Aptorum Group Limited Has Received IND Clearance From the US FDA to Initiate Clinical Trials for Repurposed Small Molecule Drug SACT-1 for the Treatment of 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 focused on novel technologies including the targeting of oncological diseases, announced that the group has received clearance from the US FDA regarding the IND application to initiate clinical trials of SACT-1, an orally administered repurposed small molecule drug for the treatment of neuroblastoma.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: "Further to our current ALS-4 clinical trial program, we are pleased to announce the clearance from the US FDA regarding our IND application to initiate clinical trials for SACT-1. This represents another key milestone for the company and one of the targeted strategic goals for the year of 2021. This milestone supports the focus of Aptorum Group in the United States and reflects the potential of our scientific rigor and novel approach of our products. Neuroblastoma is a highly unmet 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. We believe that SACT-1 has the potential to effectively target this disease and address the unmet demands of such."

Based on the prior recommendations provided by the US FDA in our Pre-IND meeting, the IND-opening clinical trial, a bioavailability/food effect study which is believed to last for approximately four months, will be conducted in the United States, followed by a planned Phase 1b/2a trial in pediatric patients suffering from relapsed or refractory high-risk neuroblastoma, subject to further clearance by the US FDA. The objective of the bioavailability/food effect study is to compare the relative bioavailability of the newly developed SACT-1 pediatric formulation in healthy adult subjects.

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 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.

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