Efficacy and Safety of Ublituximab in Combination with Umbralisib (U2) in Patients with Chronic Lymphocytic Leukemia (CLL) by Treatment Status: A Sub-analysis of the Phase 3 UNITY-CLL Study

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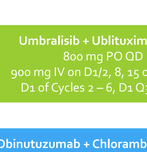
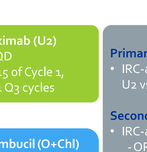
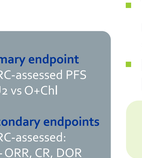
BACKGROUND AND METHODS

- Umbralisib, a selective phosphoinositide 3-kinase delta (PI3Kδ) and casein kinase-1 epsilon (CK1ε) inhibitor, is pharmacologically distinct from other PI3K inhibitors[1], with low rates of immune-mediated toxicities and discontinuations due to AEs[2]
- Ublituximab is a novel anti-CD20 monoclonal antibody glycoengineered for enhanced antibody-dependent cellular cytotoxicity (ADCC) that targets a unique epitope on CD20[3]
- Umbralisib+ublituximab (U2) prolonged progression-free survival compared to chemoimmunotherapy in the primary analysis of the randomized, multicenter, Phase 3 UNITY-CLL trial[4]
- Herein, we present a post-hoc analysis for patients treated with U2 stratified by prior treatment status

AEs: adverse events [1]Burris H, et al. Lancet Oncol 2018;19:486-96. [2]Davids M, et al. Blood Adv 2021. [3]Sawas A, et al. Br J Hematol 2017;177(2):243-253. [4]Gribben J, et al. Blood 2020;136:37-39.

Umbralisib is a Selective Inhibitor of PI3Kδ and CK1ε

	Umbralisib[1]	Idelalisib[1]	Duvelisib[1]	Copanlisib[2]
				

Isoform	K_d (nM)			
PI3Kα	>10000	600	40	0.04
PI3Kβ	>10000	19	0.89	1.5
PI3Kγ	1400	9.1	0.21	0.31
PI3Kδ	6.2	1.2	0.047	0.068
CK1ε	180	>30,000	>30,000	>6,000

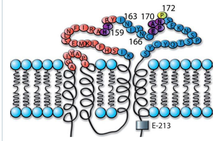
- Umbralisib is an oral, once daily, selective inhibitor of PI3Kδ and CK1ε
- Umbralisib has >1000-fold greater selectivity for PI3Kδ compared to α and β isoforms
- Umbralisib is also **>200-fold** more selective for PI3Kδ relative to **PI3Kγ**

CK1ε: casein kinase 1ε ; PI3k: phosphoinositide 3-kinase. 1. Burris HA, et al. *Lancet Oncol.* 2018;19(4):486-496. 2. Data on File [TGR 001]. TG Therapeutics, Inc, New York City, NY.

Ublituximab is a Novel Glycoengineered anti-CD20 mAb

- Ublituximab (TG-1101, UTX) is a novel, glycoengineered, Type I, anti-CD20 monoclonal antibody with several defining features:
  - Targets a unique epitope on the CD20 antigen
  - Type I maintains complement-dependent cytotoxicity (CDC)
  - Glycoengineered to enhance affinity for all variants of FcγRIIIa receptors, thereby demonstrating greater antibody-dependent cellular cytotoxicity (ADCC) activity than rituximab and ofatumumab, including in 17p deleted CLL cells[1]
- As a single agent, ublituximab is active in rituximab-refractory CLL and Non-Hodgkin's lymphoma (NHL) patients[2]
- BLA currently under review for CLL

Ublituximab



Red: Key ofatumumab epitope amino acids
Purple: Core amino acids of ublituximab epitope

Figure adapted from Ruuls et al, 2008[2]

BLA: biologics license application; CLL: chronic lymphocytic leukemia. 1. Le Garff-Tavernier M, et al. *Leukemia.* 2014;28:230-233; 2. Ruuls S, et al. *Biotechnology J.* 2008; 3:1157-1171.

RESULTS

Demographics & Baseline Characteristics

Characteristic	Treatment-naïve N=119	Previously Treated N=91
Age, median (range), years	**68 (39 – 88)**	**65 (43 – 87)**
<65 years, n (%)	43 (36)	42 (46)
≥65 years, n (%)	76 (64)	49 (54)
ECOG-PS 0 – 1 / 2, %	**96 / 3**	**98 / 2**
High-risk features, n (%)		
Del(17p)	6 (5)	13 (14)
Del(11q)	25 (21)	22 (24)
Unmutated IGHV	61 (51)	52 (57)
Prior therapies, median (range)	**-**	**2 (1 – 9)**
Prior therapy type, n (%)		
Anti-CD20 antibody	-	83 (91)
Chemoimmunotherapy	-	81 (89)
BTK inhibitor	-	14 (15)
Venetoclax	-	1 (1)
PI3K Inhibitor[a]	-	1 (1)

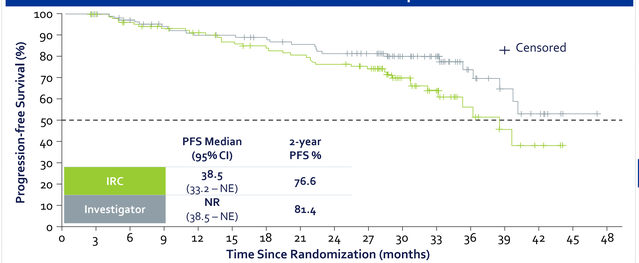
- Over 50% of TN & PT patients exhibited at least 1 high-risk feature
- In PT population, patients were heavily pretreated with a median of 2 prior lines extending up to 9 prior lines of therapy

BTK: Bruton's tyrosine kinase; ECOG PS: Eastern Cooperative Oncology Group performance status; IGHV: immunoglobulin heavy-chain variable gene; PI3k: phosphoinositide 3-kinase. [a]Trial excluded prior PI3K exposure; however, 1 patient with prior PI3K did enroll and was treated with U2.

Patient Disposition & Exposure

	Treatment-naïve N=119	Previously Treated N=91
Treated with study drug at least 1 day, n (%)	116 (97)	90 (99)
Randomized but not treated, n (%)	3 (3)	1 (1)
Treatment exposure, median (range), months		
Ublituximab	30 (0.03 – 46)	15 (0.07 – 42)
Umbralisib	27 (0.03 – 47)	16 (0.26 – 44)
Treatment status, n (%)		
Ongoing	60 (50)	21 (23)
Discontinued regimen	59 (50)	70 (77)
Progressive disease during treatment	13 (11)	39 (43)
Adverse event	25 (21)	10 (11)
Withdrawal of consent	10 (8)	13 (14)
Investigator decision	7 (6)	4 (4)
Death	3 (3)	2 (2)
Other	1 (1)	1 (1)
Lost to follow-up	-	1 (1)

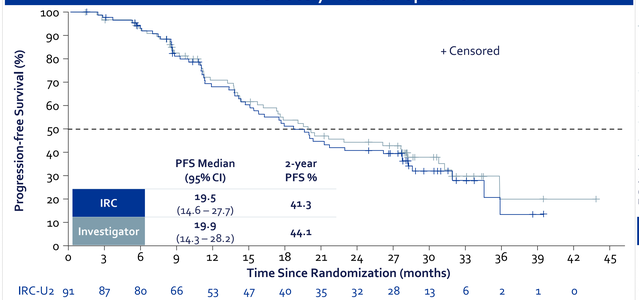
IRC-assessed & Investigator-assessed Progression-free Survival With U2 in Treatment-naïve Population



IRC-U2	119	106	100	94	90	84	79	76	72	68	39	25	12	6	3	0
Inv-U2	119	106	98	92	88	87	82	79	75	70	49	37	18	11	7	1	0

CI: confidence interval; Inv: investigator; IRC: independent review committee; NR: not reached; PFS: progression-free survival; U2: umbralisib + ublituximab

IRC-assessed & Investigator-assessed Progression-free Survival With U2 in Previously Treated Population



IRC-U2	91	87	80	66	53	47	40	35	32	28	13	6	2	1	0
Inv-U2	91	86	80	66	54	47	40	35	32	29	16	7	2	2	1	0

CI: confidence interval; Inv: investigator; IRC: independent review committee; PFS: progression-free survival; U2: umbralisib + ublituximab

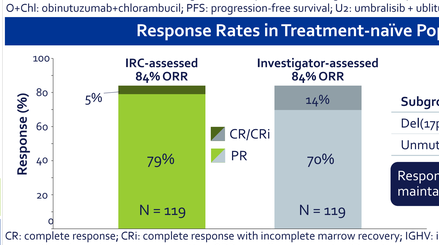
IRC-assessed PFS in Subgroups by Treatment Status

Treatment-naïve	U2 – Treatment-naïve Events/Total	O+Chl Events/Total	Hazard Ratio (95% CI)
All Subjects	36/119	61/121	0.471 (0.310, 0.716)
Age			
<65	13/ 43	22/ 48	0.469 (0.232, 0.945)
≥65	23/ 76	39/ 73	0.459 (0.271, 0.776)
Deletion 17p			
Deleted	1/ 6	9/ 13	0.000 (0.000, NE)
Not deleted	35/113	52/108	0.528 (0.342, 0.814)
IGHV status			
Unmutated	22/ 61	34/ 60	0.471 (0.270, 0.821)
Mutated	7/ 33	10/ 35	0.637 (0.241, 1.681)

Previously Treated	U2 – Previously Treated Events/Total	O+Chl Events/Total	Hazard Ratio (95% CI)
All Subjects	55/91	63/90	0.641 (0.445, 0.922)
Age			
<65	28/42	22/ 29	0.876 (0.499, 1.539)
≥65	27/49	41/61	0.485 (0.296, 0.795)
Deletion 17p			
Deleted	12/13	5/10	0.884 (0.299, 2.612)
Not deleted	43/78	58/80	0.569 (0.383, 0.846)
IGHV status			
Unmutated	34/52	46/55	0.412 (0.260, 0.653)
Mutated	10/17	10/22	1.158 (0.481, 2.786)

CI: confidence interval; IGHV: immunoglobulin heavy-chain variable gene; IRC: independent review committee; O+Chl: obinutuzumab+chlorambucil; PFS: progression-free survival; U2: umbralisib + ublituximab

Response Rates in Treatment-naïve Population

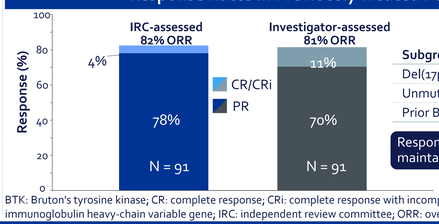


Subgroups	IRC-ORR (%)
Del(17p)	67
Unmutated IGHV	85

Responses were durable with **76%** maintaining response at **2 years**

CR: complete response; CRi: complete response with incomplete marrow recovery; IGHV: immunoglobulin heavy-chain variable gene; IRC: independent review committee; ORR: overall response rate; PR: partial response.

Response Rates in Previously Treated Population



Subgroups	IRC-ORR (%)
Del(17p)	69
Unmutated IGHV	81
Prior BTK inhibitor	57

Responses were durable, with **43%** maintaining response at **2 years**

BTK: Bruton's tyrosine kinase; CR: complete response; CRi: complete response with incomplete marrow recovery; IGHV: immunoglobulin heavy-chain variable gene; IRC: independent review committee; ORR: overall response rate; PR: partial response.

Safety Overview

AE Type, n (%)	Treatment-naïve N=116	Previously Treated N=90
Median exposure, months		
Ublituximab	29.5	14.6
Umbralisib	26.5	15.6
Patients with ≥1 AE (all grades)	116 (100)	90 (100)
Serious AEs	53 (45.7)	42 (46.7)
Grade ≥3	96 (82.8)	73 (81.1)
Discontinuations due to AEs*	25 (21.6)	10 (11.1)
Fatal AEs	4 (3.4)[a]	4 (4.4)[b]

AE: adverse event. Safety was assessed in all patients who received ≥1 dose of treatment. *Percentages for discontinuations due to AEs differ from Disposition table, which is out of ITT population (TN N=119, PT N=91). [a]Fatal AEs in TN cohort: neutropenic sepsis (related), cardiac arrest (unrelated), acute myocardial infarction (unrelated), progressive multifocal leukoencephalopathy (related). [b]Fatal AEs in PT cohort: glioblastoma (unrelated), sepsis (related), sudden cardiac death (related), pneumonia (unrelated).

All Causality AEs (≥25%) in Any Treatment Arm

	Treatment-naïve N=116				Previously Treated N=90			
AEs, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 1	Grade 2	Grade 3	Grade 4
Nausea	46 (40)	22 (19)	1 (1)	-	22 (24)	12 (13)	2 (2)	-
Diarrhea	23 (20)	23 (20)	16 (14)	-	30 (33)	14 (16)	9 (10)	-
IRR	11 (10)	49 (42)	1 (1)	-	2 (2)	29 (32)	2 (2)	1 (1)
Fatigue	27 (23)	19 (16)	4 (3)	-	8 (9)	14 (16)	-	-
Headache	31 (27)	9 (8)	-	-	10 (11)	2 (2)	1 (1)	-
Cough	24 (21)	9 (8)	-	-	12 (13)	14 (16)	-	-
Neutropenia	-	2 (2)	10 (9)	18 (16)	1 (1)	2 (2)	17 (19)	19 (21)
Decreased appetite	23 (20)	4 (3)	2 (2)	-	9 (10)	2 (2)	-	-
Chills	16 (14)	11 (10)	1 (1)	-	10 (11)	12 (13)	-	-
Pyrexia	16 (14)	8 (7)	1 (1)	-	18 (20)	8 (9)	-	-

AEs: adverse events; IRR: infusion related reaction; URTI: upper respiratory tract infection

Events of Clinical Interest – PI3K Specific

	Treatment-naïve N=116			Previously Treated N=90		
AEs, n (%)	Any	Grade ≥3	Discontinued U2[b]	Any	Grade ≥3	Discontinued U2[b]
ALT elevation	27 (23)	14 (12)	3 (3)	8 (9)	3 (3)	-
AST elevation	21 (18)	9 (8)	3 (3)	7 (8)	2 (2)	-
Rash[a]	17 (15)	4 (3)	1 (1)	9 (10)	1 (1)	1 (1)
Pneumonia	14 (12)	8 (7)	1 (1)	18 (20)	10 (11)	1 (1)
Colitis (non-infectious)[a]	8 (7)	3 (3)	-	2 (2)	1 (1)	1 (1)
Pneumonitis	4 (3)	1 (1)	2 (2)	2 (2)	-	1 (1)
Opportunistic infections[a]	3 (3)	1 (1)	1 (1)	3 (3)	1 (1)	-

AE: adverse event; PT: previously treated; TN: treatment-naïve; U2: umbralisib + ublituximab. [a]Group includes multiple MedDRA terms. [b]Reported as n (%) of patients whose primary reason for discontinuing all therapy was due to respective AEs.

CONCLUSIONS

- UNITY-CLL is the first randomized trial of a PI3Kδ inhibitor (umbralisib) versus chemoimmunotherapy in treatment-naïve CLL
- U2 is a novel, non-chemotherapeutic regimen that is highly active in the treatment of CLL, with demonstrated efficacy including prolonged progression-free survival compared to chemoimmunotherapy (O+Chl) and a well-tolerated safety profile
- U2 demonstrated a tolerable safety profile in both the treatment-naïve and previously treated populations
- U2 regimen is being explored as a backbone for triplet combinations, including combinations with venetoclax and BTK inhibitors

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- Thank you to the patients, their families and caregivers for their participation
- Thank you to the investigators, research staff, and the entire UNITY-CLL study team

STUDY DESIGN

UNITY-CLL Study Design (UTX-TGR-304)

Patients (N=421)
- Treatment-naive or relapsed/refractory CLL
- Requiring treatment per iwCLL criteria
- Adequate organ function
- ECOG PS ≤2

Stratification
- del(17p): present vs absent
- Treatment status: treatment-naïve vs previously treated

RANDOMIZE 1:1

- **Umbralisib + Ublituximab (U2)**: 800 mg PO QD; 900 mg IV on D1/2, 8, 15 of Cycle 1, D1 of Cycles 2 – 6, D1 Q3 cycles
- **Obinutuzumab + Chlorambucil (O+Chl)**: 1000 mg IV on D1/2, 8, 15 of Cycle 1, D1 of cycles 2 – 6; 0.5 mg/kg PO on D1 and D15 Cycles 1 – 6

Primary endpoint
- IRC-assessed PFS U2 vs O+Chl

Secondary endpoints
- IRC-assessed: - ORR, CR, DOR
- uMRD (central)
- Safety

UNITY-CLL Study Design (UTX-TGR-304)

- Trial also initially randomized patients to umbralisib and ublituximab monotherapy cohorts, contribution analysis on first 50 subjects per arm supported closure of enrollment to those arms
- **In primary analysis, U2 improved PFS compared to chemoimmunotherapy in both treatment-naïve and previously treated populations**

The current analysis focuses on outcomes in U2-treated patients by prior treatment status. Data cutoff is the same as primary analysis – May 1, 2020

CLL: chronic lymphocytic leukemia; CR: complete response; DOR: duration of response; ECOG PS: Eastern Cooperative Oncology Group performance status; IRC: independent review committee; IV: intravenously; ORR: overall response rate; PFS: progression-free survival; PO: orally; Q3: every 3; QD: daily; uMRD: undetectable minimal residual disease; D1/2 signifies split doses ublituximab (150 mg / 750 mg) obinutuzumab (100 mg /900 mg); cycles were 28 days. U2 combination continued until progressive disease, unacceptable toxicity, or withdrawal of consent.

Disclosures
RJ - AbbVie Inc., Adaptive Biotechnologies, ADC Therapeutics, AstraZeneca, Genentech, Janssen, MEI Pharma, Pharmacyclics LLC, an AbbVie Company, Sanofi, SecuraBio, TeneoBio, TG Therapeutics, Inc., and Verastem. **WJ** - AbbVie Inc., AstraZeneca, Bayer, BeiGene, Celgene, Celltrion Healthcare, Debiopharm, Epizyme, Incyte, Janssen, Loxo Oncology, Mei Pharma, Merck, MorphoSys, Novo Nordisk, Roche, Sandoz, Takeda, and TG Therapeutics, Inc. **IWF** - AbbVie Inc., Acerta Pharma, Agios, ArQule, AstraZeneca, BeiGene, Calithera Biosciences, Celgene, Century Therapeutics, Constellation Pharmaceuticals, Curis, FormaTherapeutics, Forty Seven, Genentech, Gilead Sciences, Inc., Great PointPartners, Hutchison MediPharma, IGM Biosciences, Ikouda Therapeutics, Incyte, Infinity Pharmaceuticals, Janssen, Johnson & Johnson, Juno Therapeutics, Karyopharm Therapeutics, Kite, a Gilead Company, Loxo Oncology, Merck, MorphoSys, Novartis, Nurix Therapeutics, Pfizer, Pharmacyclics LLC, an AbbVie Company, Portola Pharmaceuticals, Rhizen Pharmaceuticals, Roche, Sarah Cannon Research Institute, Seagen Inc., Seattle Genetics, Servier Pharmaceuticals, Takeda, Teva, TG Therapeutics, Inc., Trillium Therapeutics, Triphase Research & Development Corp., Unum Therapeutics, Verastem, Vincerx Pharma, and Yingli Pharmaceuticals. **SG, SFZ and SK** have nothing to disclose. **KG** - AbbVie Inc., Amgen, AstraZeneca, BeiGene, Gilead Sciences, Inc., GSK, Janssen, Karyopharm Therapeutics, Novartis, Pfizer, Polish Myeloma Consortium, Next Generation Hematology Association, Roche, Sandoz, Sanofi -Genzyme, Takeda, Teva, and TG Therapeutics, Inc. **TW** - BeiGene, Bristol Meyers Squibb, Janssen, Novartis, Roche, and Takeda. **JLC** - BeiGene. **AVD** - AbbVie Inc., AstraZeneca, Bayer Oncology, BeiGene, Bristol Meyers Squibb, Genentech, Gilead Sciences, Inc., Pharmacyclics LLC, an AbbVie Company, Rigel Pharm, SecuraBio, Takeda Oncology, and TG Therapeutics, Inc. **JMB** - AbbVie Inc., Adaptive Biotechnologies, AstraZeneca, BeiGene, Bristol Meyers Squibb, Epizyme, Kura Oncology, Kymera, MorphoSys, RocheGenentech, Seagen Inc., Verastem, and Xᴀ Pharmaceuticals. **JG** - Amgen, Blue Ridge Cancer Care, Bristol Meyers Squibb, Gs Therapeutics, Ontada, and TG Therapeutics, Inc. **DFB, PFM, and MKW** - TG Therapeutics, Inc. **SFH** - AbbVie Inc., AstraZeneca, Bayer, Celgene, DTRM Biopharm, Flatiron Health Inc., Genentech, Novartis, Pharmacyclics LLC, an AbbVie Company, Seagen Inc., Servier, TG Therapeutics, Inc., and Thyme Inc. **JPI** - AbbVie Inc., AstraZeneca, Janssen, MEI Pharma, Novartis, Sellas, Sunesis, Takeda, and TG Therapeutics, Inc. **JPS** - AbbVie Inc., AstraZeneca, BeiGene, Bristol Meyers Squibb, Centessa, Lilly, Pharmacyclics LLC, an AbbVie Company, and TG Therapeutics, Inc. **TS** - AbbVie Inc., AstraZeneca, BeiGene, Bristol Meyers Squibb, Celgene, Dava Oncology, Janssen, Juno therapeutics, Kite Pharma, and PCYC. **DMB** - AbbVie Inc., ArQule, ArQule/Merck, Ascentage Pharma, AstraZeneca, BeiGene, DTRM Biopharma, Genentech, Juno Therapeutics/Celgene/Bristol Myers Squibb, Loxo Oncology, MEI Pharma, NCCN, Novartis, Pfizer, Pharmacyclics LLC, an AbbVie Company, TG Therapeutics, Inc., and Verastem. **MS** - AbbVie Inc., Adaptimmune, Adaptive Biotechnologies, AstraZeneca, Atara Biotherapeutics, Inc., BeiGene, Bristol Myers Squibb, Celgene, Eli Lilly, Epizyme, Genentech, Gennab, Gilead Sciences, Inc., Innate Pharma, Kite Pharma, MorphoSys, Mustang Bio, Pharmacyclics LLC, an AbbVie Company, Sound Biologics, Sunesis, and TG Therapeutics, Inc. **JMP** - Actinium Pharmaceuticals, AstraZeneca, BeiGene, Epizyme, Gilead Sciences, Inc., Incyte/MorphoSys, Kite, a Gilead Company, MEI Pharma, and Pharmacyclics LLC, an AbbVie Company. **MDD** - AbbVie Inc., Acerta Pharma, BeiGene, Incyte, Janssen, MacroGenics, MEI Pharma, Roche, Servier, and Takeda. **NG** - AbbVie Inc., Adaptive Biotechnologies, ADC Therapeutics, AstraZeneca, Bristol Myers Squibb, Epizyme, Genentech, Genmab, Gilead Sciences, Inc., Incyte, Janssen, Karyopharm Therapeutics, Pharmacyclics LLC, an AbbVie Company, Seattle Genetics, and TG Therapeutics, Inc. **KSK** - Atara Biotherapeutics, Inc., McKesson Specialty Health, Sumitomo Dainippon Pharma, TG Therapeutics, Inc., and Tolero Pharma. **OAO** - Dren, Kymera, Mundipharma, Myeloid Therapeutics, Nomocan, and TG Therapeutics, Inc. **JGG** - AbbVie Inc., AstraZeneca, Bristol Meyers Squibb, Gilead Sciences, Inc./Kite, Janssen, Morphosys, Novartis, Takeda, and TG Therapeutics, Inc.