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NovaBiotics secures £1 million in funding from Innovate UK to support clinical development of Nylexa for COVID-19

Aberdeen, 16TH October 2020. NovaBiotics, the clinical stage antimicrobials drug discovery company, announces that it has secured £1 million in funding from Innovate UK, allowing the company to commence clinical studies for Nylexa® a potentially game-changing therapy for the treatment of COVID-19.

Nylexa has a unique dual action by targeting both the infection and hyperinflammation which are the causes of morbidity and mortality in COVID-19. Furthermore, Nylexa also acts against bacterial lung infections that, in some cases, can occur in COVID-19 patients, secondary to SARS-CoV-2 infection and which lead to much worse outcomes.

The active ingredient of Nylexa is readily available, cost-effective and scalable, offering the potential for near-term, large-scale use by healthcare systems, subject to the successful completion of clinical development. This ingredient and related compounds have been safely used in medicines that treat unrelated conditions for over 30 years.

Nylexa can proceed directly into phase 2 clinical studies and is currently being considered for inclusion in two, critically important, global platform trials. As a repurposed therapy which addresses a public health emergency, Nylexa is likely to continue to follow an expedited pathway to completion of its clinical development and regulatory approval for licensing as a medicine in the UK and globally.

The grant from Innovate UK, which was awarded as part of UK Research and Innovation's 'Call for ideas to address COVID-19' competition, will support NovaBiotics in completing manufacturing of the clinical trial material and preparation work for phase 2 clinical testing in hospitalised COVID-19 patients with moderate to severe disease.

NovaBiotics discovered Nylexa's potential benefits in COVID-19 following a decade of research as to the use of its active ingredient in difficult to treat, drug-resistant infections, including the complex chest infections and inflammation associated with cystic fibrosis (CF) lung disease. NovaBiotics' laboratory research and previous phase 2 clinical studies in patients with CF lung infections in the UK, Italy and the US demonstrated that the active component of Nylexa is anti-inflammatory, 'supercharges' antibiotics; boosting their efficacy and even reversing drug resistance in bacteria and overall, resolves infection symptoms in patients more rapidly and to a greater extent than standard of care treatments for infection alone.

Dr Deborah O'Neil, CEO of NovaBiotics commented: "There are currently no products in use or in development for COVID-19 with the established safety profile and unique, dual antimicrobial-immunomodulatory activity of Nylexa. Available treatment options are generally single-target therapies that address only the SARS-CoV-2 virus or the hyperinflammation associated with it. Nylexa, in contrast, targets multiple drivers of COVID-19 pathology and therefore offers a much greater chance of clinical success.

"Even if a vaccine becomes available, which we all hope will be the case, it will not be 100% effective or available for the entire population at the scale required for global coverage for some time, if ever.

Nylexa could de-risk the consequences of contracting SARS-CoV-2, facilitate a faster return to employment/education and mitigate its long-term health impacts of COVID-19.

As we learn to live with COVID-19 for the long term, Nylexa could increase public confidence and potentially allow a greater degree of normality to return to the way in which we live, benefiting the economy directly in addition to easing COVID-19's burden on the NHS and healthcare systems globally."

"UK Research and Innovation has awarded us this grant against stiff competition, recognising the potential of Nylexa. We're delighted that this supports us in moving towards phase 2 clinical testing in COVID-19 and ultimately confirmatory clinical studies and look forward to beginning work on this programme as soon as possible."

Graham Devereux, Consultant Professor in Respiratory Medicine, Aintree University Hospitals NHS Foundation Trust and Liverpool School of Tropical Medicine states:

"As one of the few clinicians who has used the active ingredient in Nylexa to treat lung infection with knowledge of its antimicrobial and anti-inflammatory properties, I am convinced of the need to investigate its role in COVID-19. The clinical profile of this drug is well known and my experience of this drug is that it is very well tolerated by patients with no interactions with concomitant medications.

"The study of Nylexa in COVID-19 requires a relatively simple trial. Virtually all patients, irrespective of severity, could benefit."

Dr Ian Campbell, Executive Chair of Innovate UK, added: "By tackling infection and inflammation at the same time, two of the primary causes of morbidity and mortality in COVID-19, Nylexa potentially offers not only greater chance of clinical success but the potential to help people return to their daily lives - ultimately reducing the burden on public health and supporting broader economic recovery.

"We're delighted to be able to provide the support for NovaBiotics to develop this promising programme further and look forward to following the progress of studies closely."

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About NovaBiotics

NovaBiotics Ltd www.novabiotics.co.uk is a clinical-stage biotechnology company focused on the design and development of first-in-class therapies for difficult-to-treat, medically unmet infectious diseases caused by bacteria and fungi and respiratory conditions including cystic fibrosis and COVID-19. A leading innovator in the anti-infectives space, the Company's robust technology and business model has been validated through successful development, from concept to late stage clinical development, of its most advanced product candidates.

In addition to the lead Nylexa® programme and the Company's other late-stage assets (Lynovex® 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 fungal disease and NP432 for multi-drug resistant bacterial infections.

About Nylexa®

Nylexa® is a novel, dual antimicrobial-immunomodulatory candidate therapy. It is a simple, small molecule which has broad ranging antimicrobial effects through directly targeting microbes and also modulating the body's ability to control infection. Importantly, Nylexa's active ingredient has a key role in the resolution of infection and control of inflammation which NovaBiotics has exploited as a solution to COVID-19.

For bacterial infections, Nylexa is a potential solution to a public health challenge even greater than COVID-19: the worsening antimicrobial biotic resistance (AMR) crisis. Because Nylexa's active ingredient is repurposed and has been used in medicines for other, unrelated conditions for more than 30 years, it can potentially be introduced into clinical practice within a much shorter timescale than new antibiotic(s) treatments developed from first principle.

Put simply, Nylexa 'supercharges' existing antibiotics in bacterial infections, especially against drug resistant bacteria.

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