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# **180 Life Sciences Announces That the University of Oxford Has Been Awarded a Grant From the National Institute for Health and Care Research in the U.K. to Conduct a Clinical Trial in Post Operative Delirium/Cognitive Deficit in a Jointly Funded Program With 180 Life Sciences Corp.**

PALO ALTO, Calif., July 27, 2022 (GLOBE NEWSWIRE) -- 180 Life Sciences Corp. (NASDAQ: ATNF) ("180 Life Sciences" or the "Company"), a clinical-stage biotechnology company, today announced that a team led by researchers at University of Oxford have been awarded a grant from the National Institute for Health and Care Research (NIHR) in the U.K. to conduct a feasibility trial to investigate whether anti-tumor necrosis factor (TNF) therapy, administered at the time of surgery, can reduce or prevent post operative delirium/cognitive deficit ("post-operative delirium").

The research project is entitled, 'WHiTE-DECI: World Hip Trauma Evaluation – Delirium and Cognitive Impairment; a randomised feasibility trial comparing severity of delirium symptomatology between hip fracture patients 60 years and over treated with a peri-operative infusion of anti-TNF or placebo'. University reference: *R77147*, funded under the NIHR Research for Patient Benefit (RfPB) Programme.

The trial is jointly funded by NIHR and 180 Life Sciences and is expected to be open for enrollment in the first half of 2023. "This is a major achievement by the team," said Dr. Jim Woody, CEO of 180 Life Sciences. "These grants are awarded following a robust peer-review process and are extremely competitive. It means that the team will be able to access many services essential for the conduct of the trial funded by the NIHR, and 180 Life Science is delighted to be able to make a significant contribution to further the trial. This dual funding model and collaboration between academia and industry leverages the expertise of both to develop new therapeutic strategies, for what we believe is a major unmet medical need, in the most effective way to benefit patients in the shortest possible timescale".

Under a prior Memorandum of Understanding, the anti-TNF infliximab, Remsima (a biosimilar of Remicade), approved for use in the U.K., will be supplied for this trial by Celltrion Healthcare UK Limited. The University of Oxford and Celltrion are currently completing contract terms. As previously disclosed, an issued patent to protect this potential use has been licensed by 180 Life Sciences from The Kennedy Trust for Rheumatology

Research. 180 Life Sciences also has the rights for commercialization of the trial results.

Post-operative delirium is an important problem, recognized as the most common surgical complication in older adults.(1) According to U.K. national audit data, 25% of all hip fracture patients develop post-operative delirium. Hip fracture patients who develop delirium are unfortunately twice as likely to die while in hospital and nearly four times more likely to require nursing home care compared with those who do not have delirium.(2) Patients who develop delirium are approximately 4 times more likely to develop cognitive memory deficit over 3 years, increasing to 8 fold higher likelihood over 8 years.(3) There are approximately 70,000 hip fractures each year in the U.K. and approximately 300,000 hip fractures in the U.S. each year.(4)

Post-operative delirium can also occur following many other types of surgery. For example, about 12% of older patients undergoing elective surgery can be affected. According to the Agency for Healthcare and Research Quality, there are approximately 450,000 hip replacements performed in the U.S. and 600,000 in the EU each year and the majority of these patients are over the age of 65 years.

The Oxford team found that the trauma associated with surgery leads to the release of proinflammatory mediators, especially TNF, which in turn leads to inflammation of a part of the brain called the hippocampus. The hippocampus is involved in memory and is associated with learning and emotions.(5, 6)

Prof Sir Marc Feldmann, co-chairman of 180 Life Sciences said, " It is a pleasure to see that 180 Life Sciences is following in my past footsteps where, in the 1990s, I pioneered, the use of anti-TNF in rheumatoid arthritis and 180 LS is now developing a whole series of new uses for anti-TNF, a very effective and safe medication."

Professor Matt Costa at the University of Oxford, who will lead the trial, is a trauma orthopedic surgeon with extensive expertise in clinical trials especially in hip fracture, and will work closely with Professor Nanchahal, the leader of the Oxford scientific discovery efforts, and a clinical consultant for 180 Life Sciences.

The trial potentially fills an important unmet need which affects a significant number of patients worldwide and will be increasingly important preventative treatment as the population ages. The study is designed as a multi-center, randomized placebo-controlled trial to evaluate the feasibility of a subsequent phase 3 trial in patients with hip fractures aged 60 years and above.

### **About 180 Life Sciences Corp.**

180 Life Sciences Corp. is a clinical-stage biotechnology company. The Company is driving groundbreaking studies into clinical programs, which are seeking to develop treatments for major unmet clinical needs. The Company's primary platform is a novel program to treat inflammatory disorders using anti-TNF (tumor necrosis factor).

### **About Celltrion Healthcare**

Celltrion Healthcare is committed to delivering innovative and affordable medications to promote patients' access to advanced therapies. Its products are manufactured at state-of-

the-art mammalian cell culture facilities, designed and built to comply with the US FDA cGMP and the EU GMP guidelines. Celltrion Healthcare endeavors to offer high-quality cost-effective solutions through an extensive global network that spans more than 110 different countries.

**About the National Institute for Health and Care Research (NIHR), the research partner of the NHS, public health and social care**

The mission of the National Institute for Health and Care Research (NIHR) is to improve the health and wealth of the nation through research through:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK Aid from the UK government.

**Forward-Looking Statements**

This press release includes "forward-looking statements", including information about management's view of the Company's future expectations, plans and prospects, within the safe harbor provisions provided under federal securities laws, including under The Private Securities Litigation Reform Act of 1995 (the "Act"). Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue" and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results and, consequently, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements and factors that may cause such differences include, without limitation, statements about the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results; the uncertainties associated with the clinical development and regulatory approval of 180 Life Science's drug candidates, including potential delays in the enrollment and completion of clinical trials; issues raised by the FDA and MHRA, timing to complete required studies and trials, and timing to obtain governmental approvals; the potential that earlier clinical trials and studies may not be predictive of future results; 180 Life Sciences' reliance on third parties to

conduct its clinical trials, enroll patients, and manufacture its preclinical and clinical drug supplies; the ability to come to mutually agreeable terms with such third parties and partners, and the terms of such agreements; estimates of patient populations for 180 Life Sciences planned products; unexpected adverse side effects or inadequate therapeutic efficacy of drug candidates that could limit approval and/or commercialization, or that could result in recalls or product liability claims; 180 Life Sciences' ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; the timing of filing, the timing of governmental review, and outcome of, planned Investigational New Drug (IND) applications for drug candidates; current negative operating cash flows and a need for additional funding to finance our operating plans; the terms of any further financing, which may be highly dilutive and may include onerous terms; statements relating to expectations regarding future agreements relating to the supply of materials and license and commercialization of products; the availability and cost of materials required for trials; the risk that initial drug results will not be able to be replicated in clinical trials or that such drugs selected for clinical development will not be successful; challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; the inherent risks in early stage drug development including demonstrating efficacy; development time/cost and the regulatory approval process; the progress of our clinical trials; our ability to find and enter into agreements with potential partners; our ability to attract and retain key personnel; changing market and economic conditions; our ability to produce acceptable batches of future products in sufficient quantities; unexpected manufacturing defects; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; expectations with respect to future performance, growth and anticipated acquisitions; the continued listing of the Company on The NASDAQ Stock Market; expectations regarding the capitalization, resources and ownership structure of the Company; expectations with respect to future performance, growth and anticipated acquisitions; the ability of the Company to execute its plans to develop and market new drug products and the timing and costs of these development programs; estimates of the size of the markets for its potential drug products; the outcome of current litigation involving the Company; potential future litigation involving the Company or the validity or enforceability of the intellectual property of the Company; global economic conditions; geopolitical events and regulatory changes; the expectations, development plans and anticipated timelines for the Company's drug candidates, pipeline and programs, including collaborations with third parties; access to additional financing, and the potential lack of such financing; and the Company's ability to raise funding in the future and the terms of such funding. These risk factors and others are included from time to time in documents the Company files with the Securities and Exchange Commission, including, but not limited to, its Form 10-Ks, Form 10-Qs and Form 8-Ks, and including the Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and future SEC filings. These reports and filings are available at [www.sec.gov](http://www.sec.gov) and are available for download, free of charge, soon after such reports are filed with or furnished to the SEC, on the "Investors"—"SEC Filings"—"All SEC Filings" page of our website at [www.180lifesciences.com](http://www.180lifesciences.com). All subsequent written and oral forward-looking statements concerning the Company, the results of the Company's clinical

trial results and studies or other matters and attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements above. Readers are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, including the forward-looking statements included in this press release, which are made only as of the date hereof. The Company cannot guarantee future results, levels of activity, performance or achievements. Accordingly, you should not place undue reliance on these forward-looking statements. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, except as otherwise provided by law.

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Source: 180 Life Sciences Corp.