



HIMUKA AM AUSTRALIA ANNOUNCES COMPLETION OF
PHASE 1 CLINICAL TRIAL OF HM201 IN AUSTRALIA
04 APRIL 2023

Himuka AM Australia Pty Ltd. today announced that a Phase 1 clinical trial of HM201, a novel adrenomedullin based peptide drug candidate developed for the treatment of Inflammatory bowel disease (IBD), has been completed. The preliminary results of this study demonstrated excellent data with final results scheduled to be reported in several months.

"The trial was affected by the COVID-19 pandemic and the severe flooding in Brisbane, although we overcame the difficulties with the cooperation of the subjects, the clinical site and the CRO. We are proud to have been able to submit a Clinical Trial Notification of study completion to the Therapeutic Goods Administration," said Hiroshi Shinjo, Chief Executive Officer of Himuka AM Australia.

The Phase 1 clinical trial of HM201 was a double-blind, placebo-controlled, ascending dose, multi-cohort study in healthy subjects consisting of single ascending dose and multiple ascending dose cohorts. The study aimed to assess the safety, tolerability, and pharmacokinetics of single and multiple intravenous administrations of HM201.

(ClinicalTrials.gov Identifier: NCT05088369)

About HM201

HM201 is a novel peptide drug candidate created by improving the bioactive peptide adrenomedullin.

Adrenomedullin contributes to the regulation of homeostasis in the human body through the action of regeneration of epithelial and endothelial cells, angiogenesis, and anti-inflammation. In the Phase 2a clinical trial of

adrenomedullin for steroid-resistant ulcerative colitis (UC) conducted by University of Miyazaki, Japan, they observed the complete remission at 8 weeks in patients with steroid-resistant UC receiving a certain dose of adrenomedullin. Himuka believes that HM201 may have the same pharmacological effects as adrenomedullin and is developing HM201 with the belief that it may contribute to the healing of the intestinal mucosa in suffering patients.

About Himuka

Himuka AM Australia Pty Ltd. is an Australian company which was established by Himuka AM Pharma Corp. for the development of HM201 in Australia.

Himuka AM Pharma Corp. is a multi-asset clinical-stage biopharmaceutical company focused on developing novel treatments in areas of unmet need including refractory Inflammatory bowel disease.

Regarding Himuka's first candidate, adrenomedullin (HM101), several Phase 2a investigator-initiated clinical trials have been conducted under programs of the Japan Agency for Medical Research and Development.

Himuka is also advancing HM201, its novel peptide drug candidate for the treatment of diseases through the improvement of the barrier function of epithelial or endothelial cells, and the function of angiogenesis.

For more information, visit <https://www.himuka-am.com/>

Forward-Looking Statements

This press release may contain forward-looking statements.

Statements contained in this press release concerning plans, predictions, and strategies to improve future performance ("Forward-Looking Statements") are based on information currently available to Himuka's management, and inevitably involve a certain element of risk and uncertainties.

Actual results may therefore differ from those in the Forward-Looking Statements. Therefore, forward-looking statements should not be relied upon as representing Himuka's views as of any date after the date of this press release.