

Aptorum Group Announces Further Positive Data on ALS-4 against MRSA Wound Infection and MRSA Bacteraemia against Linezolid and Vancomycin Respectively in *In Vivo* Models

LONDON--([BUSINESS WIRE](#))-- Regulatory News:

Aptorum Group Limited (NASDAQ: APM, Euronext Paris: APM) (“Aptorum Group”), a biopharmaceutical company focused on novel therapeutics including the development of next-generation approach therapeutics targeting antimicrobial resistance, announced two sets of positive data showing both significant *in vivo* activities of its lead compound ALS-4 against Methicillin-Resistant *Staphylococcus aureus* (MRSA, one of the “super-bugs”) in wound infected and bacteraemia mouse models, respectively when compared to prevailing antibiotics.

ALS-4 is currently undergoing final stages of IND enabling studies, which involves a 14-Day oral toxicity in rats and dogs, a functional observation battery study in rats and a cardiovascular telemetry and respiratory study in dogs. Subject to the final IND-enabling studies results, ALS-4 is on track to target the regulatory submission in Q4 2020 subject to which to commence Phase I clinical trials in Canada

“Despite the two current mainstay treatments, vancomycin and daptomycin, being the only FDA approved antibiotics for MRSA bacteraemia thus far, patient mortality, morbidity and recurrence rates remain significant¹. With the fragile antibiotic pipeline being at risk globally, antimicrobial resistance issues continue to gain significant attention from global bodies including the World Health Organization and the FDA, as well as the pharmaceutical industry. We believe that our oral ALS-4 drug based on a novel first-in-class anti-virulence concept can potentially tackle a variety of infections related to MRSA, including (but not limited to) bacteraemia and skin & soft tissue infections, subject to the respective clinical trials. We are greatly encouraged by the data because ALS-4 appears to be effective against MRSA superbug and could be a potential alternative and sustainable treatment for different MRSA indications including, but not limited to, MRSA bacteraemia and skin infections. ALS-4’s anti-virulent properties are a novel approach in tackling antimicrobial resistance issues as encouraged by recent global action plans. We are also pleased to report that our IND enabling studies are also at their final stages and we remain on track to target regulatory submission to commence phase 1 clinical trials,” said Mr. Darren Lui, President and Executive Director of the company.

Efficacy of ALS-4 in a MRSA Wound Infection Mouse Model

A recent study, conducted by a third party contract research organization, assessed ALS-4's effect in the healing of open wounds infected with MRSA in a mouse model. Compared with topical dosing of 2% Mupirocin and oral dosing of Linezolid at 100mg/kg twice a day, oral dosing of ALS-4 at 30mg/kg twice a day showed statistically significant improvement in wound healing. Specifically, at the end of the study on Day 7, ALS-4 exhibited 63.8% of wound closure compared with 48.4% for oral Linezolid and 43.2% for topical Mupirocin 2%. The results are further illustrated in the graph below.

Efficacy of ALS-4 in a Bacteraemia Mouse Model

In a further round of *in vivo* studies, conducted by a third party contract research organization, in a non-lethal MRSA bacteraemia mouse model, the mice were orally administered with different doses of ALS-4 from 0.3 to 30mg/kg twice a day for 7 days, compared to those who received vancomycin only group (3mg/kg of vancomycin administered intravenously) and a no treatment control group.

At the conclusion of the study on Day 7, ALS-4 brought a statistically significant reduction in bacterial counts in major organs such as the kidneys, lungs, liver and spleen compared with the no drug control and vancomycin only groups (unpaired student’s t-test, $p < 0.05$). This is in addition to the previous *in vivo* results announced in February 2020, whereby ALS-4 demonstrated on a statistically significant basis better survival rates (56% vs 0% control group) in the lethal MRSA bacteraemia rat model and higher reduction of bacterial load (by 99.5% against the control group) in the non-lethal MRSA bacteraemia rat model.

About ALS-4

As part of Aptorum Group's Acticule infectious disease platform, ALS-4 is a novel first-in-class small molecule developed in oral form based on an anti-virulence approach targeting Methicillin resistant *Staphylococcus aureus* (MRSA). ALS-4 targets the antimicrobial resistant properties of *S. aureus* and render the bacteria to become highly susceptible to the host's immune clearance and also potentially other existing antibiotics, as shown in the preclinical data.

About Aptorum Group Limited

Aptorum Group Limited (Nasdaq: APM, Euronext Paris: APM) is a pharmaceutical company dedicated to developing and commercializing novel therapeutics to tackle unmet medical needs. Aptorum Group is pursuing therapeutic projects in orphan diseases, infectious diseases, metabolic diseases, woman's health and other disease areas.

For more information about Aptorum Group, please visit www.aptorumgroup.com.

For further general presentation, please visit:

<https://ir.aptorumgroup.com/static-files/ca36cc65-6f23-4105-895e-f5f234ecca1e>

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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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¹ <https://link.springer.com/article/10.1186/s13054-017-1801-3>

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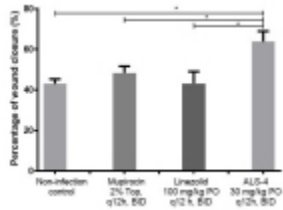
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