability data also enabled us to estimate the starting dose for pediatric neuroblastoma patients via PK modeling. We are planning to meet with the US FDA for an end of Phase 1 meeting as soon as possible and are targeting for submission for a Phase 1b/2a clinical trial in neuroblastoma patients."

**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**

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 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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