ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Recce Clinical Pipeline Update

Sydney Australia, 7 June 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**) (**FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-infectives, is pleased to provide an updated timeline on its clinical programs with several significant clinical data read-outs in 2021 and beyond.

Topical Phase I/II Human Burns Study

The Executive team recently met with trial investigators at Fiona Stanley Hospital where its WA Health Department sponsored Topical Phase I/II human clinical study of RECCE® 327 (R327) is underway, with approximately 200 vials of R327 stocked in the hospital pharmacy for dosing as suitable patients continue to present.

Anticipated timeline:

- Trial Commenced
- Trial to run for approximately eight (8) months
- Interim data read-outs anticipated throughout
- Full data end Q4, 2021

Intravenous (I.V.) Phase I Human Clinical Trial

The Company's I.V. Phase I clinical trial continues to progress with clinicians appointed, independent facility audits complete, third-party R327 plasma level assay lab ready and hundreds of vials dispatched to intermediary clinical storage facility in South Australia. With these essential steps complete, first patient dosing is indicated for August 2021 and will run for approximately 12 months.

Anticipated timeline:

- Healthy patient dosing anticipated Q3 2021
- Interim data expected late 2021
- Trial to run approximately 12 months from first patient dosed
- Full data expected mid 2022

Murdoch Children's Research Institute - *Helicobacter pylori (H. pylori)*

The Company's oral compound against *Helicobacter pylori (H. pylori) infections*, RECCE 435, continues to show significant efficacy in multiple *H. pylori* strains in preclinical studies *in-vitro* and *in-vivo* (mouse). The next stage of the *H. pylori* program is underway, with results expected July 2021

and full pre-clinical program to be completed mid-2022, which could lead to a Phase I/II clinical study in the second half of 2022.

Anticipated timeline:

- Current stage of program to run approximately one (1) month
- Full pre-clinical program to be completed mid-2022, with data readouts throughout
- Potential for oral Phase I/II human trials following.

SARS-CoV-2 (COVID-19) Studies

R327 achieved further encouraging results in Australian SARS-CoV-2 studies and has advanced to Stage 2 of the program. Overseas, COVID-19 animal studies of R327 and R529 (RECCE® 529) are taking longer than anticipated due to challenges observed with ferret study animals, which are struggling in the pre-clinical setting to achieve reliable infection levels. As is often observed amongst people in the community, some will become infected whilst others may not, and it is this variance in degree of infection across animal populations that is likewise currently causeing some challenges. Pre-determined infection levels are critical in efficacy studies to demonstrate meaningful and accurate outcomes. SARS-CoV-2 animal studies, especially those relating to newer and largely unexplored COVID variant strains, present inherent delays, and the Company has recently brought on-board an additional facility in the Netherlands to increase resources to accelerate the international COVID-19 studies and provide robust pre-clinical data.

With this new action plan in place, pre-clinical data from international testing of UK and South African SARS-CoV-2 variant strains (at a minimum), is expected Q4 2021.

Anticipated timelines:

- Stage 2 results of Australia SARS-CoV-2 testing anticipated late 2021
- International testing of UK and South African SARS-CoV-2 variant strains with data anticipated Q4 2021

The Company looks forward to a series of significant human clinical data points over the months ahead and thanks shareholders for their on-going support.

This announcement has been approved for release by Recce Pharmaceuticals Board

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of New Classes of Synthetic Anti-Infectives designed to address the urgent global health problems of antibiotic resistant superbugs and emerging viral pathogens.

Recce's anti-infective pipeline is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE® 327, RECCE® 435, and RECCE® 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE® 327 as an intravenous therapy, is being developed for treatment of serious and potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. Recce's new antibiotic compound, RECCE® 435, has been formulated for oral use.

The FDA has awarded RECCE® 327 *Qualified Infectious Disease Product* designation under the *Generating Antibiotic Initiatives Now* (GAIN) Act – labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval. Further to this designation, RECCE® 327 has been included on The Pew Charitable Trusts *Global New Antibiotics in Development Pipeline* as the only synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® technologies targeting synergistic, unmet medical needs.

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