



HIMUKA AM AUSTRALIA ANNOUNCES HREC APPROVAL FOR  
PHASE 1 CLINICAL TRIAL OF HM201 IN AUSTRALIA  
4<sup>th</sup> NOVEMBER 2021

Himuka AM Australia Pty Ltd. today announced the approval by the Human Resources Ethical Committee of Himuka's application for a Phase 1 Clinical Trial of HM201 in Australia.

"With this approval, we will continue to prepare for the initiation of our Phase 1 clinical trial in Australia, including recruitment of subjects and transport of the investigational products," said Hiroshi Shinjo, Chief Executive Officer of Himuka AM Australia. "We look forward to being ready to start of this important clinical trial."

Himuka's planned Phase 1 clinical trial of HM201 is designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study in healthy subjects. The clinical trial will be conducted at the Nucleus Network site in Brisbane, Queensland. Himuka expects to initiate the first subject dosing in December 2021.

#### 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 has the same pharmacological effects as adrenomedullin and is developing HM201 with the belief that it will contribute to the healing of the intestinal mucosa in suffering patients.

### About Himuka

Himuka AM Australia Pty Ltd. is an Australian company which is 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 unmet need areas including refractory Inflammatory bowel disease.

Regarding Himuka's first candidate, adrenomedullin (HM101), several Phase 2a investigator-initiated clinical trials have been conducted under the 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.