US DoD Naval Medical Research Center Receives FDA Guidance on the clinical development plans for new oral therapeutic

Key Points

- **NMRC received guidance from the FDA on the development of a new oral therapeutic targeting Campylobacter and ETEC**
- **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, July 20, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to announce that the Naval Medical Research Center (NMRC) has received written guidance from the U.S. Food and Drug administration (FDA) in relation to the clinical development pathway of a new investigational drug which the company is developing to treat moderate to severe campylobacteriosis and Enterotoxigenic Escherichia coli (ETEC) infections.

The Type B meeting with the FDA discussed the Chemistry, Manufacturing and Controls including the proposed release testing specifications of the product as well as the planned clinical studies evaluating the safety and efficacy of the product which the company is developing to prevent Campylobacter and ETEC mediated moderate to severe diarrhea.

The FDA were recently provided a Pre- Investigational New Drug (IND) package for the new Hyper-immune therapeutic which specifically targets Campylobacter jejuni capsule and Enterotoxigenic Escherichia coli (ETEC) colonization factor antigen 1. Following FDA review the agency provided a written response to the non-clinical questions posed in the briefing documentation as well as providing additional guidance and comments to support the planned IND submission.

“This is an important milestone in the development of any new drug for therapeutic evaluation. The information obtained from this review will assist in the development of the IND application and provides a clear roadmap forward for conducting the two planned clinical studies next year” said Dr. Jerry Kanellos, CEO of Immuron Ltd. “The company is also please to inform shareholders that the manufacturing program is proceeding as planned. We have completed the second immunisation campaign and are on schedule to harvest the Hyper-immune colostrum in September this year which will be used to manufacture the drug product that will be used to treat moderate to severe campylobacteriosis and ETEC infections.”

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

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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 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 the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

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.

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.