

08 September 2020

## **Immune Regulation Ltd receives notice of allowance for new U.S. patent for its novel protein with anti-inflammatory properties**

*Patent provides long term composition of matter protection*

(London UK, 08 September 2020) Immune Regulation Ltd, a US and UK based clinical stage biotechnology company, today announced that it has received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for a new patent covering IRL201805 ('1805). '1805 is a first-in-class compound derived from the endogenous immuno-regulatory protein Binding Immunoglobulin Protein (BiP) and is in development to treat rheumatoid arthritis and other inflammatory and autoimmune diseases. The new patent provides Immune Regulation with additional intellectual property protection covering the composition of matter of '1805.

*"This new '1805 patent significantly strengthens Immune Regulation's intellectual property portfolio," said Jonathan Rigby, Group CEO of Immune Regulation. "We will continue to prosecute patent applications for both of our first-in-class immune resetting drug candidates '1805 and '1104."*

Previously reported data from a Phase 1/2A dose range finding study in patients with active rheumatoid arthritis who had failed one or more standard therapies, '1805 given intravenously as a single dose, showed a good tolerability profile, with no drug-related toxicities. Clinical responses and remissions of disease was achieved in some patients, which correlated to early reductions in a number of inflammatory biomarkers, in those patients that had been given '1805. The activity of '1805 appeared to be long lasting, with effects on biomarkers and clinical changes still evident at the cessation of the 12-week clinical trial. The clinical responses were associated with an induction of Treg cells. This study represents early proof of concept for '1805 as a safe and effective immunomodulating treatment for rheumatoid arthritis.

A Phase 2 clinical study with '1805 is currently being planned in adult patients with moderate to severe rheumatoid arthritis to further assess remission rates and longevity of action.

### **For further enquiries**

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### **About Immune Regulation**

Immune Regulation Limited is a US and UK based clinical stage biotechnology company, pioneering new technologies for regulating and resetting the immune system and developing novel first-in-class therapies for inflammatory and immunological diseases.

Immune Regulation's first-in-class immune resetting therapies have demonstrated unique efficacy and safety in pre-clinical and human studies without suppressing the immune system. These therapies exhibit short pharmacokinetic activity but reset the immune system from a pro-inflammatory to a regulatory state to induce disease remission in patients with allergic and immune mediated diseases, without the negative effects of chronic current therapies.

At Immune Regulation our aim is to develop novel, safe and effective therapies that reset the immune system, transforming the lives of patients with inflammatory and immunological diseases.

### **About IRL201805**

Immune Regulation's IRL201805 ('1805) is a first-in-class compound derived from the endogenous immuno-regulatory protein (Binding Immunoglobulin Protein, BiP). '1805 has demonstrated long duration of activity and disease remission with a good tolerability profile in a phase 1/2A study in patients with rheumatoid arthritis who have failed previous therapies.  
<https://immuneregulation.com/science>

### **Forward-Looking Statements**

This announcement includes forward-looking statements, being statements made in the announcement that are not historical fact. Forward-looking statements can generally be identified by the use of words including "anticipate", "may", "believe", "estimate", "intend", "expect" and words of similar meaning. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the Company's actual results, performance or achievements to be materially different from the results, performance or

achievements contemplated by the forward-looking statements in this announcement. The forward-looking statements speak only to the date of this announcement. Neither the Company, nor any shareholder, affiliate, employee, adviser or representative of the Company shall be under any obligation to, and all of those persons expressly disclaim any obligation to, update or revise the forward-looking statements contained in this announcement