

# **180 Life Sciences Provides Follow-Up Information on Oxford University and the Company's Successful Dupuytren's Phase 2b Clinical Trial Results**

PALO ALTO, Calif., Dec. 06, 2021 (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 provided follow-up information on the top line results of Oxford University and the Company's Phase 2b clinical trial for Dupuytren's disease announced on December 1, 2021.

Dr. James Woody, 180 Life Sciences Chief Executive Officer, stated, "We believe the Phase 2b clinical trial for Dupuytren's disease using adalimumab was a phenomenal achievement, having met both primary and secondary endpoints by significantly diminishing the hardness and size of the Dupuytren's nodules, respectively. We believe these results affirm our team's scientific and clinical expertise and fundamentally position us to be a major leader in fibrosis therapies."

Both the primary and secondary clinical trial endpoints from the Phase 2b clinical trial for patients with early-stage Dupuytren's were statistically significant. Further, patients enrolled in the clinical trial exhibited a high compliance rate; almost all of them returned for all injections, and experienced no related serious adverse events. With approximately 1 in 10 Phase 2b clinical trials for new indications typically succeeding, this positive outcome allows the Company to move closer towards potential commercialization of a much-needed therapy with no currently approved treatment.

However, due to the strict disclosure policies of the prestigious clinical journals, which only permit limited data to be released at closed scientific meetings, the Company is unable at this time to release the entire data set with information that it believes would provide greater clarity around the results. Any further disclosures of the clinical data may disqualify the trial from publication, a situation the Company wishes to avoid. Although publication may be several months away as the peer review process typically involves several iterations of questions and clarifications, publication in a peer-reviewed journal will lend significant credence to the work and represent significant progress in the field of Dupuytren's disease. Professor Nanchahal has already submitted the manuscript to a preeminent clinical journal.

The Company believes it is in an enviable position, with the opportunity to capitalize on the clinical trial results and continue to work towards bringing what it hopes will be a highly efficacious and safe product to market for an unmet need. To its knowledge this is the first rigorous randomized, placebo-controlled, double-blinded trial for preventing the progression of Dupuytren's disease. The Company is not aware of any competitors for targeted therapies

for early-stage Dupuytren's disease, and currently possesses rights in connection with a robust, worldwide intellectual property portfolio.

The Company has engaged Kinexum as regulatory consultants to assist in discussions with the U.S. Food and Drug Administration (FDA) and the UK equivalent, the Medicines and Healthcare products Agency (MHRA), to help determine the optimal path forward to commercialization, with initial meetings currently planned for 1H, 2022. Since 2003, Kinexum has been helping clients through the pre-clinical, clinical, CMC development and regulatory process for product candidates targeting a broad range of therapeutic areas through a broad set of modalities.

## **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 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 adalimumab's potential as a treatment for Dupuytren's disease; the top-line data 180 Life Sciences has reported is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such top-line data may not accurately reflect the complete results of the trial, and that regulators, including the FDA, may not agree with 180 Life Sciences' interpretation of such 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 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; 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; 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; potential 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. These reports and filings are available at [www.sec.gov](http://www.sec.gov). All subsequent written and oral forward-looking statements concerning the Company, the studies described herein 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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