

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

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (date of earliest event reported): January 26, 2023

CENTESEA PHARMACEUTICALS PLC

(Exact name of Registrant, as specified in its charter)

England and Wales

001-04321

98-1612294

(State or other jurisdiction of incorporation)

(Commission File Number)

(I.R.S. Employer Identification Number)

Mailing address:

**3rd Floor
1 Ashley Road
Altrincham
Cheshire WA14 2DT
United Kingdom**

(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **+44 (0) 203 9206789, ext. 9999**

Former name or address, if changed since last report:

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value £0.002 per share	CNTA	Nasdaq Stock Market, LLC*
American Depositary Shares, each representing one ordinary share, nominal value £0.002 per share	CNTA	Nasdaq Stock Market, LLC

*Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market, LLC.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On January 26, 2023, Centessa Pharmaceuticals plc (the “Company”) released a press release titled “Centessa Pharmaceuticals Announces FDA Clearance of IND Application for Phase 1/2a Clinical Trial of LB101, First LockBody® Candidate, for Solid Tumors”. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On January 26, 2023, the Company announced that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate a Phase 1/2a first-in-human, clinical trial of LB101 for the treatment of solid tumors. LB101, a conditionally tetravalent PD-L1xCD47 LockBody® bispecific monoclonal antibody targeting solid tumors, is the first product candidate developed using the Company’s proprietary LockBody technology which is designed to selectively drive potent effector function activity, such as CD47, in the tumor microenvironment (TME) while avoiding systemic toxicity.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

99.1	Press Release dated January 26, 2023
104	Cover Page Interactive Data (embedded within the Inline XBRL document)

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 hereunto duly authorized.

Date: January 26, 2023

By: /s/ Saurabh Saha
Name: Saurabh Saha, M.D., Ph.D.
Title: Chief Executive Officer

Centessa Pharmaceuticals Announces FDA Clearance of IND Application for Phase 1/2a Clinical Trial of LB101, First LockBody® Candidate, for Solid Tumors

LB101 is a conditionally tetravalent PD-L1xCD47 LockBody bispecific monoclonal antibody, being developed for solid tumors

BOSTON & LONDON, January 26, 2023 – [Centessa Pharmaceuticals plc](http://www.centessa.com) (Nasdaq: CNTA), a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients, today announced that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate a Phase 1/2a first-in-human, clinical trial of LB101 for the treatment of solid tumors. LB101, a conditionally tetravalent PD-L1xCD47 LockBody® bispecific monoclonal antibody targeting solid tumors, is the first product candidate developed using the Company’s proprietary LockBody technology which is designed to selectively drive potent effector function activity, such as CD47, in the tumor microenvironment (TME) while avoiding systemic toxicity.

"We are very excited to be bringing our first LockBody candidate to the clinic and to be advancing a potentially transformative technology for patients with solid tumors," said Saurabh Saha MD PhD, Chief Executive Officer of Centessa. "The clearance of our IND for LB101 is an important milestone for our company as we have an ambitious strategy to advance multiple potential LockBody candidates in areas where there is a significant need for new cancer treatment options. We look forward to initiating the Phase 1/2a trial of LB101 as soon as possible."

About LB101

LB101 is a conditionally tetravalent PD-L1xCD47 LockBody bispecific monoclonal antibody which has two anti-CD47 domains blocked by two anti-PD-L1 domains, with proprietary human IgG-derived hinges linking the anti-CD47 and anti-PD-L1 domains. The cell-killing mechanism of action, CD47, is designed to be blocked by the PD-L1 tumor targeting domain until the IgG-derived hinges are naturally degraded in the TME, thus unlocking and activating the CD47 effector function activity in the tumor.

About Centessa Pharmaceuticals

Centessa Pharmaceuticals plc is a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients. Our programs span discovery-stage to late-stage development and cover a range of high-value indications. We operate with the conviction that each one of our programs has the potential to change the current treatment paradigm and establish a new standard of care. For more information, visit [http://www.centessa.com/](http://www.centessa.com), which does not form part of this release.

Forward Looking Statements

This press release contains forward-looking statements. These statements may be identified by words such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," "aim," "seek," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be

forward-looking statements, including statements related to the Company's ability to discover and develop transformational medicines for patients; the timing of commencement of new studies or clinical trials of LB101, the LockBody technology and other potential LockBody candidates; research and clinical development plans and the timing thereof; the Company's ability to differentiate LB101, the LockBody technology and/or other potential LockBody candidates from other treatment options; the development and therapeutic potential of LB101, the LockBody technology and other potential LockBody candidates; and regulatory matters, including the timing and likelihood of success of obtaining authorizations to initiate or continue clinical trials. Any forward-looking statements in this press release are based on our current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks related to the safety and tolerability profile of our product candidates; our ability to protect and maintain our intellectual property position; business (including commercial viability), regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company; risks inherent in developing product candidates and technologies; future results from our ongoing and planned clinical trials; our ability to obtain adequate financing, including through our financing facility with Oberland, to fund our planned clinical trials and other expenses; trends in the industry; the legal and regulatory framework for the industry, including the receipt and maintenance of clearances to conduct or continue clinical testing; future expenditures risks related to our asset-centric corporate model; the risk that any one or more of our product candidates will not be successfully developed and/or commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; geopolitical risks such as the Russia-Ukraine war and risks related to the ongoing COVID-19 pandemic including the effects of the Delta, Omicron and any other variants. These and other risks concerning our programs and operations are described in additional detail in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and our other reports, which are on file with the U.S. Securities and Exchange Commission (SEC). We explicitly disclaim any obligation to update any forward-looking statements except to the extent required by law.

Contact:

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