Aurealis Pharma Announces 7.8MCHF Financing to Advance the Chronic Wound Lead Candidate AUP-16 to Diabetic Foot Ulcer Patients under New Brand Aurealis Therapeutics AG

Basel Switzerland, Kuopio Finland – February 8th, 2019.

Aurealis Pharma, a private biopharmaceutical company developing novel three-in-one combination biologics for chronic non-healing wounds and cancer announced 7.8MCHF funding provided by Swiss and foreign private investors, Finnvera plc, and Business Finland – the Finnish Innovation Funding Agency. The Company also confirmed the de-merger and a plan to develop and commercialize the AUP-16 under a new legal entity – Aurealis Therapeutics AG. The proceeds of this financing will be used in Aurealis Therapeutics AG to fund the AUP-16 first-in-human Phase 1 clinical study for diabetic foot ulcers (DFU).

AUP-16 will be developed under a new legal entity – Aurealis Therapeutics AG

The purpose of the spin-off is to maximize the full potential of AUP-16 through the creation of a separate business unit entirely dedicated to the "development and commercialization of the product AUP-16". These activities, including the associated wholly-owned subsidiary Aurealis Oy, Kuopio, Finland, will be separated from the other parallel development activities within Aurealis Pharma AG including oncology, which will remain with it. All relevant assets of the product AUP-16 and all the associated obligations will be transferred to Aurealis Therapeutics AG. It is emphasized that the de-merger has no effect on the Board of Directors, management team and staff. They all remain at Aurealis Therapeutics and its subsidiary Aurealis Oy. Furthermore, the de-merger has no effect on the ongoing AUP-16 collaborations, contracts and obligations. They all continue under Aurealis Therapeutics and its subsidiary Aurealis Oy. The most visible changes are the new name, new web page at www.aurealistherapeutics.com, and the new email addresses in the form of firstname(at)aurealistherapeutics.com.

AUP-16 clinical plan

AUP-16 first-in-human Phase 1 clinical study for diabetic foot ulcers (DFU) clinical trial application (CTA) was submitted in Q4/2018 to the German Health Authority Paul-Ehrlich-Institute. CTA approval is expected during Q1/2019 and the first patient is planned to be treated in Q2/2019.

Study AP-W-CLI-2018-8 (EudraCT number: 2018-003415-22) is the first clinical study of AUP-16 in humans. It is a Phase 1-2A clinical study to evaluate the safety, tolerability and efficacy of a single and repeated doses of AUP-16 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 AUP-16 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 AUP-16 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 patients.

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“We are extremely pleased to have closed this funding and to complete the process of the de-merger. Aurealis Therapeutics AG is funded until diabetic foot ulcer phase 1 results and can now focus on maximizing the AUP-16 clinical development. Aurealis Pharma AG, on the other hand, will focus on oncology with its renewed strategy and plan.” said Dr. Juha Yrjänheikki, CEO of Aurealis Therapeutics AG.

“We are committed to continue our aspirations in advancing AUP-16 into patients suffering from chronic wounds, a huge unmet medical need with no effective therapies. Furthermore, we are excited to continue the development of the AUP-technology and to expand our investor discussions concerning the separate oncology entity.” continued Dr. Thomas Wirth, CSO and Chairman of the Board of Aurealis Therapeutics AG.

About AUP-16

AUP-16 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 Therapeutics

Aurealis Therapeutics is a Swiss-Finnish private biopharmaceutical company developing novel three-in-one combination biologic AUP-16 for chronic non-healing wounds and other regenerative diseases. The product is based on Aurealis Pharma technology where genetically engineered lactic acid bacteria act as millions of small bioreactors in the human tissue and produce multiple human therapeutic proteins into target tissue to effectively and safely re-educate the distorted host immune microenvironment to proper state.

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