June 14, 2022

180 Life Sciences Provides Update on Correspondence Received from U.K. and U.S. Regulatory Authorities on Pathway for a Therapy That Could Prevent Progression of Early-Stage Dupuytren's Disease

PALO ALTO, Calif., June 14, 2022 (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, today announced receipt of a written response from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and from the U.S. Food and Drug Administration (FDA) related to questions submitted in a Type C meeting request on the Company's planned use of anti-TNF treatment, adalimumab, to treat early-stage Dupuytren's disease

Dupuytren's disease is a common chronic, progressive fibrotic condition of the hand that causes the fingers to curl irreversibly into the palm and can be very disabling. Approximately 20-35% of patients with a palmar nodule of early-stage Dupuytren's disease progress to finger contractures. Roughly 12 million people in the U.S., 2.5 million in the U.K. and 18 million in the EU have early-stage progressive Dupuytren's disease. Currently, there is no approved treatment for these patients, who must wait until the disease progresses with loss of hand function before undergoing surgery or treatment with collagenase. Unfortunately, the disease tends to recur after these treatments.

The MHRA provided initial feedback following a scientific advice meeting. The agency agreed that there is no need for further non-clinical studies for the planned use of anti-TNF treatment, adalimumab, to treat early-stage Dupuytren's disease and the absence of non-clinical studies can be supported by review of the literature. The MHRA indicated that while it is biologically plausible that the primary endpoint of nodule hardness and secondary endpoint of nodule size could correlate with disease progression, they would require evidence to validate them as clinically meaningful surrogate endpoints. Without evidence that the endpoints used in the Phase 2b trial are predictive of clinical endpoints and addressing other identified study issues, it is unlikely Phase 2b study would be considered acceptable as a single pivotal study to support a Marketing Authorization Application. The Company is in the process of preparing the evidence to support the Phase 2b endpoints and to address other MHRA concerns.

The FDA provided written responses to the Company's questions on clinical trial endpoints posed in a request for a Type C meeting. The FDA indicated that the proposed outcome measures of nodule hardness and nodule size are not clinical outcome measures that measure how a patient feels, functions, or survives, which would be needed to support a

demonstration of efficacy in registrational studies. The FDA recommended considering a pre-investigational new drug (PIND) meeting request to receive further regulatory guidance. The Company plans to request a PIND meeting.

About 180 Life Sciences Corp.

180 Life Sciences Corp. is a clinical-stage biotechnology company focused on the development of novel drugs that fulfill unmet needs in inflammatory diseases, fibrosis and pain by leveraging the combined expertise of luminaries in therapeutics from Oxford University, the Hebrew University and Stanford University. 180 Life Sciences is one of the leaders into solving one of the world's biggest drivers of disease – inflammation. The Company is driving groundbreaking studies into clinical programs, which are seeking to develop novel drugs addressing separate areas of inflammation for which there are no effective therapies. The Company's primary platform is a novel program to treat fibrosis 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 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 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.