



NovaBiotics Announces Cysteamine Bitartrate (NM002) Included in REMAP-CAP Phase 3 Clinical Trial for Community Acquired Pneumonia

Randomized embedded multi-factorial platform trial to provide accelerated, real-world evidence in community acquired pneumonias including COVID-19, influenzas and bacterial pneumonias

Aberdeen, June 21, 2021. NovaBiotics Ltd, a privately held clinical stage company developing novel immune based therapies for life-threatening and life-limiting-diseases, announces that the Company's proprietary intravenous (IV) cysteamine bitartrate (NM002) therapy candidate is included in a global Phase 3 clinical trial being conducted and funded as part of REMAP-CAP (Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community Acquired Pneumonia).

REMAP-CAP is a global network of expert clinicians, medical institutions, and research facilities with the objective of evaluating treatments with the potential to reduce mortality, intensive care use, and morbidity in severely ill patients with community acquired pneumonia (CAP). This international, adaptive trial is evaluating multiple treatment options simultaneously at more than 300 clinical sites across more than 20 countries worldwide. The study is funded by a consortium of government funding agencies from participating countries, including the United Kingdom's (UK) National Institute for Health Research (NIHR). NovaBiotics has provided NM002 doses for the initial UK phase of REMAP CAP and has developed a scalable manufacturing process for NM002 to supply the balance of the trial.

NM002 is an immunomodulator-antimicrobial (antiviral and antibacterial) and NovaBiotics' data suggest that its multi-active properties could provide significant benefit in the treatment of CAP. The active pharmaceutical ingredient of NM002, cysteamine, is an endogenous innate immune effector with an underappreciated role in the treatment of the inflammatory consequences of infection.

Deborah O'Neil, OBE, PhD, FRSE, Chief Executive Officer of NovaBiotics, commented: "We are delighted that NM002 will be included as part of this important global clinical trial. Inclusion as a Phase 3 intervention is key for NovaBiotics as it gives us a second late-stage clinical product and it brings us one step closer to bringing our potentially life-saving, immunology-based treatment to patients suffering with CAP, including CAP caused by COVID-19 and difficult to treat, even drug resistant bacteria."

"This study can provide real-world clinical evidence in a range of CAPs potentially in thousands of patients across several continents. Our ambition is for REMAP-CAP to serve as a registration study for NM002 in a number of key territories in CAP, an important cause of mortality and morbidity worldwide," added Dr. O'Neil.

Professor Anthony Gordon, MD, FRCA, FFICM, Chair in Anaesthesia and Critical Care at Imperial College London and the UK Chief Investigator in REMAP-CAP, said: "REMAP-CAP was designed to be an on-going platform to develop effective treatments for severely ill patients with pneumonia. We are, therefore, thrilled to establish collaborations with new partners, such as NovaBiotics, to ensure a growing pipeline of new treatments designed to improve outcomes for some of the sickest patients in hospital."

About NIHR

The National Institute for Health Research (NIHR) is the United Kingdom's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care;
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research;
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future;
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services; and
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy.

The NIHR was established in 2006 to improve the health and wealth of the nation through research and is funded by the Department of Health and Social Care. In addition to its national role, the NIHR supports applied health research for the direct and primary benefit of people in low- and middle-income countries, using UK aid from the UK government.

About NovaBiotics

NovaBiotics Ltd is a privately held, clinical-stage biotechnology company focused on the design and development of novel therapies from two proprietary immunology platforms to address life threatening and life limiting diseases caused by bacteria and fungi and inflammatory-infectious respiratory conditions including cystic fibrosis and community acquired pneumonia (including COVID-19 pneumonia). A leading innovator bringing immunology to the anti-infectives space, the Company's robust technology and business model has been validated through successful development from concept through to the late-stage clinical development of its most advanced product candidates.

In addition to the lead NM002 programme and the Company's other late-stage assets (NM001 for cystic fibrosis, NP213/Novexatin® for onychomycosis), NovaBiotics has generated a robust pipeline of earlier stage, high-value drug candidates including NP339 (Department of Health and Social Care funded programme) for life-threatening, drug-resistant invasive and respiratory fungal disease and NP432 for multi-drug resistant bacterial infections.

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