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180 Life Sciences Provides Update Regarding Anti-TNF Frozen Shoulder Trial

PALO ALTO, Calif., Feb. 22, 2023 (GLOBE NEWSWIRE) -- 180 Life Sciences Corp. (NASDAQ: ATNF) ("180 Life Sciences" or the "Company"), today announced closure to recruitment of men and women across England with early stage Frozen shoulder for a trial to determine the feasibility of conducting a large randomized controlled trial to assess whether an intra-articular injection of anti-TNF (Adalimumab) can reduce pain and improve function in people with pain predominant early-stage frozen shoulder, which was called the Anti-Freaze-F trial. The Anti-Freaze-F trial is being run by the University of Oxford and originally sought to recruit 84 participants.

Frozen shoulder is an extremely painful and debilitating condition, affecting about 9% of adults in the UK. It is characterised by an initial pain predominant inflammatory phase that lasts around 3-9 months. This progresses to a stiffness predominant phase with restriction of shoulder movement, followed by slow improvement in motion and stiffness. Administration of steroids generally leads to improvement in pain and motion, but the effects do not typically extend beyond 6 weeks.

The Anti-Freaze-F trial opened to recruitment at the end of May 2022 following delays in gaining approvals due to backlogs in the National Institute of Health Research (NIHR) system due to COVID-19 and consequential staff vacancies. Nine participants were recruited for participation in the trial through mid-February 2023.

The UK research system has faced unprecedented challenges following the COVID-19 pandemic both in terms of support services and at the point of delivery of clinical care. This has resulted in the NIHR instituting their Recovery and Reset programme to identify and close trials that are facing challenges. Unfortunately, we recently learned that our Anti-Freaze-F trial was considered to be one of the very numerous trials deemed one of such trials, due to the considerable challenges we faced to open recruitment sites and enroll sufficient participants. Therefore, the NIHR has asked the chief investigators to close the trial for further recruitment. The participants enrolled to date will receive their injections and follow up according to the established protocol. The Company had previously requested a no-cost extension, which was denied. The result of the closure of the trial means that another trial will likely need to be undertaken at a future time to recruit additional participants.

"We are obviously disappointed that the trial was unable to recruit sufficient patients despite the best efforts of the team led by Professors Nanchahal and Hopewell at the University of Oxford", said Professor Sir Marc Feldmann, co-chairman of 180 Life Sciences.

Dr. James Woody, CEO of 180 Life Sciences, stated, "the challenges faced by the United Kingdom National Health Service and the systems associated with delivery of clinical research have made it extremely difficult to conduct some clinical trials, especially those

initiated soon after the COVID-19 pandemic. We will assess the data from Anti-Freaze-F when available to refine the strategy for any subsequent trials for this unmet need. We are confident in the scientific rational for the study, and in the future we may determine that this trial may be best conducted in another country where the health and research systems are less constrained, and patients are readily available. This option is currently under consideration." The discontinuation of the Anti-Freaze-F trial will have no impact on the Post Operative Cognitive Delirium trial, which is currently in the process of obtaining final approvals to proceed.

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 regarding the timing of, outcome of, and results of, clinical trials, including those discussed above; timing of our planned marketing authorization application (MAA) submission to the UK Medicines and Healthcare products Regulatory Agency (MHRA), our ability to obtain approval and acceptance thereof, the willingness of MHRA to review such MAA, and our ability to address outstanding comments and questions from the MHRA; 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 Sciences' drug candidates, including potential delays in the enrollment and completion of clinical trials, closures of such trials prior to enrolling sufficient participants in connection therewith; issues raised by the U.S. Food and Drug Administration (FDA) and MHRA; the ability of the Company to persuade MHRA that 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 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's securities 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; 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.

Investors:

Jason Assad
Director of IR
180 Life Sciences Corp
Jassad@180lifesciences.com

Source: 180 Life Sciences Corp.