## **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

### FORM 6-K

**Report of Foreign Private Issuer** Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of March 2022

Commission File Number: 001-40106

# **4D pharma plc** (Translation of Registrant's name into English)

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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F ⊠ Form 40-F □		
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):		
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):		

On March 23, 2022, 4D pharma plc (the "Company," "4D," "4D pharma," "we," "us" or "our") issued a press release entitled "4D pharma Announces Positive Interim Results from the Phase I/II Study of the Combination of MRx0518 and KEYTRUDA® (pembrolizumab) for the Treatment of Renal Cell Carcinoma."

A copy of the press release is attached as Exhibit 99.1 to this current report on Form 6-K and is incorporated by reference herein.

#### INDEX TO EXHIBITS

Exhibit Number	Exhibit Title
99.1	Press Release, dated March 23, 2022.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

4D pharma plc

Date: March 23, 2022

/s/ Duncan Peyton

Duncan Peyton Chief Executive Officer



# 4D pharma Announces Positive Interim Results from the Phase I/II Study of the Combination of MRx0518 and KEYTRUDA<sup>®</sup> (pembrolizumab) for the Treatment of Renal Cell Carcinoma

- Primary Efficacy Endpoint Met Early in Renal Cell Carcinoma Group in Part B of Study - Company to Host Conference Call and Webcast Today March 23, 10:00 am EST (2:00 pm GMT)

**Leeds, UK, March 23, 2022 – 4D pharma plc (AIM: DDDD, NASDAQ: LBPS),** a pharmaceutical company leading the development of Live Biotherapeutic products (LBPs), a novel class of drug derived from the microbiome, today announces that in Part B of its signal finding study of MRx0518 in combination with MSD's anti-PD-1 therapy, KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with solid tumors that have progressed on a prior immune checkpoint inhibitor (ICI), the renal cell carcinoma (RCC) group has met its primary efficacy endpoint ahead of enrollment completion.

The ongoing study is being conducted in heavily pre-treated metastatic patients with solid tumors who have previously experienced clinical benefit on prior ICI therapy and subsequently developed progressive disease. The study is being conducted in collaboration with MSD (Merck & Co., Inc., Kenilworth, NJ, USA). The primary efficacy endpoint for Part B of the study is more than three out of 30 patients per tumor group achieving clinical benefit, defined as complete response, partial response, or stable disease for at least six months.

Part B of the study has to date enrolled 20 patients with RCC, of which four out of the first 16 evaluable patients have achieved clinical benefit, each having achieved at least 6 months of stable disease. To date, Part B of the study has enrolled 47 patients of up to a total of 120 patients with RCC, non-small cell lung cancer, bladder cancer, and head and neck squamous cell carcinoma. MRx0518 continues to be safe and well tolerated.

"Today's results in renal cell carcinoma, meeting the predefined primary efficacy endpoint early in this difficult to treat population, marks another important step forward for MRx0518 and the increasing importance of the microbiome in cancer treatment," commented Dr. Alex Stevenson, Chief Scientific Officer, 4D pharma. "Meeting the primary efficacy endpoint for this group is crucial for the future development of MRx0518, and these data are highly informative for our strategy going forward as we determine next steps in RCC."

4D pharma intends to discuss next steps with partners and its Genitourinary Cancers Advisory Board regarding the development path of MRx0518 and a potentially pivotal study in patients with ICI-refractory RCC. 4D pharma will continue to recruit patients into the ongoing study of MRx0518 and Keytruda in RCC and the three tumor groups, with potential expansion into other types of ICI resistance.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.



#### **Conference Call & Webcast Information**

4D pharma will host a conference call and live webcast on Wednesday, March 23, 2022, at 10:00 am ET (2:00 pm GMT) to discuss the interim results of the Phase I/II study of the combination of MRx0518 and Keytruda for the treatment of renal cell carcinoma.

4D pharma management will be joined by key opinion leaders (KOLs) Dr. Petros Grivas, Associate Professor Clinical Research Division at the Fred Hutchinson Cancer Research Center, and Dr. Scott T. Tagawa, Professor of Medicine and Urology at Weill Cornell Medicine, both members of the 4D pharma's Genitourinary Cancers Advisory Board.

To access the live webcast, please visit the 'Events' section of the 4D pharma website. To access audio only, please dial (866) 939-3921 (United States) and (678) 302-3550 (International) and reference Confirmation Number 50287940. A replay of the webcast and accompanying slides will be available on the 4D pharma website following the event.

#### About 4D pharma

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 pharma 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 five clinical programs, namely a Phase I/II study of MRx0518 in combination with KEYTRUDA® (pembrolizumab) in solid tumors, a Phase I study of MRx0518 in patients with pancreatic cancer, a Phase I/II study of MRx-4DP0004 in asthma, and Blautix® in irritable bowel syndrome (IBS) which has completed a successful Phase II trial. A Phase I study of MRx0005 and MRx0029 in patients with Parkinson's disease is expected to commence in 2022. Additional preclinical-stage programs include candidates for CNS disease, immune-inflammatory conditions and cancer. The Company has a research collaboration with MSD (Merck & Co., Inc., Kenilworth, NJ, USA), to discover and develop Live Biotherapeutics for vaccines.

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

#### **Contact Information:**

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#### **Forward-Looking Statements**

This announcement contains "forward-looking statements." All statements other than statements of historical fact contained in this announcement, including without limitation statements regarding the efficacy of Live Biotherapeutics including MRx0518, the informative nature of the data for the Company's strategy, the Company's next steps with its partners and the potential expansion of the study into other types of ICI resistance, 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 present expectations or projections. The foregoing factors and the other risks that could cause actual results to differ materially include risks relating to the efficacy of its Live Biotherapeutic drug candidates including MRx0518, the risk that the Company changes its expected strategy and plans, risk related to safety of investigational therapeutics, clinical development risk, and those additional risks and uncertainties described in the documents filed by the Company with the US Securities and Exchange Commission ("SEC"). 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.