August 3, 2023

180 Life Sciences Provides Update on Regulatory Approval Process in the UK and US for Dupuytren's Disease Treatment; Continues Consultations with the UK MHRA and Initiates a Type C Meeting Request With the US FDA

PALO ALTO, Calif., Aug. 03, 2023 (GLOBE NEWSWIRE) -- 180 Life Sciences Corp. (NASDAQ: ATNF) ("180 Life Sciences" or the "Company"), a clinical-stage biotechnology company focused on the development of novel drugs that fulfill unmet needs in inflammatory diseases, fibrosis and pain announces that it has submitted a request to the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) for a follow up scientific advice meeting where the Company will seek guidance on a plan to obtain Conditional Marketing Authorization (CMA) for the use of adalimumab in the treatment of early stage Dupuytren's disease.

A meeting with the MHRA is anticipated to take place in late Q3 of 2023 with the written responses anticipated to be received prior to year end. The Company's regulatory consultants have indicated that initiation of an additional clinical trial (Phase 3) may be required to obtain CMA approval, and such a trial has been designed. The regulatory consultants of the Company believe that it may be possible to obtain a CMA due to the long safety history of anti-tumor necrosis factor (TNF) therapies, conditional on a successful Phase 3 trial, which CMA may be granted prior to the completion of the Phase 3 trial, once patients have been enrolled, verifying the commitment of the Company to complete the trial. A CMA would allow the Company to market its therapy for Dupuytren's disease in the UK, between the granting of the CMA and completion of a successful Phase 3 trial. The Phase 3 trial might utilize sites from various countries, including the United States (US). Therefore, the Company has submitted a request to the US Food and Drug Administration (FDA) for a Type C meeting to seek advice as to requirements for obtaining US marketing approval including the potential design requirements of the planned Phase 3 clinical trial. Guidance from the FDA is expected to shape the Company's clinical development strategy in the US and possibly in other countries. In support of our FDA Type C meeting request, a leading pharmaceutical biosimilar manufacturer will be participating with 180 Life Sciences in the FDA advice discussion. It is anticipated that the advice discussion will take place in late Q3 or early Q4 of 2023.

Promising data from a Phase 2b Dupuytren's treatment trial was published in the June 2022 issue of *The Lancet Rheumatology*[(1)]. A follow up publication showed that the therapy likely would be cost effective, and was economically beneficial[(2)]. "We believe our results present the potential for an earlier treatment for patients with Dupuytren's disease," said James

Woody, M.D., Chief Executive Officer of 180 Life Sciences, who continued, “We look forward to feedback from the regulatory agencies which we believe may help us bring this potential treatment to patients to prevent the disease from advancing to the stage that surgery, which is not always effective and pain-free, is needed to maintain hand function.”

About 180 Life Sciences Corp.

180 Life Sciences Corp. is a clinical stage biotechnology company focused on the development of therapeutics for unmet medical needs in chronic pain, inflammation and fibrosis by employing innovative research, and, where appropriate, combination therapy. The Company’s current primary focus is a novel program to treat several inflammatory disorders using anti-TNF (tumor necrosis factor).

1. J. Nanchahal *et al.*, Anti-tumour necrosis factor therapy for early-stage Dupuytren's disease (RIDD): a phase 2b, randomised, double-blind, placebo-controlled trial. *Lancet Rheumatol* **4**, E407-E416 (2022)
2. H. Dakin *et al.*, Cost-effectiveness of adalimumab for early-stage Dupuytren's disease : an economic evaluation based on a randomized controlled trial and individual-patient simulation model. *Bone Jt Open* **3**, 898-906 (2022).

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, risks regarding the outcome of a planned pharmacokinetics (PK) study, the timing and costs thereof, and the ability to obtain sufficient participants; our ability to commercialize our drugs, if proven successful for treatment in trials; risks regarding whether the administrative processes required for the issuance of patents will be completed in a timely manner or at all, whether patents, if issued, will provide sufficient protection and market exclusivity for the Company, whether any patents held by the Company may be challenged, invalidated, infringed or circumvented by third parties; events that could interfere with the continued validity or enforceability of a patent; the Company’s ability generally to maintain adequate patent protection and successfully enforce patent claims against third parties; the timing of, outcome of, and results of, clinical trials statements regarding the 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 and FDA; 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, the costs thereof,

closures of such trials prior to enrolling sufficient participants in connection therewith, issues raised by the U.S. Food and Drug Administration (FDA), the MHRA and the European Medicines Agency (EMA); the ability of the Company to persuade regulators that chosen endpoints do not require further validation; timing and costs 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 the Company's 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, economic downturns and recessions, declines in economic activity or global conflicts. 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, 2022, and Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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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Source: 180 Life Sciences Corp.