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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**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 **September 2021**

**Commission File Number: 001-40106**

**4D pharma plc**

*(Translation of Registrant's name into English)*

**5th Floor, 9 Bond Court  
Leeds  
LS1 2JZ  
United Kingdom  
Tel: +44 (0) 113 895 013**

*(Address of principal executive offices)*

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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): \_\_\_\_\_

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## **Announcement of European Medical Oncology Poster Presentation**

On September 15, 2021, 4D pharma plc (the “Company”) issued a press release to announce new biomarker analyses from two ongoing clinical trials of their lead immune-oncology single strain Live Biotherapeutic, MRx0518, in both neoadjuvant and refractory solid tumor settings, at the European Society for Medical Oncology (ESMO) Congress, September 16-21, 2021.

Highlights of the two ESMO 2021 poster presentations:

Baseline biomarkers associated with clinical benefit in patients with solid tumors refractory to immune checkpoint inhibitors (ICIs) treated with live biotherapeutic MRx0518 in combination with pembrolizumab.

Presentation Number: 1024P

- Tumor biomarkers were assessed in patients with evaluable baseline samples (N = 12) in the ongoing Phase I/II study of MRx0518 in combination with anti-PD-1 immune checkpoint inhibitor (ICI) Keytruda® (pembrolizumab).
- At baseline, patients who achieved complete response, partial response or stable disease for at least six months (collectively ‘responders’, N=4) from the combination of MRx0518 with Keytruda® (pembrolizumab) had significantly greater densities of CD3+FOXP3+CD8-regulatory T cells (Tregs) and CD3+KI67+ proliferating T cells in tumors at baseline, compared to patients with progressive disease (PD, N=8), p=0.0381 and p=0.0048, respectively.
- In addition, significantly lower densities of CD68+ macrophages at baseline were observed in the tumor microenvironment of responders compared to patients with progressive disease, p=0.0303.

These data indicate the potential for MRx0518 to overcome Treg-mediated acquired resistance to cancer treatment, and presents a biomarker potentially able to identify patients most likely to respond to immunotherapy based on MRx0518. Further tumor sample analysis is ongoing for additional patients recruited into the study.

Neoadjuvant MRx0518 treatment is associated with significant gene and metagene signature changes in solid tumours.

Presentation Number: 543P

- Gene expression profiling of paired tumor samples pre- and post-MRx0518 monotherapy across multiple solid tumor types (N=15) showed that treatment with MRx0518 for two to four weeks was associated with anti-tumor immune activity including antigen presentation, innate immune processes, and interferon response.
- Analysis of paired tumor samples also identified significant increases in mast cells, Th1, CD8+ T cell, neutrophil, endothelial cell and inflammatory chemokine metagene signatures following MRx0518 monotherapy.
- Effects were particularly pronounced in the cohort of breast cancer patients (N=7), with significant increases observed in total and activated dendritic cells, CD8+ T cells and cytotoxic cells in the tumor micro-environment.
- Functional metagene analysis also identified positive changes in prognostic indicators and metagene signatures predictive of immunotherapy response in patients with breast cancer, including inflammatory chemokines, cytotoxicity, lymphoid scores, and the Tumor Inflammation Signature (TIS)<sub>1</sub> - demonstrated to retrospectively predict clinical benefit of anti-PD-(L)1 ICI therapy efficacy in various cancer types.

The immune biomarker data from this study of MRx0518, as a monotherapy dosed over a short period of just two to four weeks, demonstrates the potent activity of this oral Live Biotherapeutic directly on the human immune system, and the positive implications for clinical outcomes. This study is being conducted in collaboration with Imperial College London.

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.

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**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: September 23, 2021

*/s/ Duncan Peyton*

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Duncan Peyton  
Chief Executive Officer

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INDEX TO EXHIBITS

**Exhibit  
Number** **Exhibit Title**

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99.1 [Press Release, dated September 17, 2021.](#)

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**4D pharma presents two clinical posters for Live Biotherapeutic MRx0518 at the European Society for Medical Oncology (ESMO) Congress 2021**

- One presentation details baseline biomarkers associated with clinical benefit from MRx0518, indicating a potential tumor biomarker predictive of response
- The second presentation describes gene and metagene signature changes with MRx0518 monotherapy demonstrating anti-tumor immune activation

**Leeds, UK, September 15, 2021 - 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 new biomarker analyses from two ongoing clinical trials of its lead immuno-oncology single strain Live Biotherapeutic, MRx0518, in both neoadjuvant and refractory solid tumor settings, at the European Society for Medical Oncology (ESMO) Congress, September 16-21, 2021.

*“At the core of 4D pharma’s platform is the importance of understanding the impact of Live Biotherapeutics on human biology to rationally select and develop candidates, predict and measure response. These new biomarker data provide us with critical guidance on the biological and mechanistic impact of MRx0518 therapy in patients with various solid tumors,”* said Dr. Alex Stevenson, Chief Scientific Officer, 4D pharma. *“These new findings indicate the potential to predict patients most likely to respond to MRx0518 therapy based on tumor biology.”*

*“Furthermore, the monotherapy data demonstrates that a short course of MRx0518 treatment is able to positively modulate prognostic indicators of immunotherapy response,”* he added. *“We look forward to utilizing and implementing these important new findings as we work to progress this novel oncology Live Biotherapeutic through development towards approval.”*

Highlights of the two ESMO 2021 poster presentations:

**Baseline biomarkers associated with clinical benefit in patients with solid tumors refractory to immune checkpoint inhibitors (ICIs) treated with live biotherapeutic MRx0518 in combination with pembrolizumab**

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- At baseline, patients who achieved complete response, partial response or stable disease for at least six months (collectively ‘responders’, N=4) from the combination of MRx0518 with Keytruda<sup>®</sup> (pembrolizumab) had significantly greater densities of CD3+FOXP3+CD8- regulatory T cells (Tregs) and CD3+KI67+ proliferating T cells in tumors at baseline, compared to patients with progressive disease (PD, N=8), p=0.0381 and p=0.0048, respectively.
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Both ePosters will be available under the “Posters and Publications” section of the 4D pharma website at [www.4dpharmapl.com](http://www.4dpharmapl.com) at 7:30 GMT on Thursday 16<sup>th</sup> September 2021.

<sup>1</sup> Ayers M, et al. *J Clin Invest.* 2017;127:2930–40

### 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 cancer patients. 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<sup>®</sup> (pembrolizumab) in patients who have 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, in collaboration with Merck KGaA and Pfizer Inc., of BAVENCIO<sup>®</sup> (avelumab) 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, is expected to commence in Q4 2021.

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## 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 has developed a proprietary platform, MicroRx<sup>®</sup>, 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<sup>®</sup> (pembrolizumab) in solid tumors, a Phase I study of MRx0518 in a neoadjuvant setting for patients with 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<sup>®</sup> in Irritable Bowel Syndrome (IBS) which has completed a successful Phase II trial. Preclinical-stage programs 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.

For more information, refer to <https://www.4dpharmapl.com>

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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, their ability to impact cancer treatment outcomes, and the potential use of biomarkers to predict response 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 relating to the activity and efficacy of its Live Biotherapeutic drug candidates including MRx0518, the ability to identify and validate biomarkers predictive of clinical outcomes, and those additional risks and uncertainties described in 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.

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