

Aptorum Group Announces Submission of Clinical Trial Application for ALS-4, an Orally Administered Small Molecule Drug for the Treatment of Infections caused by *Staphylococcus aureus* including Methicillin-resistant *Staphylococcus aureus* (MRSA)

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New York & London & Paris - Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) (“Aptorum Group” or “Aptorum”), a biopharmaceutical company focused on novel technologies for the treatment of a variety of medical conditions including infectious diseases, announced that the company, through its wholly owned subsidiary Aptorum International Limited, has submitted a Clinical Trial Application (CTA) with the Public Health Agency of Canada (Health Canada) to conduct a Phase 1 clinical trial of ALS-4, an orally administered small molecule drug for the treatment of infections caused by *Staphylococcus aureus* including Methicillin-resistant *Staphylococcus aureus* (MRSA). Pending Health Canada’s approval, the Phase 1 trial is designed to test the safety, tolerability and pharmacokinetics of ALS-4 in healthy volunteers.

Dr. Clark Cheng, Chief Medical Officer and Executive Director of Aptorum Group, commented: “Further to our previous update in September 2020, we are pleased to announce this CTA submission which represents a major development milestone for our ALS-4 antimicrobial program. ALS-4 is a novel small molecule adopting an anti-virulence (non-antibiotic) approach to address the growing unmet medical needs of infections caused by *Staphylococcus aureus*. ALS-4 is an orally administered drug and thereby aligning with global healthcare policy to actively promote the switch from an IV to oral based antimicrobial treatment^{1,2,3}. As shown in our internal preclinical data and subject to further clinical trials, ALS-4 can be potentially used on a standalone basis or in combination with existing antibiotics (for example, vancomycin) with the aim to reduce mortality and morbidity of the infected patients especially in severe cases. We believe that our orally administered ALS-4 drug can potentially also tackle a variety of infections caused by *Staphylococcus aureus*, including (but not limited to) MRSA bacteremia and skin & soft tissue infections, subject to the respective clinical trials.”

The Phase 1 clinical trial is planned to be conducted in Canada and targeted to recruit up to 48 and 32 healthy volunteers for the single-ascending dose (SAD) and multiple- ascending dose (MAD) cohorts, respectively. The primary objective of the trial is to evaluate the safety and tolerability of SAD and MAD of ALS-4 administered orally to healthy subjects. The secondary objective is to assess the pharmacokinetic profile of SAD and MAD of ALS-4 administered orally to healthy subjects.

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 (non-antibiotic) approach targeting *Staphylococcus aureus* including MRSA. ALS-4 targets to inhibit the virulence properties of the bacteria and render them highly susceptible to the host’s immune clearance and also potentially provide added benefits in combination with existing antibiotics.

¹ <https://www.gloshospitals.nhs.uk/gps/antimicrobial-resources/adult-antibiotic-treatment-guidelines-site-infection/iv-oral-switch-guideline/> and <https://www.dbth.nhs.uk/wp-content/uploads/2017/10/IV-to-oral-switch-and-5-day-stop-policy.pdf>

² <https://hgs.uhb.nhs.uk/wp-content/uploads/Guidelines-for-Antimicrobial-Prescribing-v5.0.pdf>

³ <https://www.jwatch.org/na48403/2019/02/12/sequential-intravenous-oral-treatment-mrsa-bacteremia>

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 the establishment of drug discovery platforms that enable the discovery of new therapeutics assets through programs such as the systematic screening of existing approved drug molecules and microbiome-based research platform for treatments of metabolic diseases. In addition to the above main focus, the company is also pursuing therapeutic and diagnostic projects in neurology, gastroenterology, metabolic disorders, women's health and other disease areas. Aptorum also has projects focused on surgical robotics and natural supplement for women undergoing menopause and experiencing related symptoms.

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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