# Aptorum Group Announces Dosing First Human Subject in a Phase I Clinical Trial of ALS-4, a First-in-Class Small Molecule Drug Designed to Treat Infections caused by Staphylococcus Aureus including Methicillin-resistant Staphylococcus aureus (MRSA)

NEW YORK & LONDON & PARIS--(BUSINESS WIRE)-- Regulatory News:

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) ("Aptorum Group" or "Aptorum"), a biopharmaceutical company focused on novel technologies including the targeting of infectious diseases, announced dosing the first human subject in its Phase I clinical trial evaluating ALS-4, an orally-administered small molecule drug for the treatment of infections caused by *Staphylococcus aureus* including MRSA.

The first-in-human Phase I trial is a randomized, double-blinded, placebo-controlled, single and multiple ascending dose study designed to evaluate safety, tolerability, and pharmacokinetics of orally administered ALS-4 in healthy male and female adult volunteers. The study plans to enroll up to 48 and 24 healthy volunteers for the single-ascending dose (SAD) and multiple-ascending dose (MAD) cohorts, respectively. Enrollment for the first cohort of SAD has been completed and we continue to enroll individuals for other cohorts of the trial.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: "The first human subject dosed in the ALS-4 clinical trial marks a significant milestone toward delivering a new mechanism of action for the potential treatment of infections caused by *Staphylococcus aureus* including MRSA. Since 1958, when vancomycin was first approved, only one additional agent, daptomycin (of which both antibiotics are primarily IV based treatment requiring patients to remain in in-patient settings during treatment) has gained regulatory approval for the treatment of MRSA bacteremia and despite this, clinical failure and mortality rates for this major infectious disease remain critically high. Subject to the upcoming clinical trial, we believe ALS-4 could be a potential new anti-infective agent adopting a unique anti-virulence approach to achieve effective outcomes for these patients. We are excited to embark on our Phase I trial and are looking forward to completing the trial as swiftly as possible."

## About ALS-4

As part of Aptorum Group's Acticule 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 both on a standalone or a combined basis with other existing antibiotics such as vancomycin.

## **About Aptorum Group**

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) is a biopharmaceutical company dedicated to the discovery, development and commercializing of therapeutic assets to treat diseases with unmet medical needs, particularly infectious diseases and cancers (including orphan oncology indications). 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 ("RPIDD") technology with Accelerate Technologies Pte Ltd, commercialization arm of the Singapore's Agency for Science, Technology and Research ("A\*STAR").

In addition to the above main focus, we are also pursuing therapeutic projects in neurology, gastroenterology, metabolic disorders, women's health and other disease areas. We also have projects focused on natural supplements for women undergoing menopause and experiencing related symptoms.

For more information about Aptorum Group, please visit <u>www.aptorumgroup.com</u>.

## **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.

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

### Contacts

Aptorum Group Limited Investor Relations Department: <u>investor.relations@aptorumgroup.com</u> +44 20 80929299

Redchip – Financial Communications United States Investor relations Dave Gentry <u>dave@redchip.com</u> +1 407 491 4498

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

Source: Aptorum Group Limited