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UNION receives approval from Danish Medicines Agency to initiate clinical study with niclosamide for treatment of COVID-19

- Niclosamide has been identified as a potent inhibitor of SARS-Cov-2 by Institut Pasteur Korea, with potency >40x higher than remdesivir
- UNION has leveraged existing deep knowledge of niclosamide, derivatives and formulation technologies to rapidly advance a treatment candidate for COVID-19
- The Danish Medicines Agency has approved UNIONs Clinical Trial Application to initiate study with niclosamide in healthy volunteers
- The COVID-19 program has been awarded financial support from the Innovation Fund Denmark

COPENHAGEN, Denmark: UNION therapeutics A/S (“UNION”), a privately held clinical stage pharmaceutical company dedicated to the discovery and development of novel medicines for patients with unmet medical needs in inflammatory and infectious diseases, announced this morning that the Danish Medicines Agency has approved initiation of a clinical study with an optimized salt form of niclosamide as a new treatment candidate for COVID-19.

Chief Medical Officer of UNION, Dr Philippe Andres states: *“The approval of our Clinical Trial Application is a major milestone, enabling us to further assess the safety and tolerability profile of UNI911 which has the potential to be a uniquely differentiated treatment candidate for COVID-19”.*

Over a number of years, UNION has built a deep understanding of niclosamide and its mechanism of action. Professor Morten Sommer, Chief Scientific Officer and Co-founder of UNION, explains: *“Niclosamide is a truly differentiated candidate for the treatment of COVID-19, with its method of action, effectively blocking replication of SARS-CoV-2 by targeting host cells to disrupt the viral life cycle. The extensive experience and data generated to date by UNION with niclosamide, and in particular optimized salt forms thereof, have enabled rapid progress leading to the successful approval of the Clinical Trial Application”.*

CEO and Co-founder of UNION, Dr. Rasmus Toft-Kehler concludes: *“UNION has been through an amazing period of process leading to approval of the Clinical Trial Application. The team, including all stakeholders, partners, physicians, Innovation Fund Denmark, The European Investment Bank, global organizations, investors and not least regulatory authorities, have acted with passion and in concert to advance UNI911 at an incredible pace. We are honored to be part of this venture and excited to be at the cusp of initiating clinical studies with the ultimate goal of making a differentiated product available for patients in need”.*

UNION is conducting the first human study at the Zelo Phase I Unit at Bispebjerg and Frederiksberg Hospital as well as Center for Physical Activity Research at Rigshospitalet, in collaboration with Trial Nation Denmark and the Technical University of Denmark, and with financial support from the Innovation Fund Denmark.

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About UNION

UNION therapeutics A/S is a privately held, clinical stage, pharmaceutical company dedicated to the development of

novel treatments for inflammatory and infectious diseases. The company is working on a versatile new mode-of-action chemistry platform, including well-characterized compounds as well as new chemical entities. The leadership team of UNION has successfully developed multiple approved drugs. UNION is headquartered in Copenhagen (Denmark) and managed by an experienced team across Europe and the USA. UNION has received financial support from the European Investment Bank's InnovFin program under Horizon 2020. Visit the Company's website at <https://uniontherapeutics.com>

About niclosamide

Niclosamide is approved as an oral anthelmintic. UNION has been working with niclosamide and the related chemical class for over six years and is currently conducting a Phase 2b study with niclosamide in atopic dermatitis patients. The Company has built extensive knowledge and intellectual property rights around the compound class, formulations and various methods of delivery as well as broadening the pipeline to cover additional diseases within inflammatory and infectious diseases.

About niclosamide in COVID-19

Recent studies undertaken by the Institut Pasteur Korea, an infectious disease-focused research institute, have identified niclosamide as one of the most potent inhibitors of SARS-Cov-2; the virus causing COVID-19 based on in vitro studies. Niclosamide has the potential to become a truly differentiated treatment of COVID-19, effectively blocking replication of SARS-CoV-2 by targeting host cells to disrupt the viral life cycle.