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): May 12, 2022

CRISPR THERAPEUTICS AG

(Exact name of Registrant as Specified in Its Charter)

Switzerland	**001-37923**	**Not Applicable**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Baarerstrasse 14 **6300 Zug, Switzerland** **(Address of Principal Executive Offices)**		**Not Applicable** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 41 (0)41 561 32 77

(Former Name or Former 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:

☐ 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**
Common Shares, nominal value CHF 0.03	CRSP	The Nasdaq Global Market

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 May 12, 2022, CRISPR Therapeutics AG (the "Company") issued a press release announcing that an abstract providing safety and efficacy data from the ongoing CTX130™ clinical trial for patients with T-cell lymphoma has been accepted for oral presentation at the Annual European Hematology Association (EHA) 2022 Hybrid Congress, taking place June 9 – 12, 2022, at the Messe Wien Exhibition and Congress Center in Vienna, Austria, and online. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of Form 8-K, including the accompanying Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On May 12, 2022, EHA published online an abstract submitted by the Company that provides safety and efficacy data from the ongoing CTX130 clinical trial for patients with T-cell lymphoma. A copy of the abstract is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release by CRISPR Therapeutics AG, dated May 12, 2022
99.2	ABSTRACT: EHA-1957 THE COBALT-LYM STUDY OF CTX130: A PHASE 1 DOSE ESCALATION STUDY OF CD70-TARGETED ALLOGENEIC CRISPR-CAS9–ENGINEERED CAR T CELLS IN PATIENTS WITH RELAPSED/REFRACTORY (R/R) T-CELL MALIGNANCIES
104	Cover Page Interactive Data File (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 thereunto duly authorized.

CRISPR Therapeutics AG

Date: May 12, 2022

By: /s/ Samarth Kulkarni
Samarth Kulkarni, Ph.D.
Chief Executive Officer

Exhibit 99.1

CRISPR Therapeutics Announces Oral Presentation of New Clinical Data on Anti-CD70 Allogeneic CAR-T Therapy CTX130™ for Patients with T-cell Lymphoma at the Annual European Hematology Association (EHA) 2022 Hybrid Congress

ZUG, Switzerland and CAMBRIDGE, Mass. – May 12, 2022 -- (GLOBE NEWSWIRE) -- CRISPR Therapeutics (Nasdaq: CRSP), a biopharmaceutical company focused on creating transformative gene-based medicines for serious diseases, today announced that an abstract providing safety and efficacy data from the ongoing CTX130™ clinical trial for patients with T-cell lymphoma has been accepted for oral presentation at the Annual European Hematology Association (EHA) 2022 Hybrid Congress, taking place June 9 – 12, 2022, at the Messe Wien Exhibition and Congress Center in Vienna, Austria, and online. This will be the first clinical data presented from the CTX130 program.

Abstract #S262 entitled, "*The COBALT-LYM Study of CTX130: A Phase 1 Dose Escalation Study of CD70-Targeted Allogeneic CRISPR-Cas9–Engineered CAR-T Cells in Patients with Relapsed/Refractory (R/R) T-cell Malignancies*," will be presented by Swaminathan P. Iyer, M.D., Professor, Department of Lymphoma/Myeloma, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, during the Gene Therapy and Cellular Immunotherapy – Clinical 2 session on Saturday, June 11, 2022, from 16:30 - 17:45 CEST/ 10:30 – 11:45 AM EST, in session room Hall Strauss 1-2.

The accepted abstract is now available online on the EHA website.

CTX130 is currently being investigated in two ongoing Phase 1 clinical trials for the treatment of relapsed or refractory renal cell carcinoma and various subtypes of lymphoma, respectively.

About CTX130
CTX130, a wholly-owned program of CRISPR Therapeutics, is a healthy donor-derived gene-edited allogeneic CAR-T investigational therapy targeting cluster of differentiation 70, or CD70, an antigen expressed on various solid tumors and hematologic malignancies. CTX130 is being developed for the treatment of both solid tumors, such as renal cell carcinoma, and T-cell and B-cell hematologic malignancies. CTX130 is being investigated in two ongoing independent Phase 1, single-arm, multi-center, open-label clinical trials that are designed to assess the safety and efficacy of several dose levels of CTX130 for the treatment of relapsed or refractory renal cell carcinoma and various subtypes of lymphoma, respectively.

About CRISPR Therapeutics
CRISPR Therapeutics is a leading gene editing company focused on developing transformative gene-based medicines for serious diseases using its proprietary CRISPR/Cas9 platform. CRISPR/Cas9 is a revolutionary gene editing technology that allows for precise, directed changes to genomic DNA. CRISPR Therapeutics has established a portfolio of therapeutic programs across a broad range of disease areas including hemoglobinopathies, oncology, regenerative medicine and rare diseases. To accelerate and expand its efforts, CRISPR Therapeutics has established strategic collaborations with leading companies including Bayer, Vertex Pharmaceuticals and ViaCyte, Inc. CRISPR Therapeutics AG is headquartered in Zug, Switzerland, with its wholly-owned U.S. subsidiary, CRISPR Therapeutics, Inc., and R&D operations based in Cambridge, Massachusetts, and business offices in San Francisco, California and London, United Kingdom. For more information, please visit www.crisprtx.com.

CRISPR Therapeutics Forward-Looking Statement

This press release may contain a number of "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, as well as statements regarding CRISPR Therapeutics' expectations about any or all of the following: (i) the safety, efficacy and clinical progress of CRISPR Therapeutics' various clinical programs, including expectations regarding the abstract that will be made available on the virtual platform and the clinical data that are being presented from the ongoing CTX130 clinical trial during the EHA Hybrid Congress and (ii) the therapeutic value, development, and commercial potential of CRISPR/Cas9 gene editing technologies and therapies. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and similar expressions are intended to identify forward-looking statements. You are cautioned that forward-looking statements are inherently uncertain. Although CRISPR Therapeutics believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, existing and prospective investors are cautioned that forward-looking statements are inherently uncertain, are neither promises nor guarantees and not to place undue reliance on such statements, which speak only as of the date they are made. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: the potential for initial and preliminary data from any clinical trial and initial data from a limited number of patients not to be indicative of final or future trial results; the potential that CTX130 clinical trial results may not be favorable or may not support registration or further development; that future competitive or other market factors may adversely affect the commercial potential for CTX130; potential impacts due to the coronavirus pandemic, such as to the timing and progress of clinical trials; uncertainties regarding the intellectual property protection for CRISPR Therapeutics' technology and intellectual property belonging to third parties; and those risks and uncertainties described under the heading "Risk Factors" in CRISPR Therapeutics' most recent annual report on Form 10-K, quarterly report on Form 10-Q, and in any other subsequent filings made by CRISPR Therapeutics with the U.S. Securities and Exchange Commission, which are available on the SEC's website at www.sec.gov. CRISPR Therapeutics disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

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Abstract Submission

25. Gene therapy, cellular immunotherapy and vaccination - Clinical

EHA-1957

THE COBALT-LYM STUDY OF CTX130: A PHASE 1 DOSE ESCALATION STUDY OF CD70-TARGETED ALLOGENEIC CRISPR-CAS9–ENGINEERED CAR T CELLS IN PATIENTS WITH RELAPSED/REFRACTORY (R/R) T-CELL MALIGNANCIES

Swaminathan P. Iyer[* 1], R. Alejandro Sica[2], P. Joy Ho[3], Boyu Hu[4], Jasmine Zain[5], Anca Prica[6], Wen-Kai Weng[7], Youn H. Kim[8], Michael S. Khodadoust[9], M. Lia Palomba[10], Francine M. Foss[11], Kimberly Tipton[12], Erika L. Cullingford[12], Qiuling He [12], Anjali Sharma[12], Steven M. Horwitz[10]

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Background: Overall survival (OS) in a subset of patients (pts) with T-cell lymphoma (TCL) has improved with front-line combination chemotherapy; however, R/R TCL pts continue to have very limited treatment options. For pts with R/R peripheral (PTCL) and transformed cutaneous TCL (CTCL), median OS is 1-2.5 and <5 yrs, respectively. Adapting autologous chimeric antigen receptor (CAR) T cell therapy for TCL continues to be challenging due to poor function of donor T cells, fratricide effect, and risk of infusing transduced malignant CAR T cells into pts. CTX130^{TM} is a first-in- class, CD70-targeting allogeneic (allo) CAR T therapy that may allow for CAR T therapy in pts whose own T cells are not ideal to manufacture auto CAR T cells. CD70 is a co-stimulatory protein with temporally limited expression on activated lymphocytes and is highly expressed in many TCLs. CTX130 is modified with CRISPR/Cas9-editing to eliminate expression of: 1) T-cell receptor (TCR) by TCR alpha constant disruption, 2) major histocompatibility complex class I expression by β2-microglobulin disruption, and 3) CD70 to mitigate fratricide and enhance performance.

Aims: Investigate safety and efficacy of CTX130 in pts with R/R TCL.

Methods: COBALT^{TM}-LYM (NCT04502446) is an open-label, multicenter, global study evaluating the safety and efficacy of CTX130 in pts ≥18 y with CD70+ (≥10% by immunohistochemistry) R/R TCL (PTCL or CTCL). Pts with PTCL and CTCL must have received ≥1 or ≥2 prior lines of systemic therapy, respectively. Pts received lymphodepleting chemotherapy (LDC) with fludarabine 30mg/m^2 and cyclophosphamide 500mg/m^2 for 3 days, followed by CTX130. Pts were treated with CTX130 at doses from 3x10^7 (dose level [DL]1) to 9x10^8 (DL4) CAR+ T cells. Pts could receive a second course of CTX130 if response was not achieved but had experienced clinical benefit or disease progression. The primary endpoint is safety (incidence of dose limiting toxicities [DLTs]). Key secondary endpoints include overall response rate (ORR, by Lugano and ISCL criteria for PTCL and CTCL, respectively), disease control rate (DCR; ≥stable disease [SD]), duration of response and OS.

Results: As of 6 Dec, 2021, 17 pts with TCL were enrolled; 15 received CTX130, were evaluable for a Day 28 assessment and are included in the analysis. Among the pts who received CTX130, median age was 67 y, 7 pts had PTCL, and 8 pts had CTCL. Median CD70 expression was 90% (range, 20-100%). Median follow up was 3.1 months. At DL ≥3, ORR was 71%, CR rate was 29% and DCR was 100% (**Table**). Responses were observed in PTCL (75% ORR at DL≥3) and CTCL (67% ORR at DL≥3) and across disease compartments. CTX130 had an acceptable safety profile across all DLs. There were no instances of graft versus host disease, tumor lysis syndrome, hemophagocytic lymphohistiocytosis, or infusion reactions with LDC or CTX130. There were no DLTs, no Grade (Gr) ≥3 cytokine release

syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS); Gr 1-2 CRS and ICANS were 47% and 20%. There was no increase in frequency or severity of CRS in pts who received second infusions of CTX130. 1 pt (7%) experienced a Gr ≥3 infection. There was a sudden death in 1 pt with William's syndrome in the context of a lung infection.

Image:

Dose Level (CAR+ T Cells)	DL1 $3x10^7$	DL2 $1x10^8$	DL3 $3x10^8$	DL4 $9x10^8$	DL3+ DL4	Total
N	4	4	5	2	7	15
Age, median yrs (range)	58 (41-67)	66 (39-71)	67 (54-78)	68 (68-68)	68 (54-78)	**67 (39-78)**
ECOG PS at Screening, n (%)						
0	1 (25)	3 (75)	2 (40)	2 (100)	4 (57)	**8 (53)**
1	3 (75)	1 (25)	3 (60)	0	3 (43)	**7 (47)**
Prior lines of therapy, median n (range)	3 (1-6)	6 (3-8)	5 (1-7)	3 (2-3)	3 (1-7)	**3 (1-8)**
TCL subtype, n (%)						
PTCL	**2 (50)**	**1 (25)**	**2 (40)**	**2 (100)**	**4 (57)**	**7 (47)**
ATLL	1 (25)	1 (25)	1 (20)	0	1 (14)	**3 (20)**
AITL	0	0	1 (20)	2 (100)	3 (43)	**3 (20)**
PTCL-NOS	1 (25)	0	0	0	0	**1 (7)**
CTCL (MF or SS)	**2 (50)**	**3 (75)**	**3 (60)**	0	**3 (43)**	**8 (53)**
Skin Involvement, n (%)	3 (75)	3 (75)	4 (80)	0	4 (57)	**10 (67)**
Blood Involvement, n (%)	1 (25)	1 (25)	2 (40)	0	2 (29)	**4 (27)**
Bone Marrow Involvement, n (%)	0	0	3 (60)	0	3 (43)	**3 (20)**
ORR, n (%)	**2 (50)**	**0**	**4 (80)**	**1 (50)**	**5 (71)**	**7 (47)**
CR	1 (25)	0	2 (40)	0	2 (29)	3 (20)
PR	1 (25)	0	2 (40)	1 (50)	3 (43)	4 (27)
DCR, n (%)	**3 (75)**	**1 (25)**	**5 (100)**	**2 (100)**	**7 (100)**	**11 (73)**
SD	1 (25)	1 (25)	1 (20)	1 (50)	2 (29)	4 (27)
CRS, n (%)	1 (25)	1 (25)	4 (80)	1 (50)	5 (71)	**7 (47)**
Gr ≥3 CRS	0	0	0	0	0	**0**
ICANS, n (%)	0	0	3 (60)	0	3 (43)	**3 (20)**
Gr ≥3 ICANS	0	0	0	0	0	**0**
Gr ≥3 Infection, n (%)	1 (25)	0	0	0	0	**1 (7)**
GvHD, n (%)	0	0	0	0	0	**0**

AITL, angioimmunoblastic T-cell lymphoma; ATLL, adult T-cell leukemia/lymphoma; CAR, chimeric antigen receptor; CR, complete response; CRS, cytokine release syndrome; CTCL, cutaneous T-cell lymphoma; DCR, disease control rate; DL, dose level; ECOG, Eastern Cooperative Oncology Group; Gr, grade; GvHD, graft versus host disease; ICANS, immune effector cell-associated neurotoxicity syndrome MF, mycosis fungoides; NOS, not otherwise specified; PR, partial response; PS, performance status; PTCL, peripheral T-cell lymphoma; SD, stable disease; SS, Sezary syndrome; TCL, T-cell lymphoma.

Summary/Conclusion: We have observed clinically meaningful responses, including CRs with CTX130, the first CAR T directed against the novel target, CD70. CTX130 has an acceptable safety profile in pts with heavily pretreated R/R TCL and will be investigated further in an expansion phase of the study.

Keywords: CAR-T, Mycosis fungoides, Peripheral T-cell lymphoma, T cell lymphoma