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4D pharma announces clinical trial collaboration and supply agreement with Merck KGaA, Darmstadt, Germany and Pfizer to evaluate MRx0518 in combination with BAVENCIO® for the treatment of locally advanced or metastatic urothelial carcinoma

Leeds, UK, February 8, 2021 - 4D pharma plc (AIM: DDDD), a pharmaceutical company leading the development of Live Biotherapeutic products (LBPs), a novel class of drug derived from the microbiome, today announced a clinical trial collaboration and supply agreement with Merck KGaA, Darmstadt, Germany and Pfizer Inc. for BAVENCIO® (avelumab), the first and only immunotherapy approved as a first-line maintenance treatment for patients with locally advanced or metastatic urothelial carcinoma. BAVENCIO is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc.

Under the collaboration, 4D pharma intends to commence a clinical trial in 2021 to evaluate BAVENCIO in combination with MRx0518 as a first-line maintenance therapy for patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy.

"With this second clinical trial collaboration for MRx0518 with a leading immune checkpoint inhibitor, 4D is able to evaluate MRx0518 in a new combination and earlier treatment setting. Following the promising data already generated in combination with checkpoint inhibitor pembrolizumab in refractory patients, and MRx0518 monotherapy data demonstrating single agent immuno-modulation presented last year at SITC, this collaboration allows us to continue to build a broad understanding of the safety and efficacy of MRx0518 across a range of solid tumors and stages of disease," said Duncan Peyton, Chief Executive Officer, 4D pharma. "The combination of MRx0518 with BAVENCIO has the potential to further enhance the positive clinical outcomes achieved by BAVENCIO for the significant number of patients in this treatment setting."

About MRx0518

MRx0518 is single strain Live Biotherapeutic product in development for the treatment of cancer. It is delivered as an oral capsule and stimulates the body's immune system, directing it to produce cytokines and immune cells that are known to attack tumours. It is currently being evaluated in three clinical trials in patients with cancer. MRx0518-I-001 is a neoadjuvant monotherapy study in a variety of solid tumours and is being conducted at Imperial College (London, UK). MRx0518-I-002 is in combination with KEYTRUDA® (pembrolizumab) in patients whose disease has previously progressed on anti-PD-1 therapies. The Coordinating Investigator of the study is at The University of Texas MD Anderson Cancer Center, Houston, USA, with multiple additional sites in the US. The study is being conducted in collaboration with MSD, the tradename of Merck & Co., Inc., Kenilworth, NJ, USA. MRx0518-I-003 is in combination with preoperative radiotherapy in resectable pancreatic cancer. A fourth clinical trial of MRx0518 in combination with BAVENCIO® (avelumab) in the first-line maintenance setting for urothelial carcinoma, conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc., is expected to initiate in 2021.

Avelumab Approved Indications

Avelumab (BAVENCIO®) is indicated in the US for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. BAVENCIO is also indicated for the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Avelumab in combination with axitinib is approved in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

In the US, the FDA granted accelerated approval for BAVENCIO for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab Important Safety Information from the US FDA-Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis and hepatitis including fatal cases, colitis, endocrinopathies, nephritis, and other immune-mediated adverse reactions as a single agent or in combination with axitinib which can be severe and have included fatal cases), infusion-related reactions, hepatotoxicity in combination with axitinib, major adverse cardiovascular events (MACE) in combination with axitinib which can be severe and have included fatal cases, and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® monotherapy include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite, urinary tract infection and rash. Common adverse reactions (reported in at least 20% of patients) in patients receiving BAVENCIO® in combination with axitinib include diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain and headache. Grade 3-4 hematology laboratory value abnormalities reported in at least 10% of patients with Merkel cell carcinoma treated with BAVENCIO® monotherapy include lymphopenia; in patients receiving BAVENCIO® in combination with axitinib, grade 3-4 clinical chemistry abnormalities include blood triglyceride increased and lipase increased.

For full US Prescribing Information and Medication Guide for BAVENCIO®, please see http://www.BAVENCIO.com.

About 4D pharma

Founded in February 2014, 4D pharma is a world leader in the development of Live Biotherapeutics, a novel and emerging class of drugs, defined by the FDA as biological products that contain a live organism, such as a bacterium, that is applicable to the prevention, treatment or cure of a disease. 4D has developed a proprietary platform, MicroRx®, that rationally identifies Live Biotherapeutics based on a deep understanding of function and mechanism.

4D pharma's Live Biotherapeutic products (LBPs) are orally delivered single strains of bacteria that are naturally found in the healthy human gut. The Company has six clinical programmes, namely a Phase I/II study of MRx0518 in combination with KEYTRUDA® (pembrolizumab) in solid tumours, a Phase I study of MRx0518 in a neoadjuvant setting for patients with solid tumours, a Phase I study of MRx0518 in patients with pancreatic cancer, a Phase I/II study of MRx-4DP0004 in asthma, a Phase II study of MRx-4DP0004 in patients hospitalised with COVID-19, and Blautix® in Irritable Bowel Syndrome (IBS) which has completed a successful Phase II trial. Preclinical-stage programmes include candidates for CNS disease such as Parkinson's disease and other neurodegenerative conditions. The Company has a research collaboration with MSD, a tradename of Merck & Co., Inc., Kenilworth, NJ, USA, to discover and develop Live Biotherapeutics for vaccines.

In October 2020 4D pharma announced its intention to merge with Longevity Acquisition Corporation (NASDAQ: LOAC), a special purpose acquisition company (SPAC), and seek a NASDAQ listing. The merger is expected to be completed and the NASDAQ listing of 4D pharma American Depositary Shares (ADSs) under the ticker symbol ‘LBPS’ is currently expected to become effective in early 2021, subject to approval of 4D Shareholders and Longevity Shareholders, and the SEC review process.

For more information, refer to https://www.4dpharmaplc.com

Forward-Looking Statements

This press release contains "forward-looking statements." All statements other than statements of historical fact contained in this announcement, including without limitation statements regarding timing of the clinical trial are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the words "believe," "expect," "anticipate," "plan," "intend," "foresee," "should," "would," "could," "may," "estimate," "outlook" and similar expressions, including the negative thereof. The absence of these words, however, does not mean that the statements are not forward-looking. These forward-looking statements are based on the Company's current expectations, beliefs and assumptions concerning future developments and business conditions and their potential effect on the Company. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

All of the Company's forward-looking statements involve known and unknown risks and uncertainties, some of which are significant or beyond its control, and assumptions that could cause actual results to differ materially from the Company's historical experience and its present expectations or projections. The foregoing factors and the other risks and uncertainties that affect the Company's business, including the risks of delays in the commencement of the clinical trial and those additional risks and uncertainties described the documents filed by the Company with the US Securities and Exchange Commission (“SEC”), should be carefully considered. The Company wishes to caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update or revise any of its forward-looking statements after the date they are made, whether as a result of new information, future events or otherwise, except to the extent required by law.

Additional Information about the Transaction and Where to Find it

This press release is being made in respect of a proposed business combination involving 4D and Longevity. Following the announcement of the proposed business combination, 4D filed a registration statement on Form F-4 (the “Registration Statement”) with the SEC. This press release does not constitute an offer to sell or the solicitation of an offer to buy or subscribe for any securities or a solicitation of any vote or approval nor shall there be any sale, issuance or transfer of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. The Registration Statement includes a preliminary prospectus with respect to 4D’s ordinary shares and ADSs to be issued in the proposed transaction and a proxy statement of Longevity in connection with the merger. The information in the Registration Statement is not complete and may be changed. 4D may not sell the ordinary shares referenced in the Registration Statement until the Registration Statement becomes effective. The proxy statement/prospectus will be provided to the Longevity shareholders. 4D and Longevity also plan to file other documents with the SEC regarding the proposed transaction.

This press release is not a substitute for any prospectus, proxy statement or any other document that 4D or Longevity may file with the SEC in connection with the proposed transaction. Investors and security holders are urged to read the Registration Statement and, when they become available, any other relevant documents that will be filed with the SEC carefully and in their entirety because they will contain important information about the proposed transaction.

You may obtain copies of all documents filed with the SEC regarding this transaction, free of charge, at the SEC's website (www.sec.gov). In addition, investors and security holders will be able to obtain free copies of the Registration Statement and other documents filed with the SEC without charge, at the SEC's website (www.sec.gov) or by calling +1-800-SEC-0330.

Participants in the Solicitation

Longevity and its directors and executive officers and other persons may be deemed to be participants in the solicitation of proxies from Longevity's shareholders with respect to the proposed transaction. Information regarding Longevity's directors and executive officers is available in its annual report on Form 10-K for the fiscal year ended February 29, 2020, filed with the SEC on April 30, 2020. Additional information regarding the participants in the proxy solicitation relating to the proposed transaction and a description of their direct and indirect interests is contained in the Registration Statement.

4D and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of Longevity in connection with the proposed transaction. A list of the names of such directors and executive officers and information regarding their interests in the proposed transaction is included in the Registration Statement.

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