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## Immune Regulation announces positive results from Phase 1 clinical trial of IRL201104

Immune Regulation Ltd. ('Immune Regulation' or the 'Company', formerly known as Peptinnovate), a biopharmaceutical company developing "first in class" immune-resetting therapies for asthma and other inflammatory diseases, announces positive results from a Phase 1 study of its lead compound IRL201104 ('1104).

- Confirmed clean safety profile
- No serious or severe adverse effects
- Primary endpoints of safety and pharmacokinetic data achieved

Study C1104-001 was a First Time in Human, randomised, double blind, placebo controlled, parallel group study in healthy volunteers and patients with asthma to assess the safety, tolerability and pharmacokinetics of single ascending and repeat doses of '1104.

The Phase 1 trial recruited 94 subjects, including 16 mild asthmatics, administered with '1104 as a single ascending dose up to 8mg or repeat doses of 2mg on a single day or placebo and then followed for 21 days.

The Phase 1 trial confirmed the clean safety profile of '1104 seen in pre-clinical studies, with the drug having a side effect profile comparable to placebo; the majority of events were classed as mild and no serious or severe adverse events were reported. No dose limiting safety or tolerability was reported in the study and no injection site reactions were seen in the small cohort of healthy subjects receiving subcutaneous (s.c.) dosing. Pharmacokinetic data from the trial showed exposure to '1104 was in-line with expectations based on pre-clinical work and was similar in both healthy volunteers and mild asthmatics.

Based on these successful Phase 1 results, Immune Regulation is moving forward with a Phase 2a proof of concept study, due to commence in the second half of 2019.

Richard Nagle, CEO of Immune Regulation, commented, "These results for '1104 are a great validation of the safety of our immune-resetting platform. It is exciting to now be embarking upon the next stage of development and the data from this study will inform the preparations and protocols for our Phase 2a trial starting next year."

### Details of the Phase 1 (C1104-001) study

- Single site study conducted by Parexel in the UK
- 78 healthy volunteers (HV) and 16 mild asthmatics were enrolled
- The trial advanced through eleven cohorts of HV (44 active, 22 placebo) with a dose range of 0.02ng to 8mg, administered as a single i.v. bolus injection. Mild asthmatic patients received single i.v. doses of placebo, 2mg or 8mg (10 active, 6 placebo)
- 6 HV (4 active, 2 placebo) received 2mg via a s.c. injection
- 6 HV (4 active, 2 placebo) received 3x2mg doses 2 hours apart
- Subjects were followed over 21 days post dose
- Primary endpoints were safety and pharmacokinetic data

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#### About Immune Regulation

Formerly known as Peptinnovate Ltd, Immune Regulation is a drug development company developing 'first in class' immune resetting therapies for asthma and other chronic inflammatory diseases. The products under development by Immune Regulation have the potential to significantly advance the control and management of a range of chronic inflammatory diseases, with the potential for immune regulation, disease modification and remission.

#### About IRL201104

IRL201104, is uniquely safe and efficacious demonstrating immunoregulatory activity in a number of preclinical models. It has successfully completed Phase 1 clinical development and has the potential to be the first Immune Resetting Asthma Drug (IMRAD).