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Administering Tafasitamab, Lenalidomide, and Rituximab for Follicular Lymphoma: A Single Institution Experience From the Phase 3 inMIND Study

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Objective

- Evaluate institution-specific approaches to premedication use and R administration enabling reduced clinic time for delivery of tafa plus len and R at the Fred Hutchinson Cancer Center (Fred Hutch)

Conclusions

- **Implementation of the *rapid infusion protocol* for R allowed for a reduction in infusion time by >2 hours compared with the C1D1 infusion protocol in R/R FL patients treated at Fred Hutch**
  - **Reduced infusion time may facilitate an improved rate of treatment delivery and shorter in-clinic time for patients, thereby reducing patient burden**
- **The *rapid infusion protocol* was generally well tolerated in the patients enrolled at Fred Hutch**
- **Additionally, limiting intervals between premedication and infusion could further enable clinics to complete all infusions reliably in a single day**
- **The small sample size and single-center nature of this cohort may limit the generalizability of the data**

Abbreviations

AE, adverse event; C, cycle; D, day; IRR, infusion-related reaction; IV, intravenous; len, lenalidomide; mAb, monoclonal antibody; pbo, placebo; R, rituximab; RDI, relative dose intensity; R/R FL, relapsed/refractory follicular lymphoma; tafa, tafasitamab.

Disclosures

Zhao: Nothing to disclose. **Rasmussen:** Nothing to disclose. **Poh:** Advisory board – *Acrotech, AstraZeneca, Ipsen, Seagen*; Research funding – *Astex, Dren Bio, Incyte Corporation, Seagen*. **Janiszewski, Ren, Arbushites:** Employment and stock ownership – *Incyte Corporation*. **Gopal:** Research Funding – *AstraZeneca, Beigene, BMS, Genmab, Lilly, Pfizer, Pfizer, Takeda, Umoja*. Consultancy/Honoraria – *SciTech*. Stock options – *Compliment Corporation, SciTech.*

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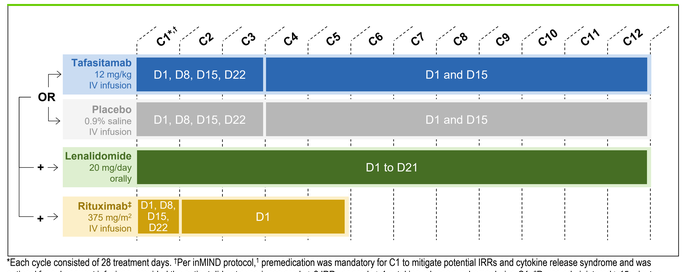
Introduction

- Based on the findings from the global, phase 3, randomized, controlled inMIND trial (NCT04680052),[1] tafa, a CD19-targeting mAb, in combination with len and R was approved for the treatment of adult patients with R/R FL[2-4]
- While the inMIND protocol and product labels provide guidance on tafa premedication and infusion,[1,2] R administration during the study followed local product label requirements and institutional practice
- Extended clinic visits and reduced scheduling flexibility due to long infusion times can impact patients' experience and disrupt their daily life, especially for those with frequent treatment regimens
  - There is a need for practical strategies to optimize treatment delivery and reduce patient burden
  - Implementing rapid infusion protocols with R has successfully improved both patient experience and clinic resource allocation in outpatient centers without compromising safety[5-7]

Methods

- Eligible patients were adults with R/R FL (grade 1-3a) who received ≥1 prior line of systemic therapy, including an anti-CD20 mAb, enrolled at Fred Hutch (Seattle, WA, USA) as part of the inMIND trial[1]
- Enrolled patients received up to 12×28-day cycles of tafa or pbo combined with len and R (**Figure 1**)

Figure 1. Treatment Regimen for Patients With R/R FL Enrolled in the inMIND Trial at Fred Hutch



*Each cycle consisted of 28 treatment days. [1]Per inMIND protocol,[1] premedication was mandatory for C1 to mitigate potential IRRs and cytokine release syndrome and was optional for subsequent infusions, provided the patient did not experience grade ≥2 IRRs or grade ≥1 cytokine release syndrome during C1. ‡R was administered ≥15 minutes after the completion of tafa or pbo infusion.

- Per inMIND protocol,[1] premedication was mandatory for C1 to mitigate potential IRRs and cytokine release syndrome and was optional for subsequent infusions (**Figure 1**)
- Fred Hutch site staff managed infusions as follows:
  - Premedication consisted of oral acetaminophen (325-650 mg), diphenhydramine hydrochloride (25-50 mg orally or IV), and methylprednisolone (81.25-125 mg IV), administered 30-60 minutes prior to tafa/pbo infusion or 20 minutes prior to R infusion, if not given prior to tafa/pbo
  - Following the C1D1 R infusion, subsequent R doses could be administered via the institutional *rapid infusion protocol*: 110 mL/h for 30 minutes, followed by 220 mL/h for 60 minutes for a 250 mL IV bag
  - Patients were eligible for the *rapid infusion protocol* if they did not experience an IRR following their last infusion and had their last R dose <4 months prior
  - R was administered ≥15 minutes after the completion of tafa/pbo infusion
    - Dose interruptions or discontinuations were followed by additional medication depending on severity and type of AE
    - Additional supportive care management was implemented as clinically indicated
    - At resolution of symptoms, R infusion rates would resume at ≥50% reduction in infusion rate
  - To ensure infusions could be completed in a single day, the first dose of R was allotted a 6-hour slot and started by 10:00 AM
- Data collected included treatment patterns and safety, including IRRs

Results

Patient Characteristics

- Overall, inMIND enrolled 548 patients with R/R FL
  - Fred Hutch randomized 9 of these patients to receive tafa+len+R (n=6) or pbo+len+R (n=3)
  - Among these 9 patients, the mean (range) age was 59 (42-75) years, and 6 (67%) patients were male (**Table 1**)

Table 1. R/R FL Patient Characteristics

	Tafa+Len+R (n=6)	Pbo+Len+R (n=3)
Male/female, n (%)	3 (50) / 3 (50)	3 (100) / 0
Age, years, mean (range)	62 (42-75)	53 (45-63)
R/R status, n (%)		
Relapsed to most recent treatment	4 (67)	1 (33)
Refractory to most recent treatment	1 (17)	2 (67)
Undetermined	1 (17)	0

Treatment Administration

- Standard provider visit duration ranged from 30-60 minutes, and standard blood draw appointments ranged from 15-30 minutes
- Treatment administration details are summarized in **Table 2**
- All tafa/pbo and R infusions were completed in a single day, except for 2 patients: 1 patient (pbo arm) had C1D8 R infusion given over 2 days with the interval being <24 hours, and 1 patient had their C1D1 tafa and R infusions split over 2 days due to history of R desensitization
- The *rapid infusion protocol* could be applied to all patients including those with history of R desensitization, with exceptions based on patient-specific factors
  - 1 patient received R desensitization without complication, then proceeded to start C1 but split infusions over 2 days (D1 tafa, D2 R); the patient did have a grade 2 IRR after desensitization, but not as severe as initial reaction. R was administered via the *rapid infusion protocol* starting with the C1D15 dose
  - 1 patient (pbo arm) had 3 prior R desensitizations; after the third infusion, the provider agreed to proceed with subsequent (pbo and R) infusions but continued with R at the C1D1 dosing rate. Subsequent R doses were tolerated
- The *rapid infusion protocol* reduced the R infusion time by >2 hours (~64%; **Table 2**)
  - This reduction was evident from when the *rapid infusion protocol* was first introduced at C1D8 and sustained in subsequent cycles (**Figure 2**)

Figure 2. Duration of R Infusions by Study Cycle in Patients With R/R FL Enrolled in the inMIND Trial at Fred Hutch (N=9)

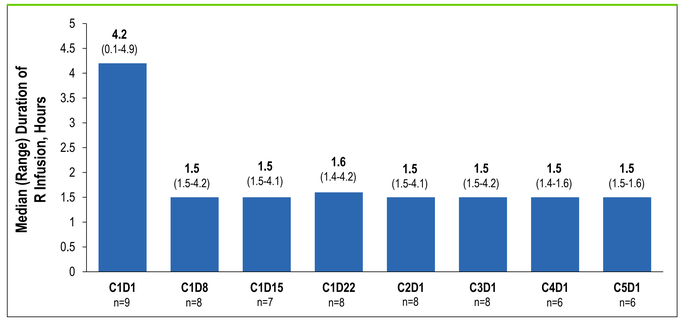


Table 2. Treatment Patterns of Patients With R/R FL Enrolled in the inMIND Trial at Fred Hutch

	All Patients (N=9)
Duration of tafa/pbo infusion, hours, median (range)	2.3 (1.4-3.0)
Duration of C1D1 R infusion, hours, median (range)	4.2 (0.1-4.9)
Duration of R infusion per *rapid infusion protocol*,* hours, median (range)	1.5 (1.4-4.2)
RDI of tafa/pbo across all cycles, %, median (range)	100 (0-100)
RDI of R across 5 administered cycles, %, median (range)	100 (0-100)

*From C1D8.

Safety

- The safety summary is described in **Table 3**
- Grade ≥3 IRRs occurred in 2 patients in the tafa+len+R group, 1 of which was tafa related
  - There were no grade 4 or 5 IRRs reported
- Dose interruptions of R due to an AE occurred in 3 patients in the tafa+len+R group and 2 patients in the pbo+len+R group
- All AEs resolved

Table 3. Safety Summary for Patients With R/R FL Enrolled in the inMIND Trial at Fred Hutch (N=9)

Variable	Tafa+Len+R (n=6)	Pbo+Len+R (n=3)
Grade ≥3 IRR, n (%)	2 (33)*	0 (0)
Dose interruption of tafa/pbo due to AE, n (%)	2 (33)†	2 (67)‡
Dose interruption of len due to AE, n (%)	4 (67)§	1 (33)¶
Dose interruption of R due to AE, n (%)	3 (50)‖	2 (67)#

*Grade 3 rash (n=1, related to tafa, R, and len), grade 3 maculopapular rash (n=1, len-related). †Grade 2 IRR, grade 1 paresthesia, and grade 2 tooth infection (n=1), grade 3 neutropenia (n=1). ‡Grade 1 IRR (n=1), grade 3 pleural effusion (n=1). §Grade 3 neutropenia (n=1), grade 3 rash (n=1), grade 2 maculopapular rash (n=1), grade 2 and 3 tooth infection, grade 2 COVID-19 infection, and grade 2 pyrexia (n=1). ¶Grade 3 pleural effusion (n=1). ‖Grade 1 anxiety (n=1), grade 1 oropharyngeal pain (n=1), grade 2 IRR (n=1). #Grade 1 IRR and grade 3 pleural effusion (n=1), grade 1 and 2 IRR (n=1).