Aptorum Group Announces Completion of End of Phase 1 (EOP1) Meeting with US FDA on its SACT-1, a Repurposed Small Molecule Drug 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 the completion of an end of Phase 1 (EOP1) meeting with the US Food and Drug Administration ("US FDA"). SACT-1 is a repurposed small molecule drug formulated in oral suspension targeting neuroblastoma in pediatric patients and has also received orphan drug designation previously from the US FDA.

The EOP1 meeting was focused on gaining alignment with the US FDA regarding the clinical and regulatory pathway for SACT-1 for the treatment of neuroblastoma in pediatric patients aged 2-18. The FDA generally agreed with the chemistry-manufacturing-control (CMC) strategy and our proposed clinical development plan for Phase 1/2 trials.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: "We are pleased to announce the completion of End of Phase 1 Meeting with US FDA and this represents another key milestone for the company and one of the targeted strategic goals for the year of 2023. With additional supportive information from US FDA on the clinical development of SACT-1, this supports the continued focus of Aptorum Group to embark on the exciting Phase 1/2 clinical trials for SACT-1, subject to further FDA's clearance of the final clinical protocol."

About SACT-1

SACT-1 is an oral suspension based repurposed small molecule drug formulated in oral suspension 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. SACT-1 has been observed to be potentially applicable to neuroblastoma and other cancers in the preclinical studies.

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), autoimmune and infectious diseases. Aptorum has completed two phase I clinical trials for its ALS-4 (MRSA) and orphan drug designated SACT-1 (Neuroblastoma) small molecule drugs and commercializing its NLS-2 NativusWell® nutraceutical (menopause). 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 and ongoing clinical validation of its novel molecular-based rapid pathogen identification and detection diagnostics technology with 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.

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

Contacts

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

Redchip – Financial Communications United States
Investor relations
Craig Brelsford
craig@redchip.com
+1 407 571 0902

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

Source: Aptorum Group Limited