Pre-IND Discussion with U.S. FDA Helps BetterLife Set Up AP-003 Clinical Trials in Australia

VANCOUVER, Nov. 10, 2020 -- BetterLife Pharma Inc. (“BetterLife” or the “Company”) (CSE: BETR / OTCQB: BETRF / FRA: NPAT) an emerging biotech company focused on development and commercialization of interferon based treatments, today announced a clinical and regulatory update for its AP-003 COVID-19 clinical trials following discussions with the U.S Food and Drug Administration (FDA).

"Due to the critical unmet medical need and rapid nature of COVID-19 development programs, we pursued an early partnering meeting with FDA to identify a mutually agreeable nonclinical and clinical path that could ultimately lead to a pivotal trial. We are pleased with the outcome of our recent interaction with the FDA, as they provided clear guidance that would result in a successful IND filing and subsequent initiation of clinical trials in the United States following our Australia trials,” said Ahmad Doroudian, CEO of BetterLife Pharma.

"The FDA also provided some inputs on the proposed Australia trial which we have implemented. Our aim as a company is FDA approval with or without Emergency Use authorization for our treatment as soon as possible following completion of the trials in Australia. The FDA identified and suggested one additional nonclinical study, which is scheduled to begin in the next months, to strengthen the available nonclinical information to highlight the unique pharmacology of AP-003, the formulation of which is exclusive to BetterLife and to which no other company in the world has access.

“BetterLife plans an additional pre-IND interaction with FDA prior to submitting the IND in the U.S. to discuss the data from the nonclinical study, clinical trial data from Australia, and to outline the remaining path to a timely application for marketing approval,” he concluded.

AP-003 is the Company’s proprietary and patented inhalation-based interferon alpha 2b formula. While AP-003 will be initially investigated for efficacy against COVID-19, the Company believes AP-003 has other potential clinical targets such as prevention and prophylaxis of other viral infections, such as Ebola and those caused by other coronaviruses, which BetterLife intends to consider as supplementary development programs.

Furthermore, since interferon treatment is hypothesized to work by ‘awakening’ the immune system and circumventing the interferon resistance of SARS-CoV-2 (the virus which

causes COVID-19) the Company also believes that its AP-003 treatment could be effective in potential SARS-CoV-2 mutations, such as mutations of the spike proteins.

Scientific Rationale for AP-003

"The early stage of COVID-19, distinct from other viral lung infections, is characterized by hypoxia (low blood oxygen) in advance of the devastating pulmonary damage that, too frequently, leads to death," said Dr. Angela Ogden, Chief Medical Officer at Altum. "Our clinical program is focused on developing a treatment approach for patients presenting early in the disease course in an effort to prevent progression to ICU care and mechanical ventilation. AP-003 will be administered by inhalation, delivering Interferon to the primary entry site of infection. We will take advantage of the inherent susceptibility of SAR-CoV-2 to interferon thereby bolstering the body's natural immune defence against the infection."

There have been other Interferon based treatment trials: In May of this year, Frontiers of Immunology quoted a study from Wuhan which concluded that the use of interferon alpha-2b on 77 patients with moderate cases of COVID-19 significantly accelerated clearance of the virus from the airways of patients. Moreover, not only did IFN a2b help patients' immune systems clear the coronavirus faster, it also seemed to reduce certain inflammatory proteins linked to severe COVID-19 complications.

More recently, a UK trial by Synairgen PLC also caused much excitement, strongly demonstrating that treatments using an interferon beta inhalation in COVID-19 patients significantly improved their condition and sped up recovery by 79%.

While both AP-003 and interferon beta are hypothesized to bypass the COVID-19 induced interferon production blockade, BetterLife believe that their proprietary inhaled alpha 2b (exclusively owned and developed by the Company) could be much more effective against the severity and duration of COVID-19 than interferon beta.

Planned Clinical Study Design

The AP-003 trials is a multicenter randomized placebo-controlled trial that will enroll 150 patients with COVID-19 with mild to moderate symptoms to hasten recovery and thus prevent disease progression. Inhaled dosing allows delivery of AP-003 directly to the lung tissue most at risk from the coronavirus.

The trial will be conducted in 10 sites in Australia. Patients will be randomized to receive inhaled AP-003 plus standard of care or placebo plus standard of care. The primary endpoints will be improvement in patient function over 14 days and improvement in blood oxygenation. Secondary endpoints will include clinical deterioration and hospitlaizations, changes in vital signs including blood oxygenation as measured by pulse oximetry, changes in COVID symptoms such as dyspnea, and changes in levels of cytokines.

About BetterLife Pharma Inc.:

BetterLife Pharma Inc. is an emerging biotechnology company engaged in the development and commercialization of therapeutic pharmaceuticals as well as drug delivery platform technologies. BetterLife is refining drug candidates, developed by Altum Pharmaceuticals Inc. ('Altum') based on a set of complementary interferon-based technologies which have the potential to engage the immune system to fight virus infections, such as the coronavirus disease (COVID-19) and human papillomavirus (HPV), and/or to directly inhibit tumours to treat specific types of cancer. Altum is a wholly owned brand and subsidiary of BetterLife and the official sponsor of the AP-003 COVID-19 clinical trials.

For further information please visit www.blifetherapeutics.com.

Cautionary Note

The Company is not making any express or implied claims that AP-003 or any other product has the ability to eliminate, cure or contain the COVID-19 (or SARS-2 Coronavirus) or any other viral infections at this time.

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Except for historical information, the matters set forth above may be forward-looking statements that involve risks and uncertainties that could cause actual results to differ from those in the forward-looking statements. Such forward-looking statements are based on the current beliefs of management, as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors. Reliance should not be placed on forward-looking statements, as they involve known and unknown risks, uncertainties and other factors that may cause the actual results to differ materially from the anticipated future results expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially from those set forward in the forward-looking statements include, but are not limited to: our ability to obtain, on satisfactory terms or at all, the capital required for research, product development, operations and marketing; general economic, business and market conditions; our ability to successfully and timely complete clinical studies; product development delays and other uncertainties related to

new product development; our ability to attract and retain business partners and key personnel; the risk of our inability to profitably commercialize our proposed products; the risk that our proposed clinical trials will not be launched in a timely manner (or at all) or if launched yield positive results or that we will not obtain regulatory market approvals for our products; the extent of any future losses; the risk of our inability to establish or manage manufacturing, development or marketing collaborations; the risk of delay of, or failure to obtain, necessary regulatory approvals and, ultimately, product launches; dependence on third parties for successful commercialization of our products; inability to obtain product and raw materials in sufficient quantity or at standards acceptable to health regulatory authorities to commence and complete clinical trials or to meet commercial demand; our ability to obtain patent protection and protect our intellectual property rights; commercialization limitations imposed by intellectual property rights owned or controlled by third parties; uncertainty related to intellectual property liability rights and liability claims asserted against us; the impact of competitive products and pricing; and future levels of government funding; additional risks and uncertainties, many of which are beyond our control.

Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.