



## Immuron and CSIRO to produce a new oral therapeutic for clinical evaluation by the US Department of Defense

### Key Points

- Immuron executes a Research Agreement with The Henry M. Jackson Foundation for Advancement of Military Medicine Inc.
- Immuron executes a Research Agreement with CSIRO to develop a new oral therapeutic targeting *Campylobacter* and ETEC for clinical evaluation
- Vaccination program initiated
- NMRC submits Pre-Investigational New Drug (IND) information package to FDA
- NMRC plans to file an IND application with FDA
- Two human phase II clinical trials to be conducted in 2021
- One trial will focus on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis
- The second trial will focus on ETEC infections

Melbourne, Australia, June 19, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to provide shareholders with an update on the progress made to date on the company's research collaboration with the Naval Medical Research Center (NMRC) previously announced in October 2019.

Immuron has now executed a research agreement with Australia's national science agency, CSIRO, to produce the new therapeutic against *Campylobacter* and Enterotoxigenic *Escherichia coli* (ETEC) for clinical evaluation by the US Department of Defense. Under the terms of the research agreement CSIRO has been engaged to produce a hyper-immune bovine colostrum product using vaccines developed by the NMRC. The work will be conducted at the Department of Agriculture and Water Resources Biosecurity Approved Arrangement facilities located in Armidale NSW.

*"This is the second R&D program CSIRO has been engaged to undertaken recently with Immuron"* said CSIRO's Dr Peter Hunt, principal research scientist.

*"We are pleased to once again offer the services, expertise and facilities of CSIRO to produce this new therapeutic product for clinical assessment by the Naval Medical Research Center (NMRC). Approval was obtained from Biosecurity Australia early this year to import the NMRC vaccines and they have been in storage since the COVID-19 pandemic hit the world. I am pleased to report the vaccination campaign has been finally initiated and the finished product should be available by the end of this year."*

Immuron is also pleased to inform shareholders that the NMRC submitted the Pre-IND information package as planned on the 10<sup>th</sup> of June 2020 and expects to receive written comments on the non-clinical information from the U.S. Food and Drug Administration (FDA) within 30-days regarding its planned investigational new drug application to treat moderate to severe campylobacteriosis and ETEC infections. The company has also recently fully executed the Research Subaward Agreement with The Henry M. Jackson Foundation for Advancement of Military Medicine Inc. the Pass-Through Entity managing the Federal Award.

Immuron CEO, Dr Jerry Kanellos commented.

*“We are grateful that the CSIRO is such a strong supporter of the Australian Biotechnology Industry. The current program is now back on track and we will have the hyper-immune bovine colostrum harvested in September 2020. The drug substance and drug product will be manufactured by the end of this year and will be available for the clinical development program to prevent acute infectious diarrhea which the NMRC plans to initiate early next year.”*

This release has been authorised by the directors of Immuron Limited.

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#### About Travelers' diarrhea

Travelers' diarrhea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever, Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. *Campylobacter* spp. are also responsible for a significant proportion of cases. The more serious infections with *Salmonella* spp. the bacillary dysentery organisms belonging to *Shigella* spp. and *Vibrio* spp. (the causative agent of cholera) are often confused with travelers' diarrhea as they may be contracted while travelling and initial symptoms are often indistinguishable.

#### About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases. Immuron has a novel and safe technology platform with one commercial asset generating revenue. In Australia, Travelan® is a listed medicine on the Australian Register of Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travellers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licenced natural health product (NPN 80046016) and is indicated to reduce the risk of Travellers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection in accordance with section 403 (r)(6) of the Federal Drug Administration (FDA).

#### About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tableted preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers' diarrhea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travelers' Diarrhea, reduce

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For more information visit: <http://www.immuron.com>

**FORWARD-LOOKING STATEMENTS:**

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.