# Golcadomide, a CELMoD™ agent, ± rituximab in patients with relapsed/refractory follicular lymphoma: updated Phase 1/2 study results

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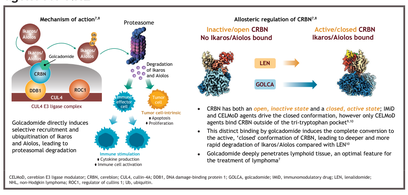

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## Introduction

- While outcomes in patients with relapsed/refractory (R/R) follicular lymphoma (FL) have improved since the availability of T-cell-redirecting therapies, such as chimeric antigen receptor (CAR) T-cell therapy and bispecific antibodies, there remains an unmet need to develop safe, efficacious and easier-to-administer treatments[1–4]
- Golcadomide is a potential, first-in-class, oral CELMoD agent designed for the treatment of lymphoma, with preferential distribution to lymphoid organs and enhanced activity in lymphoma cell lines. Golcadomide drives the closed, active conformation of cereblon to induce rapid and deep degradation of Ikaros and Aiolos, leading to direct cell killing (agnostic of cell of origin) and immunomodulatory activity (**Figure 1**)[5]
- In the first-in-human Phase 1/2 study (NCT03930953), golcadomide was well tolerated and effective in patients with R/R FL, with manageable on-target neutropenia[6]
- Here, we report longer follow-up results for golcadomide ± rituximab in patients with R/R FL from Part B of the Phase 1/2 CC-99282-NHL-001 trial

### Figure 1. Golcadomide is a potential, first-in-class, oral CELMoD agent for NHL

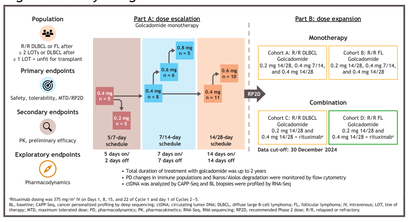



CELMoD, cereblon E3 ligase modulator; CRBN, cereblon; CUL4, cullin-4A; DDB1, DNA damage-binding protein 1; GOLCA, golcadomide; IMiD, immunomodulatory drug; LEN, lenalidomide; NHL, non-Hodgkin lymphoma; RBX1, regulator of cullins 1; Ub, ubiquitin.

## Methods

- CC-99282-NHL-001 is a two-part, multicenter, first-in-human study of dose escalation (Part A) of golcadomide monotherapy and expansion (Part B) with golcadomide ± combination partners (**Figure 2**)
  - Patients with R/R FL and disease progression after ≥ 2 lines of therapy (LOTs) were included
  - Following dose escalation in Part A, golcadomide was dosed orally once daily at 0.2 or 0.4 mg (14 days on/14 days off) + rituximab in Part B (dose expansion)
  - The total duration of treatment with golcadomide was up to 2 years or until disease progression or unacceptable toxicity occurred
  - Primary objectives included safety and determination of the recommended Phase 2 dose
- The efficacy-evaluable population consisted of patients completing ≥ 1 cycle of golcadomide (taking ≥ 75% of assigned doses) and having baseline and ≥ 1 post-baseline tumor assessment
- The safety population consisted of patients receiving ≥ 1 dose of golcadomide or rituximab
- Flow cytometry was used to assess immune modulation by golcadomide by measuring shifts across T-cell populations. Paired tumor biopsies were used for RNA exome sequencing (50 M 50 bp PE). Pathway enrichment analysis was performed using the single-sample gene-set variation analysis method

### Figure 2. Study design




[a]Rituximab dosing was 375 mg/m² IV on Days 1, 8, 15, and 22 of Cycle 1 and day 1 of Cycles 2–5.
BL, baseline; GAIN Seq, cancer personalized profiling by deep sequencing; LDNA, circulating tumor DNA; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; IV, intravenous; LOT, line of therapy; MTD, maximum tolerated dose; PD, pharmacodynamics; PK, pharmacokinetics; RNA Seq, RNA sequencing; RP2D, recommended Phase 2 dose; R/R, relapsed or refractory.

## Results

### Baseline characteristics and patient disposition

- As of 30 December 2024, 72 patients were treated with golcadomide ± rituximab, including 12 who received golcadomide in Part A and 60 who received golcadomide + rituximab in Part B Cohort D
- Patients were similar in terms of age, sex, diagnosis, treatment history and other features across the study parts (**Table 1**)
  - The median time from diagnosis to treatment with golcadomide + rituximab (Part B) was 59 months (range, 10—420 months)
  - Patients receiving golcadomide + rituximab had received a median of 3 (range, 1—12) prior LOTs
  - 28% of patients had received prior T-cell-redirecting therapy, and 30% had received prior lenalidomide-based therapy
  - 30% of patients had disease that was refractory to their last therapy regimen

### Table 1. Demographic and baseline characteristics

| Characteristic | Part A: Golcadomide monotherapy (n = 12) | Part B: Rituximab combination: Golcadomide 0.4 mg (n = 38) | Part B: Rituximab combination: Golcadomide 0.2 mg and 0.4 mg overall (n = 60) |
|---|---|---|---|
| **Age, median (range), years** | 61 (44–81) | 64 (38–82) | 63 (33–83) |
| **Sex, male, n (%)** | 5 (42) | 20 (53) | 30 (50) |
| **Diagnosis, n (%)** | | | |
| FL stage III/IV | 12 (100) | 32 (84) | 50 (83) |
| **Time from initial diagnosis to first dose, median (range), months** | 72 (23–136) | 57 (10–420) | 59 (10–420) |
| **ECOG PS, n (%)** | | | |
| 0 | 4 (33) | 18 (47) | 28 (47) |
| 1 | 8 (67) | 20 (53) | 31 (52) |
| 2 | - | - | 1 (2) |
| **Treatment history** | | | |
| **No. of prior LOTs, median (range)** | 4.5 (2–6) | 3 (1–12) | 3 (1–12) |
| Prior T-cell-redirecting therapy (CAR T and/or TCE) | 3 (25) | 11 (29) | 17 (28) |
| Prior lenalidomide treatment, n (%) | 4 (33) | 11 (29) | 18 (30) |
| **Best response to last regimen** | | | |
| CR or PR | 7 (58.3) | 18 (47) | 30 (50) |
| Never achieved objective response | 4 (33.3) | 11 (29) | 18 (30) |
| Unknown | 1 (8.3) | 7 (18) | 10 (17) |

Data cut-off: 30 December 2024.
CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; LOT, line of therapy; PR, partial response; TCE, T-cell engager.

- In Part A, 4 patients completed 2 years of golcadomide treatment, remaining in remission at last follow-up (**Table 2**)
  - 8 patients (67%) discontinued due to progressive disease
- In Part B, treatment was ongoing with golcadomide 0.4 mg + rituximab in 27 patients (71%) and was ongoing with golcadomide 0.2 mg + rituximab and 0.4 mg + rituximab overall in 38 patients (63%)
  - Of the 35% who discontinued treatment in the overall group, the most common cause of discontinuation was progressive disease (n = 12 [20%])
- At the time of the data cut-off, there were no golcadomide-related treatment-emergent adverse events (TEAEs) leading to discontinuations among the patients receiving the combination regimen of golcadomide + rituximab

### Table 2. Patient disposition

| | Part A: Golcadomide monotherapy (n = 12) | Part B: Rituximab combination: Golcadomide 0.4 mg (n = 38) | Part B: Rituximab combination: Golcadomide 0.2 mg and 0.4 mg overall (n = 60) |
|---|---|---|---|
| **Treatment disposition, n (%)** | | | |
| Completed 2 years of golcadomide tx | 4 (33) | 0 | 1 (2) |
| Ongoing | 0 | 27 (71) | 38 (63) |
| Discontinued | 8 (67) | 11 (29) | 21 (35) |
| **Primary reason for tx discontinuation, n (%)** | | | |
| Progressive disease | 5 (42) | 3 (8) | 12 (20) |
| Physician decision | 0 | 3 (8) | 4 (7) |
| Symptomatic deterioration | 3 (25) | 0 | 0 |
| Adverse event | 0 | 2 (5) | 2 (3) |
| Death[a] | 0 | 1 (3) | 1 (2) |
| Withdrawal by patient | 0 | 1 (3) | 1 (2) |
| Loss to follow-up | 0 | 1 (3) | 1 (2) |
| Lack of efficacy | 0 | 0 | 0 |
| Disease relapse | 0 | 0 | 0 |
| Pregnancy | 0 | 0 | 0 |

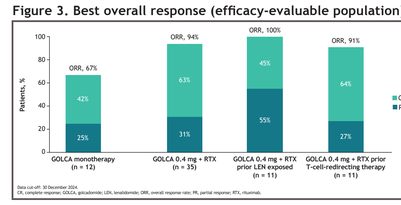
Data cut-off: 30 December 2024.
[a]Death was reported 16 days after the last dose of golcadomide: 1 sudden death 16 days after the last dose; 1 death due to respiratory failure due to progressive disease 24 days after the last dose of rituximab combination; tx, treatment.

### Efficacy

- In efficacy-evaluable patients receiving golcadomide monotherapy (Part A; n = 12), the overall response rate (ORR) was 67% (complete response rate [CRR], 42%) (**Figure 3**)
  - At a median follow-up of 30 months, responses were durable with a median observed duration of response (DOR) of 26 months (range, 1.7—58.2 months)
  - One-third of patients (n = 4) completed 2 years of protocol-defined treatment and remain in CR
  - The median time to response was 1.9 months (range, 1.6—1.9 months)
- In efficacy-evaluable patients receiving golcadomide + rituximab in Part B, the ORR was 94% (CRR, 63%) in the 0.4 mg (n = 35) group (**Figure 3**)
  - Notably, the ORR and CRR in high-risk subsets, including patients with prior treatment with lenalidomide and/or T-cell-redirecting therapy, were consistent with the results in the overall 0.4 mg golcadomide + rituximab treatment group
  - At a median follow-up of 5.75 months, the median observed DOR was 4.8 months (range, 0.9—26 months) in the 0.4 mg golcadomide + rituximab treatment group
  - Among patients who responded to the golcadomide 0.4-mg dose, subsequent progression was rare, occurring in only 3 of 33 responders at the time of data cut-off
    - 8 patients had responses lasting > 12 months, including 3 who received prior T-cell-redirecting therapy and 4 who received prior lenalidomide (**Figure 4**)

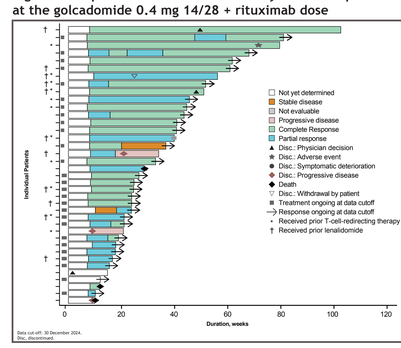
Note: Observed duration of response is measured from the time at which measurement criteria are first met for CR or PR (whichever is first recorded) until the first date at which progressive disease (PD) or death is objectively documented, whichever comes first. If no PD or death, then patients are censored and calculated as cutoff date - first recorded date of CR/PR + 1. Based on responders only.

### Figure 3. Best overall response (efficacy-evaluable population)




Data cut-off: 30 December 2024.
CR, complete response; GOLCA, golcadomide; LEN, lenalidomide; ORR, overall response rate; PR, partial response; RTX, rituximab.

### Figure 4. Disposition of individual efficacy-evaluable patients at the golcadomide 0.4 mg 14/28 + rituximab dose

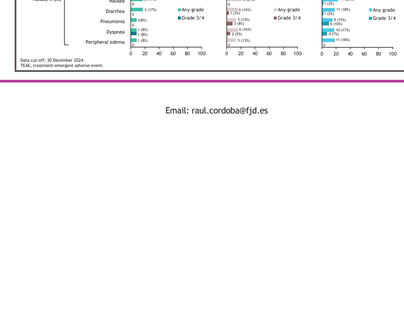



Data cut-off: 30 December 2024.
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### Safety

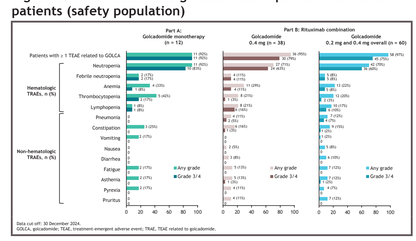
- In the safety population in Part B, the most common any-grade TEAEs were neutropenia, an on-target effect resulting from golcadomide-mediated Ikaros degradation leading to reversible neutrophil maturation arrest, and anemia (in 70% and 33%, respectively) (**Figure 5**)
  - Golcadomide-related Grade 3/4 neutropenia and febrile neutropenia occurred in 60% and 8% of patients, respectively (**Figure 6**)
  - Median time to resolution of febrile neutropenia was 5 days
- Non-hematologic AEs such as fatigue, diarrhea, and rash were infrequent and mostly low grade
- Overall, golcadomide dose reduction was infrequent, with neutropenia (5%) and febrile neutropenia (3%) being the most common reasons for dose reduction in Part B (**Table 3**)
- Golcadomide interruptions were attributed to infections (28%), neutropenia (20%), gastrointestinal disorders (7%), and metabolism and nutrition disorders (3%) in Part B
- 2 patients (in the golcadomide 0.4 mg cohort in Part B) had Grade 5 TEAEs of sudden death and respiratory failure (n = 1 each)
  - No discontinuations or deaths were due to golcadomide-related TEAEs
- No new safety signals were observed with golcadomide + rituximab

### Figure 5. TEAEs reported in ≥ 10% of patients in Parts A and B (safety population)




Data cut-off: 30 December 2024.
TEAE, treatment-emergent adverse event.

### Figure 6. TEAEs related to golcadomide reported in ≥ 10% of patients (safety population)




Data cut-off: 30 December 2024.
GOLCA, golcadomide; TEAE, treatment-emergent adverse event; TRAE, TEAE related to golcadomide.

### Table 3. TEAEs leading to golcadomide dose reduction (safety population)

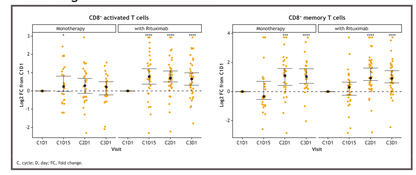
| TEAEs leading to dose reduction, n (%) | Part A: Golcadomide monotherapy (n = 12) | Part B: Rituximab combination: Golcadomide 0.4 mg (n = 38) | Part B: Rituximab combination: Golcadomide 0.2 mg and 0.4 mg overall (n = 60) |
|---|---|---|---|
| **Patients with ≥ 1 TEAE leading to dose reduction of golcadomide** | 6 (50) | 9 (24) | 10 (17) |
| **Neutropenia** | 4 (33) | 3 (8) | 3 (5) |
| Febrile neutropenia | 0 | 2 (5) | 2 (3) |
| **Thrombocytopenia** | 1 (8) | 0 | 1 (2) |
| **Pneumonitis** | 1 (8) | 0 | 0 |
| **Respiratory syncytial virus infection** | 0 | 1 (3) | 1 (2) |
| **COVID-19** | 0 | 0 | 0 |
| **Fatigue** | 0 | 1 (3) | 1 (2) |
| **Asthenia** | 0 | 1 (3) | 1 (2) |
| **Abdominal pain** | 0 | 0 | 0 |
| **Anal abscess** | 0 | 1 (3) | 1 (2) |
| **Exertional dyspnea** | 0 | 1 (3) | 1 (2) |

Data cut-off: 30 December 2024.
TEAE, treatment-emergent adverse event.

### Biomarkers

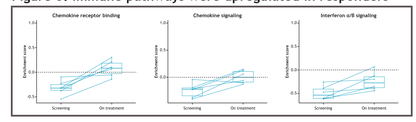
- Immunophenotyping confirmed significant immune activation with golcadomide + rituximab, as indicated by the increase in $CD8^+$ activated T cells and $CD8^+$ memory T cells from Cycle 1 Day 1 to Cycle 1 Day 15 (**Figure 7**)
  - Evidence of immune activation appeared stronger with golcadomide + rituximab than golcadomide monotherapy
- Analysis of paired biopsies from responders showed that golcadomide + rituximab increased chemokine receptor binding and signaling from the time of screening to when patients were on treatment, suggesting immune infiltration and upregulation of immune activation pathways (**Figure 8**)

### Figure 7. Peripheral T-cell subsets were activated within 2 weeks of golcadomide treatment




C, cycle; D, day; FC, fold change.

### Figure 8. Immune pathways were upregulated in responders




## Conclusions

- With additional follow-up, golcadomide continued to show encouraging efficacy with durable responses in patients with heavily pretreated R/R FL with a median of 3 prior LOTs (range, 1—12)
  - A higher ORR with similar tolerability was observed with golcadomide 0.4 mg + rituximab (94%) compared with golcadomide 0.2 mg + rituximab (77%) and golcadomide monotherapy
  - Efficacy with golcadomide 0.4 mg + rituximab was similar across key populations, including patients with prior lenalidomide-based and/or prior T-cell-redirecting therapy
- The safety profile of golcadomide + rituximab was manageable and predictable, and no new safety signals were observed with longer follow-up
  - On-target neutropenia was manageable with the use of granulocyte colony-stimulating factors and/or dose interruption
  - Incidence of Grade 3/4 febrile neutropenia in patients receiving golcadomide + rituximab was 8%
  - Non-hematologic AEs were primarily low grade and manageable with supportive care, with low incidence of dose interruption or dose reduction
- Immune activation upon golcadomide treatment in peripheral blood was more pronounced when combined with rituximab. Pathways associated with immune activation were also upregulated in lymph nodes during treatment
- These data support continued development of golcadomide 0.4 mg + rituximab as a fixed-duration, chemotherapy-free, outpatient option in R/R FL, to be evaluated in the Phase 3 GOLSEEK-4 study in patients who have received ≥ 1 line of systemic therapy (NCT06911502)


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