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Adalimumab Found To Be A Likely Cost-Effective Treatment for Early-Stage Dupuytren's Disease

PALO ALTO, Calif., Nov. 15, 2022 (GLOBE NEWSWIRE) -- 180 Life Sciences Corp. (NASDAQ: ATNF) ("180 Life Sciences" or the "Company"), a clinical-stage biotechnology company today announced that researchers at Oxford Population Health's Health Economics Research Centre and the Kennedy Institute of Rheumatology have found that anti-TNF treatment (adalimumab), which is commonly used to treat conditions such as rheumatoid arthritis and psoriasis, is likely to be a cost-effective treatment for people affected by early-stage Dupuytren's disease.

Dupuytren's disease affects more than 5 million people in the UK. It causes the fingers to irreversibly curl into the palm due to nodules of tissue forming cords under the skin, impairing hand function and quality of life. There is currently no approved treatment for early-stage disease. All treatments available for late-stage disease have limitations, including the potential for recurrence.

A recent phase 2b trial (an early stage trial designed to test whether a treatment provides a beneficial effect) led by Professor Jagdeep Nanchahal of the Kennedy Institute of Rheumatology, University of Oxford, who is also a consultant to the Company, found that a course of four adalimumab injections significantly reduced hardness and size of early-stage Dupuytren's disease nodules.

Based on the results of the Repurposing Anti-TNF for Treating Dupuytren's Disease (RIDD) trial, the study's researchers analysed data on costs and quality of life. They extrapolated the trial results using a patient-level simulation model, which estimated the lifetime cost-effectiveness of adalimumab for treatment of Dupuytren's Disease. The simulated model also evaluated hypothetical repeated courses of adalimumab each time the nodule reactivated (every three years) in patients who initially responded to treatment.

The researchers' simulation found that repeated courses of intranodular injections of adalimumab are likely to be cost-effective for treating progressive early-stage Dupuytren's disease. The model-based extrapolation showed that, over a lifetime, repeated courses of adalimumab are likely to cost £14,593 per quality-adjusted life-year (QALY)* gained, compared with current UK National Health Service (NHS) practice. This would be considered highly cost-effective compared with the £20,000 per QALY* gained that the NHS is typically willing to pay.

Lead author, Dr Helen Dakin, University Research Lecturer at Oxford Population Health's Health Economics Research Centre, said: "Adalimumab is likely to be a cost-effective treatment for progressive early-stage Dupuytren's disease."

The study's authors estimated that around 2.6 million people in the UK may have

progressive early-stage Dupuytren's disease. "Our phase 2b data shows that Adalimumab has the potential to transform the management of progressive early-stage Dupuytren's disease. It is important that the treatment is cost-effective if it is to become available to patients," said Professor Nanchahal.

"Determining that Adalimumab is likely to be cost effective for early-stage Dupuytren's disease is an important step towards working to successfully bring the treatment to market and making it widely available to patients. This, combined with our extensive patent estate, has provided strong interest in ongoing preliminary partnership discussions for the commercialization of this novel therapeutic approach," said Dr. James Woody, CEO of 180 Life Sciences.

The research was funded by the Health Innovation Challenge Fund (Wellcome, Department of Health and Social Care) and 180 Life Sciences. Dr. Dakin is part-funded by the National Institute for Health and Care Research Oxford Biomedical Research Centre. The study is published in *Bone and Joint Open*.

* Quality Adjusted Life Years (QALYs) are a standard metric used to compare the cost-effectiveness of different healthcare interventions. One QALY is equivalent to an additional year gained at full health.

About 180 Life Sciences Corp.

180 Life Sciences Corp. is a clinical-stage biotechnology company driving ground-breaking studies into clinical programs which are seeking to address major unmet medical needs. The Company's focus is a novel program to treat several inflammatory disorders using anti-TNF (tumor necrosis factor).

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 U.S. Food and Drug Administration (FDA) and Medicines and Healthcare products Regulatory Agency (MHRA); the timing and outcome of the Company's planned meeting with MHRA, including the Company's ability to persuade MHRA that such chosen endpoints do not require further validation; timing to complete required studies and trials, and timing to obtain governmental approvals; the accuracy of simulations and the ability to reproduce the outcome of such simulations in real world trials; 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, increases in interest rates which may make borrowing more expensive and increased inflation which may negatively affect costs, expenses and returns; 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 are not predictive of future results or 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 behaviour 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's securities on The NASDAQ Stock Market, including the Company's current non-compliance with such continued listing requirements due to the trading price of the Company's securities; 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; and the effect of rising interest rates and inflation, and economic downturns and recessions. 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 September 30, 2022, and future SEC filings. These reports and filings are available at 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. 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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