

Aptorum Group Announces Completion of Pre-IND Discussions with US FDA on its ALS-4, a First-in-Class Small Molecule Drug Targeting Methicillin Resistant Staphylococcus Aureus

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 the Pre-IND discussions with the US Food and Drug Administration (“US FDA”). ALS-4 is a first-in-class small molecule anti-virulence drug targeting infections caused by Staphylococcus aureus, including but not limited to Methicillin Resistant Staphylococcus Aureus (“MRSA”).

Upon the completion of ALS-4’s respective Phase I clinical trials in Canada, ALS-4 has been targeting to obtain the necessary IND clearance for Phase II clinical trials in the United States. The Pre-IND discussions with US FDA focused on overall development plan in preparation for the IND application of ALS-4 targeting Acute Bacterial Skin and Skin Structure Infections (ABSSSI) initially. With the positive feedback on the overall development strategy from the US FDA, Aptorum is now proceeding towards the IND submission of ALS-4.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: “We are pleased to announce the completion of Pre-IND discussions with the US FDA which represents another key milestone the company’s strategic goals for the year of 2023 and for the eventual objective to deliver an exciting novel potential therapeutic solution for the unmet needs of MRSA related infections in human. With additional supportive information from US FDA on the Phase 2 clinical development of ALS-4, it is also the continued focus of Aptorum Group to embark on the exciting Phase 2 clinical trials for ALS-4, subject to further US FDA’s clearance of the IND application”.

About ALS-4

As part of Aptorum Group’s 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. ALS-4 has completed its first-in-human Phase I trial which was a randomized, double-blinded, placebo-controlled, single and multiple ascending dose studies (“SAD” and “MAD” respectively) designed to evaluate safety, tolerability, and pharmacokinetics of orally administered ALS-4 in a total of 72 healthy male and female adult volunteers. No Serious Adverse Events were observed on ALS-4 and no relevant clinical changes in respect of vital signs; ECG, clinical laboratory test results and physical examinations were observed compared to the relevant baseline in both SAD (25-200mg) and MAD (50-100mg).

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.

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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

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