

Aptorum Group Updates on a Phase 1b/2a Clinical Trial for Repurposed Small Molecule Drug SACT-1 for Neuroblastoma

NEW YORK & LONDON & PARIS--([BUSINESS WIRE](#))-- Aptorum Group Limited (Nasdaq: APM) (“Aptorum Group” or “Aptorum”), a clinical stage biopharmaceutical company focused on novel technologies including the targeting of oncological diseases, announced that the group has submitted the relevant Phase 1b/2a clinical trial protocol of SACT-1, an orally administered repurposed small molecule drug for the treatment of neuroblastoma to US FDA. The Phase 1b/2a study of SACT-1 submitted is for the combination with chemotherapy for first relapse or refractory high risk neuroblastoma.

Mr. Darren Lui, Chief Executive Officer of Aptorum Group, commented, “Pursuant to an IND opened in September 2021, we have recently submitted a clinical protocol for a Phase 1b/2a trial of SACT-1 (in combination with chemotherapy) to the US FDA and no further comments have been received from the agency in the past 30 days. As a result, we are ready to advance the relevant Phase 1b/2a trials for SACT-1 in neuroblastoma patients subject to patient recruitment.

This Phase 1b/2a trial represents another key milestone for the company and one of the targeted strategic goals for the year of 2023. Neuroblastoma is a solid tumor arising in the nervous system outside of the brain predominantly in pediatric patients. The clinical behavior of neuroblastoma is highly variable with majority cases being highly aggressive. SACT-1 has the potential to effectively target this disease and address the unmet demands of such.”

The targeted objectives of the Phase 1b part of the study based on neuroblastoma patients to be enrolled is to determine the recommended phase 2 dose (RP2D) based on safety, pharmacokinetics and efficacy and the Phase 2a part of the study based on neuroblastoma patients to be enrolled will be used to assess the preliminary efficacy of SACT-1. We will work closely with the regulatory agency in our journey towards the approval of our drug.

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) 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.

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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 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.

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