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Results from the First Phase 1 Clinical Study of DR-01, a Non-Fucosylated Anti-CD94 Targeting Antibody in Patients with Relapsed/Refractory Cytotoxic Lymphomas: Dose Escalation and Optimization

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Introduction: DR-01 is a non-fucosylated human IgG antibody targeting CD94, a receptor selectively expressed on cytotoxic terminal effector CD8+T cells, $\gamma\delta$ T cells, and NK cells, leading to rapid depletion of target cells primarily by antibody-dependent cellular cytotoxicity including fratricide.

DR-01-ONC-001 (NCT05475925) is a Phase 1/2 study of DR-01 in relapsed/refractory (RR) cytotoxic lymphomas (CTL) driven by CD94-expressing

cytotoxic cells of origin. In RR disease, these CTLs including hepatosplenic TCL, EATL, MEITL, ENKTL, CD8+ PTCL-NOS, primary cutaneous $\gamma\delta$ TCL(PC $\gamma\delta$ TCL), SPTCL, and aggressive CD8+ epidermotropic TCL among others, have no established effective treatment options. Patients with RR CTL have a poor prognosis with shortened survival, often only weeks to months.

Aims: To evaluate the safety and efficacy of DR-01 for the treatment of CTLs and to select doses for dose optimization.

Methods: This is a multi-center, open-label, 2-part study. Part A, dose escalation and extension, included CTL patients who failed at least 2 prior lines of therapy. Patients received IV DR-01 at 1 of 5 dose levels ranging from 0.3 to 10 mg/kg, and 1 of 3 induction dose regimens followed by monthly dosing. Additional CTL patients were enrolled in Part A extension at selected dose-regimens to inform dose optimization. Part B2 expansion will assess efficacy and safety of DR-01 in CTL patients who have failed at least 1 prior therapy at 2 dose levels to optimize dose selection. Study goals include disease response assessments, DR-01 concentrations, and pharmacodynamic/biomarker evaluations.

Results

Safety: 39 patients have been enrolled from July 2022 to May 2024 in the safety cohort including CTL and a separate cohort of LGLL not further described here. There were no dose-limiting toxicities, and the only significant treatment-related adverse event (TRAE) observed was infusion-related reaction (IRR) in 33.3% (N=13) most commonly with first administration and managed with supportive measures. No IRR led to dose reduction or discontinuation other than in the first patient enrolled into the study prior to optimization of IRR prophylaxis. The one TRAE causing a dose modification (missed dose) was grade 1 constipation. TRAEs like headache and fatigue had maximum incidence of 15.4%. One event of pyrexia (grade 2) and 1 event of possible CRS (grade 2), both of which resolved without sequelae, were serious AEs considered possibly related to DR-01. There were no DR-01 related deaths.

Efficacy: Part A enrolled 21 patients with CTL. 74% were resistant/intolerant to the most recent line of therapy and 26% refractory to all prior lines. 18.5% had a prior autologous or allogeneic hematopoietic stem cell transplant (HSCT). The observed objective response rate (ORR) was 33.3% (3 complete responses [CR] and 4 partial responses [PR]) in the 21 intention-to-treat patients. Among 16 response evaluable patients at minimally efficacious dose (determined by exposure-response analysis) of 1 mg/kg the ORR was 43.8%. Responses were observed in patients who had no response to any line of prior treatment and were observed across 7 different CTL histologies. Time to response in the 7 subjects who achieved CR or PR ranged from 0.85 to 1.38

months, and duration of response (DoR) ranged from 1.97 to 11.14 months. Two of 3 patients achieving CR proceeded to allogeneic HSCT after 14 cycles (SPTCL) and 7 cycles (ENKTL) on study, and they continue in CR at 4.1 and 6.3 months, respectively, since last dose of DR-01. The third patient achieving CR (PCyδTCL) had previously relapsed post allo-HSCT with ongoing response at 7.89 months.

Dose optimization: Exposure is approximately dose proportional within the dose range tested, and preliminary population pharmacokinetic (PK) modeling predicts a half-life of approximately 2 weeks. No safety/exposure relationship was observed, and the C_{min} associated with responses was best achieved with dose levels of ≥ 1 mg/kg and with the induction regimen dosing on C1D1, D8 and D15. These data supported initiating enrollment into phase 2, Part B2 at doses up to 10 mg/kg.

Conclusion: DR-01 is safe and tolerable in heavily pretreated patients. An encouraging response rate including 3 durable CRs points to the potential for DR-01 as a viable treatment option for CTL. Study DR-01-ONC-001 is currently enrolling an international cohort of patients with CTL into phase 2, part B2 of the trial.

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Results from the First Phase 1 Clinical Study of DR-01, a Non-Fucosylated Anti-CD94 Targeting Antibody in Patients with Relapsed/Refractory Cytotoxic Lymphomas: Dose Escalation and Optimization

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First Time Submitting:

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Agree

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Yes

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Does not apply

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No

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Daichi Sankyo	Research Funding
Secura Bio	Research Funding

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Trillium	Research Funding
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Merck	Research Funding
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Vittoria Biotherapeutics	Consultancy
Seagen	Honoraria
Acrotech	Honoraria
Everest Clinical Research	Consultancy
Kyowa Kirin	Honoraria
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Sanofi Ad Board 12/2022	Membership on an entity's Board of Directors or advisory committees

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CRISPR Therapeutics	Research Funding
DrenBio	Research Funding
Eisai	Research Funding
Elorac	Research Funding
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Innate-Pharma	Membership on an entity's Board of Directors or advisory committees and Research Funding
Kyowa Kirin Pharma	Honoraria, Membership on an entity's Board of Directors or advisory committees and Research Funding
Mundipharma	Membership on an entity's Board of Directors or advisory committees
Pfizer/Seattle Genetics	Research Funding

Portola/Alexion Pharma	Research Funding
Regeneron	Honoraria and Membership on an entity's Board of Directors or advisory committees
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Soligenix	Research Funding
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CRISPR Therapeutics	Research Funding
Nutcracker Therapeutics	Research Funding

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Incyte	Other: Trial Support and Research Funding
Secura Bio, INc.	Consultancy

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Incyte	Research Funding
Seagen	Consultancy, Membership on an entity's Board of Directors or advisory committees and Research Funding
Ipsen	Consultancy and Membership on an entity's Board of Directors or advisory committees
Astex	Research Funding
Dren Bio	Research Funding

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ONO	Consultancy and Research Funding
SOBI	Consultancy, Honoraria and Speakers Bureau
Teva	Consultancy and Research Funding
Viracta therapeutics	Honoraria, Membership on an entity's Board of Directors or advisory committees and Research Funding

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Name of Organization	Type of relationship
AbbVie, Inc	Current equity holder in publicly-traded company
BMS	Current equity holder in publicly-traded company
Dren Bio	Current Employment and Current holder of <i>stock options</i> in a privately-held company
Nektar	Current equity holder in publicly-traded company

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CRISPR	Current equity holder in publicly-traded company
Abbvie	Current equity holder in publicly-traded company
Amgen	Current equity holder in publicly-traded company
Biogen	Current equity holder in publicly-traded company
BMS	Current equity holder in publicly-traded company
Gilead	Current equity holder in publicly-traded company
Johnson and Johnson	Current equity holder in publicly-traded company
Moderna	Current equity holder in publicly-traded company
Pfizer	Current equity holder in publicly-traded company
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Vertex	Current equity holder in publicly-traded company

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Aurinia Pharmaceuticals	Current equity holder in publicly-traded company

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AbbVie	Research Funding
Johnson and Johnson	Honoraria
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