Aurealis Pharma Submitted Clinical Trial Application for First-in-Human Phase 1-2A Clinical Study to German Health Authority Paul-Ehrlich-Institute (PEI)

Basel Switzerland, Kuopio Finland – October 15th, 2018.

Aurealis Pharma, a private biopharmaceutical company developing novel three-in-one combination biologics for chronic non-healing wounds and cancer announced today the successful submission of its first Clinical Trial Application to the German Health Authority Paul-Ehrlich-Institute (PEI) for the lead development candidate AUP1602-C to be studied in a first-in-human phase 1-2A clinical study as treatment of diabetic foot ulcers (DFU).

Study AP-W-CLI-2018-8 (EudraCT number: 2018-003415-22) is the first clinical study of AUP1602-C in humans. It is a Phase 1-2A clinical study to evaluate the safety, tolerability and efficacy of a single and repeated doses of AUP1602-C as topical treatment of DFU. The Phase 1 part will be a multicenter, open-label, non-randomized, uncontrolled dose-finding study with sequential dose escalations performed in dose cohorts comparing three doses of AUP1602-C administered three times per week (low, medium, and high dose cohorts). The Phase 2A part, an extension of the Phase 1, will be a multi-center, open-label, randomized, placebo-controlled study of the recommended AUP1602-C dose and administration schedule from Phase 1 to confirm safety and to assess efficacy of the selected recommended phase 2 dose and schedule in DFU and potentially also venous leg ulcer (VLU) patients compared to a placebo arm.

"We are very proud of bringing our innovative AUP1602-C treatment for the first time to patients suffering from chronic wounds. Diabetic patients with chronic, non-healing foot ulcers not responding to standard of care treatment experience a devastating personal burden with major socio-economic consequences. Treatment options are very limited for this large patient group. With AUP1602-C, we are addressing a highly unmet medical need and are delighted making a new therapeutic option available to patients." stated CMO Dirk Weber, MD, PhD.

"AUP1602-C is the first ever three-in-one multitherapy option for chronic wound sufferers and it is a great momentum to see that from a scientific idea and years of research and non-clinical development, our first product candidate AUP1602-C is now reaching clinical testing in patients." said Thomas Wirth, PhD, CSO and Chairman of Aurealis Pharma.

"The development of our unique mode of action therapeutics represent the start of a new era not only in chronic wounds, but also for other indications. I would like to sincerely thank the whole team who

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made this happen – the staff, the Board, the large pool of service providers and advisors, and the shareholders and investors. Reaching clinical development stage is a major milestone in validating our product and technology. Execution of the plan continues." said CEO Juha Yrjänheikki, PhD.

AUP1602-C is the lead product from Aurealis Pharma "combination biologics in one product" technology platform. It is a genetically engineered *Lactococcus lactis*, a non-pathogenic, probiotic bacteria, expressing human basic fibroblast growth factor (FGF2, bFGF), interleukin-4 (IL-4) and macrophage colony stimulating factor (CSF-1, mCSF) – all in one product and accepted as one active pharmaceutical ingredient from regulatory perspective.

AUP-16 is topically applied on chronic wounds and covered by wound dressing (e.g. in diabetic foot ulcers, venous leg ulcers and pressure ulcers). In the wound AUP-16 acts as millions of bioreactors producing the therapeutic proteins, which are designed to i) halt chronic inflammation in the wound, ii) induce growth of new blood vessels, and iii) promote granulation tissue formation and skin re-epithelization – all in one product.

About Aurealis Pharma
Aurealis Pharma is a Basel, Switzerland and Kuopio, Finland based privately-held biopharmaceutical company focusing on developing broadly applicable proprietary technology to re-educate the distorted host immune microenvironment in chronic inflammation and cancer to its proper state. Company´s technology is based on safe food-grade lactic acid bacteria delivering multiple human therapeutic proteins in target tissue effectively, safely and economically to address the unmet medical need in chronic wounds and cancer.

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