

180 Life Sciences Announces Allowance of Claims for a US Patent for Dupuytren's Disease Treatment and Application

PALO ALTO, Calif., Feb. 23, 2023 (GLOBE NEWSWIRE) -- 180 Life Sciences Corp. (NASDAQ: ATNF) ("180 Life Sciences" or the "Company"), today announced that the United States Patent and Trademark Office (USPTO) has issued the Company a Notice of Allowance for United States (US) patent application number 17/721,106 entitled "Method of Treating Dupuytren's disease Using a Pre-filled Syringe", which includes claims relating to the use of a citrate-free formulation of 40mg in 0.4mL of adalimumab to be injected into nodules of early-stage Dupuytren's disease every 3 months over a period of 12 months using a syringe with a 25 gauge needle. This reflects the dosage and method used in the RIDD trial led by Professor Nanchahal and his colleagues at the University of Oxford, the results of which were published in *The Lancet Rheumatology*.

A Notice of Allowance is issued after the USPTO makes the determination that a patent should be granted from an application. A patent from the recently allowed application is expected to be issued in the coming months. The issued patent would have a term that expires no earlier than in 2037.

"Current treatments for Dupuytren's disease are largely limited to patients with finger contractures of late-stage disease. There is a pressing need for an effective therapy for patients with early-stage disease to prevent or delay disease progression. We believe that treatment with intranodular injections of adalimumab has the potential to achieve this," said Professor Sir Marc Feldmann, co-chairman of 180 Life Sciences.

Dr. James Woody, CEO of 180 Life Sciences, stated, "This allowance by the US Patent Office, and the expected formal patent, represent an important addition to our extensive patent estate on the use of anti-tumor necrosis factor (TNF) for the treatment of Dupuytren's disease, which we hope in the future may be able to apply to a range of fibrotic disorders and postoperative cognitive decline. The patent relating to the allowance will represent another important step towards our overall strategy for advancing the use of adalimumab for early-stage Dupuytren's disease".

With the addition of this potential patent, the patent portfolio of 180 Life Sciences will have twelve issued patents and twelve pending patent applications within the US. Outside of the US, assuming the EU as a single jurisdiction and including the UK, there are an additional twelve issued patents and 21 pending patent applications.

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, risks regarding whether the administrative processes required for the issuance of a patent as indicated in the Notice of Allowance will be completed in a timely manner or at all, whether the patent, if issued as indicated in the notice of allowance, 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; 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.

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Source: 180 Life Sciences Corp.