

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 31, 2015**

TG Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-32639
(Commission File Number)

36-3898269
(IRS Employer Identification No.)

3 Columbus Circle, 15th Floor
New York, New York 10019
(Address of Principal Executive Offices)

(212) 554-4484
(Registrant's telephone number, including area code)

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.
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
 - Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.
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Item 8.01. Other Events.

On May 31, and June 1, 2015, TG Therapeutics, Inc. (the "Company") issued press releases announcing certain data regarding its clinical studies of TGR-1202, TG-1101 in combination with TGR-1202, and TG-1101 in combination with TGR-1202 and ibrutinib, respectively. Copies of the press releases are being filed as Exhibits 99.1 and 99.2 and incorporated in this Item by reference. In addition, the Company hosted an analyst and investor event on Sunday, May 31st, 2015 with formal presentations from Nathan Fowler, MD, with MD Anderson Cancer Center, Anthony Mato, MD, with University of Pennsylvania and Owen O'Connor, MD, PhD, with Columbia University Medical Center. A copy of the presentation from the event is being filed as Exhibit 99.3 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated May 31, 2015.

99.2 Press Release, dated June 1, 2015.

99.3 Investor and Analyst Event Presentation, dated May 31, 2015

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 hereunto duly authorized.

TG Therapeutics, Inc.
(Registrant)

Date: June 1, 2015

By: /s/ Sean A. Power
Sean A. Power
Chief Financial Officer

INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated May 31, 2015.
99.2	Press Release, dated June 1, 2015.
99.3	Investor and Analyst Event Presentation, dated May 31, 2015

**TG Therapeutics, Inc. Announces Presentations of its Proprietary Combination of
TG-1101 plus TGR-1202 as well as TGR-1202 as a Single Agent in Ongoing Phase
I/Ib Dose Escalation Clinical Studies**

Triple therapy cohort of the combination study to be presented separately as an oral presentation tomorrow morning, Monday, June 1st, 2015, at 51st American Society of Clinical Oncology (ASCO) Annual Meeting

Data from both studies (over 135 patients combined between single agent and combination studies) continues to demonstrate a favorable safety profile with a high level of activity and a significant dose-response relationship observed

85% (11 of 13) CLL/SLL patients treated at the higher doses of 1202 as a single agent and in combination with TG-1101 achieved a nodal response, with most CLL patients achieving a Partial Response per iwCLL (Hallek 2008) criteria with patients on study pending further assessment

50% (3 of 6) Overall Response Rate (ORR) in Follicular Lymphoma (FL) patients treated with the higher doses of single agent TGR-1202

41% (3 of 7) ORR in patients with Diffuse Large B-Cell Lymphoma (DLBCL) treated at the higher doses of the combination of TG-1101 and TGR-1202, and a clinical benefit rate (patients achieving stable disease or better) of 86% (6 of 7)

TGR-1202 alone and in combination with TG-1101 continues to be well-tolerated with limited Grade 3/4 events and ≤5% of the patients across both studies discontinuing for adverse events, none of which were hepatic toxicity or colitis, with over 50 patients between both studies on therapy 6+ months

NEW YORK, May 31, 2015-- TG Therapeutics, Inc. (Nasdaq:TGTX), today announced clinical results from two ongoing studies of its oral, once-daily, PI3K delta inhibitor, TGR-1202, as a single agent and in combination with TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody. Data from these two Phase I dose escalation studies are being presented today at the morning poster sessions (8-11:30am CT) during the 51st American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "We continue to be impressed with the safety and efficacy profile of TGR-1202, as a single agent, and in combination with TG-1101, and we believe the high level of activity and our differentiated safety profile seen to date, where elevations of ALT/AST are rarely seen and colitis has yet to be observed will position our proprietary combination to play an important role in the management of patients with B-cell malignancies. Unfortunately, in the United States alone, approximately 100,000 individuals will be diagnosed with NHL and CLL per year and a similar amount will relapse from their disease annually. Even with the best new treatments options, few of these patients will actually be cured. We believe the safety, and activity profile seen to date with TG-1101 plus TGR-1202 will compare quite favorably to alternative doublet treatment options and provides us a strong base regimen to build upon as we push further into novel triple and quad therapies." Mr. Weiss, continued, "As we are nearing completion of our dosing work, we are excited to turn our attention to the next phase of development for our proprietary '1303' combination in CLL and NHL, with the goal of launching at least two Phase 3 studies before the end of this year. These new Phase 3 studies will complement our on-going GENUINE Phase 3 trial exploring the combination of TG-1101 plus ibrutinib in previously treated patients with high-risk CLL, which is now aggressively recruiting patients."

The following summarizes the posters presented today:

Abstract Number 8548: Ublituximab plus TGR-1202 activity and safety profile in relapsed/refractory B-cell NHL and high-risk CLL

Today's poster presentation includes data from 55 patients with advanced relapsed and refractory high-risk CLL and NHL patients treated with the combination of TG-1101 and TGR-1202 at doses through 1200 mg micronized QD.

Highlights from this poster include:

- 83% (5 of 6) of CLL/SLL patients in the "high dose" cohort achieved a partial response (CLL evaluated per iwCLL 2008 criteria)
- 64% (7 of 11) ORR in patients with FL treated at the higher doses
- 50% (4 of 8) ORR in patients with DLBCL and Richter's treated at the higher doses
- Significant dose-response relationship was observed between the high and low doses in all patients, particularly in FL and DLBCL, where a significant increase in complete response rates was observed in the higher dose group
- Combination well tolerated with only 5% of patients discontinuing due to an adverse event and 33% of patients on study for 6+ months

Overview of the data presented on TGR-1202 in combination with TG-1101 (ublituximab):

Safety and Tolerability

TG-1101 in combination with TGR-1202 (referred to as "TG-1303") has been well tolerated in the 55 patients evaluable for safety, at all dose levels up through 1200 mg micronized, the highest dose level tested to date. Day 1 infusion related reactions (IRR) have been the most frequently reported adverse event in 29% of patients, with all but 1 event being Grade 1 or 2 in severity and occurring more frequently in patients with CLL. Neutropenia was the only Grade 3/4 event reported in > 5% of patients (24%), however, the inclusion criteria in this study allowed enrollment of patients with existing baseline Grade 3 neutropenia. Of the 55 patients to date, only 3 (5%) have discontinued due to an adverse event. Notably, with respect to preliminary long-term tolerability, 18 patients (33%) have now been on TG-1101 plus TGR-1202 for 6+ months, with no reported events of colitis.

Clinical Activity

The study design evaluated sequential dosing cohorts with fixed doses of TG-1101 and escalating doses of TGR-1202 with both the original formulation and the micronized formulation, which have been classified based on exposure into “lower dose” and “higher dose” cohorts (higher dose classified as 1200 mg of the original formulation or ≥600 mg of the micronized formulation). A significant dose-response relationship was observed between the high and low doses in all 39 patients evaluable for efficacy at the time of the study cut-off, particularly in the NHL patients (FL, DLBCL), where a significant increase in complete response rates was observed in the higher dose group. A breakdown of responses by high and low dose is illustrated in the table below:

Type	TGR-1202 Higher* Dose						Type	TGR-1202 Lower** Dose					
	Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)		Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)
CLL/SLL	6	-	5	5 (83%)	1	-	CLL/SLL	7	1	3	4 (57%)	3	-
DLBCL	7	2	1	3 (43%)	3	1	DLBCL	3	-	-	-	1	2
FL/MZL	11	2	5	7 (64%)	4	-	FL/MZL	4	-	1	1 (25%)	3	-
Richter’s	1	-	1	1 (100%)	-	-	Richter’s	-	-	-	-	-	-
Overall	25	4	12	16 (64%)	8	1	Overall	14	1	4	5 (36%)	7	2
*Higher Dose = 1200 original formulation and 600 or > micronized						**Lower Dose = 800 original formulation and 400 micronized							

Of the 15 patients evaluable for efficacy with FL and Marginal Zone lymphoma (MZL), the dose-response relationship observed was significant, with the higher dose cohorts demonstrating a 64% ORR, with 2 Complete Responses compared to a 25% ORR in the lower dose cohort. The same trend has been observed in the more aggressive lymphomas (DLBCL and Richter’s) where 50% (4 of 8) achieved an objective response (2 CR and 2 PR) compared to no responses seen in the lower dose cohorts. Of note, 86% (6 of 7) of the DLBCL patients in the higher dose cohorts who had at least one efficacy assessment (week 8) remain on study progression free, with 71% (5 of 7) having GCB subtype, which has historically been less responsive to BCR targeted therapy.

As seen with TGR-1202 as a single agent, responses have been shown to improve over time, with 3 of the 5 CR’s achieved at subsequent efficacy assessments.

Commenting on the combination data, Dr. Matthew Lunning, Division of Hematology/Oncology, University of Nebraska Medical Center and lead author of the presentation stated, "We continue to remain impressed not only by the safety profile of the combination, but especially by the efficacy demonstrated in this very advanced CLL and NHL patient population. We look forward to continuing enrolling in the CLL and NHL expansion cohorts, with a focus on refractory DLBCL patients who have very limited options, to further evaluate this novel and exciting combination." Dr. Lunning continued, "The safety and efficacy profile of the combination of TG-1101 and TGR-1202 is well suited as a platform regimen for further combination studies and I look forward to the presentation of the first ever triple combination of TG-1101 plus TGR-1202 plus ibrutinib in an oral presentation tomorrow to be given by Dr. Nathan Fowler of MD Anderson."

Abstract Number 7069: “Clinical activity and safety profile of TGR-1202, a novel once daily PI3K delta inhibitor, in patients with CLL and B-cell lymphoma”

Today’s poster presentation includes data from 66 patients with relapsed and refractory hematologic malignancies treated with single agent TGR-1202 at escalating doses up through 1200 mg micronized QD. Highlights from this poster include:

- 88% (14 of 16) CLL patients achieved a nodal response with 63% achieving a partial response per iwCLL (Hallek 2008) criteria
- Significant exposure-response trend observed in both CLL and NHL, with higher plasma TGR-1202 exposures correlating with increased responses at 800 and 1200 mg once daily micronized doses
- TGR-1202 continues to be well tolerated with limited Grade 3/4 events with 44% of patients on study 6+ months and <5% of patients discontinuing TGR-1202 due to an adverse event, differentiating TGR-1202 from other PI3K-delta inhibitors, especially with respect to hepatic toxicity and colitis

Overview of the data presented on single agent TGR-1202:

Safety and Tolerability

In the 66 patients evaluable for safety, TGR-1202 has been well-tolerated with no dose-related trends in adverse events observed and patients on study for upwards of 2+ years. Grade 3 events continue to be limited with only 3 patients (< 5%) having discontinued study due to an adverse event, none of which were for hepatic toxicity or colitis which have been common and potentially serious and life threatening with other PI3K-delta inhibitors. Neutropenia was the only Grade 3/4 event reported in >10% of patients (11%). Notably, with respect to preliminary long-term tolerability, 29 patients (44%) have now been on TGR-1202 for 6+ months, with some patients on TGR-1202 for 2+ years, with no reported events of colitis.

Clinical Activity

Significant clinical activity was observed in patients with CLL treated at doses \geq 800 mg with 88% of CLL patients (14 of 16) achieving a nodal PR, and 10 of 16 (63%) of patients achieving a response per iwCLL (Hallek 2008) criteria. The remaining two patients exhibited nodal reductions and remain on study awaiting upcoming efficacy assessments.

In patients with NHL, 83% (10 of 12) of FL patients had a reduction in their disease burden with 50% (3 of 6) of patients treated at the higher doses achieving a partial response. Of the more aggressive lymphomas including MCL and DLBCL, 55% (6 of 11) had a disease burden reduction, many associated with long-term stable disease and 3 of these patients achieving a PR. An exposure-response trend was noted in both CLL and NHL patients. Higher plasma TGR-1202 exposures correlated with increased responses in the majority of patients treated. In addition, similar to other BCR antagonists, late onset responses and evolving responses have been common, especially in CLL and FL.

Enrollment into the study continues in the 800 mg micronized dose expansion cohort for CLL patients as well as in the 1200 mg micronized dose expansion cohort for NHL and Hodgkin's patients.

Dr. Howard A. Burris, a principal investigator for the study and Chief Medical Officer and Executive Director of the Drug Development Program at the Sarah Cannon Research Institute in Nashville, Tennessee stated, "Since treating our first patient back in January 2013, we have been very pleased with the safety profile and clinical activity of TGR-1202, coupled with the convenience of once daily dosing. The ability to keep patients on therapy where they have the opportunity for greater response and a longer duration of disease control is of importance in this advanced population. Having participated in the development of other PI3K delta inhibitors, the minimal side effects of TGR-1202, including a lack of hepatotoxicity, is noticeable to our physicians and nurses. We are excited to continue developing TGR-1202 and look forward to participating in the phase 3 trials."

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing TGR-1202, an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. The Company also has pre-clinical programs to develop IRAK4 inhibitors, and anti-PD-L1 and anti-GITR antibodies. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release, particularly those with respect to anticipating future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, and the anti-PD-L1 and anti-GITR antibodies may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially are the following: our ability to successfully and cost-effectively complete pre-clinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 study; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical and clinical trials, particularly with respect to the incidence of colitis and liver toxicity; the risk that trials will take longer to enroll than expected; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.tgtherapeutics.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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TG Therapeutics Announces the Triple Combination of TG-1101, TGR-1202 and Ibrutinib is Safe and Highly Active in Patients with Advanced B-Cell Malignancies

Data presented this morning by Dr. Nathan Fowler, MD Anderson Cancer Center, at the 51st American Society of Clinical Oncology (ASCO) Annual Meeting, provides proof of concept that the chemotherapy-free triple combination of TG-1101, TGR-1202 and ibrutinib can be safely administered at active doses in patients with relapsed or refractory high-risk CLL and advanced NHL

Minimal adverse events reported to date with Grade 3 or 4 events seen in 6% of patients, with no patients discontinuing treatment due to an adverse event up through 800 mg micronized TGR-1202 and patients remaining on treatment now up to 9.5+ months

100% (4/4) ORR in patients with CLL/SLL with all CLL patients having high-risk features (17p del) and 75% ORR in iNHL (FL/MZL) with one ibrutinib refractory Follicular Lymphoma patient achieving a durable Partial Response

All responses were rapid and profound with a 76% median reduction in disease burden at first efficacy assessment, with all patients who had a subsequent efficacy assessment achieving a deeper response with a median 92% reduction

NEW YORK, June 1, 2015-- TG Therapeutics, Inc. (Nasdaq: TGTX), today announced clinical results from its ongoing study with TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with the Company's oral, once-daily, PI3K delta inhibitor, TGR-1202 and ibrutinib, a BTK inhibitor. Data from this Phase I dose escalation study was presented today by Dr. Nathan Fowler, Director, Developmental Therapeutics, Department of Lymphoma, MD Anderson Cancer Center at the Lymphoma Oral Session during the 51st American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commented on the data, "The ability to safely combine these three agents highlights why we have been so focused on the importance of the safety profile of our proprietary combination of TG-1101 plus TGR-1202, which we refer to as "TG-1303". We firmly believe the future paradigm for the treatment of B-cell malignancies will consist of the combination of multiple novel non-chemotherapy agents, where the safety profile of the chosen backbone regimen, like TG-1303, will be critical. A favorable safety profile is critical to unlocking the potential to explore whether dramatic activity with these novel multiple drug combinations can be seen. We believe Dr. Fowler presented some intriguing evidence of significant activity across multiple B-cell malignancy sub-types using this novel chemotherapy-free triple combination made possible by the 1303 safety profile." Mr. Weiss continued, "We look forward to continuing to explore this and other novel triple combinations in the future as we drive to create best-in-class combinations that can materially and positively impact the lives of those living with B-cell malignancies."

The following summarizes the oral presentation:

Abstract Number 8501: Safety and activity of the chemotherapy-free triplet of ublituximab, TGR-1202, and ibrutinib in relapsed B-cell malignancies

Today's oral presentation includes data from 16 patients with advanced relapsed and refractory high-risk CLL and NHL patients treated with the combination of TG-1101, TGR-1202 and ibrutinib at doses up through 800 mg micronized QD with TGR-1202.

Safety and Tolerability

TG-1101 in combination with TGR-1202 and ibrutinib has been well tolerated in the 16 patients evaluable for safety, at dose levels up through 800 mg micronized, the highest dose level tested to date in the study. Three cohorts for each CLL and NHL were evaluated with TGR-1202 dose escalation starting with micronized doses of 400 mg (cohort 1), followed by 600 mg (cohort 2) and 800 mg (cohort 3), in combination with TG-1101 at 900 mg and ibrutinib daily at 420 mg (CLL) and 560 mg (NHL). Day 1 infusion related reactions (IRR) have been the most frequently reported adverse event in 25% of patients, with no Grade 3 or 4 events of IRR. Other adverse events were manageable, with Grade 3 and 4 events occurring in only 6% of patients. Of the 16 patients treated to date, no patients discontinued due to an adverse event. One patient in the CLL cohort at 400 mg had a reactivation of varicella zoster which delayed dosing and met the definition of a dose limiting toxicity requiring an additional 3 patients in the CLL cohort 1 (400 mg micronized), which are currently being recruited. No DLT's were observed in the NHL cohorts up through 800 mg micronized.

Clinical Activity

Clinical activity was observed at all 3 dose levels with 13 of 16 patients evaluable for efficacy (1 patient was removed per investigator discretion and 2 were too early to evaluate). The following is a highlight of responses by CLL and NHL:

- In the CLL/SLL cohort, 100% of patients (4 of 4) achieved an objective response at the first efficacy assessment, with all CLL patients having 17p deletion. All 4 responding patients remain on study now up to 7+ months.
- In patients with heavily pre-treated (≥ 4 prior lines of therapy) Follicular or Marginal Zone lymphoma 75% (3 of 4) achieved an objective response including one ibrutinib refractory patient achieving a PR at the first efficacy assessment. The one patient who achieved stable disease (achieved a 39% nodal reduction) was duvelisib refractory. All FL and MZL patients remain on study awaiting further assessments, now up through 9.5+ months.
- Both Mantle Cell lymphoma (MCL) patients achieved an objective response with 1 patient who had previously relapsed after an autologous stem cell transplant subsequently achieving a complete response. As with the other responding patients, both MCL patients remain on study now through 9.5+ months.
- Of the 3 patients who progressed on study, 1 patient was a Richter's Transformation and 2 were Diffuse Large B-Cell who were both of ABC subtype.

Of importance, patients who responded to the triple combination at their first efficacy assessment (week 8) and were evaluable for a second efficacy assessment (week 20), had an improved response. All responses were rapid and profound with a 76% median reduction in disease burden at the first efficacy assessment, with all patients who had a second response assessment achieving a deeper response with a median 92% reduction.

Commenting on the triple combination data, Dr. Nathan Fowler stated: "Combining multiple targeted agent drugs has long been a goal for investigators but has proved to be a challenge as evidenced by recent studies combining PI3K Delta and SYK inhibitors, and PI3K delta inhibitors and immunomodulators. The fact that we are able to safely combine these 3 novel compounds, a PI3K delta inhibitor, a BTK inhibitor and a glycoengineered anti-CD20 antibody, is a great leap forward in bringing novel non-chemotherapy combinations to patients with advanced disease." Dr. Fowler added, "The triple combination of TG-1101 + TGR-1202 + ibrutinib was not only well tolerated but displayed significant activity in a heavily pretreated and high-risk patient population that has limited options at this stage of their disease. We look forward to continuing to build upon this data and evaluate the triple combination further."

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TG Therapeutics

2015 ASCO Analyst & Investor Event

May 31, 2015

Forward Looking Safe Harbor Statement

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as “anticipates”, “expects”, “plans”, “believes”, “intends”, and similar words or phrases. Such statements involve risks and uncertainties that could cause TG Therapeutics’ actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in clinical trials, drug development, and commercialization. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and TG Therapeutics undertakes no obligation to update these statements, except as required by law.

Event Agenda & Speakers

AGENDA	SPEAKER
Overview & Introductions	Michael S. Weiss, CEO of TGTX
TG-1101 & TGR-1202 Overview	Dr. Owen A. O'Connor
TG-1101 & TGR-1202 in NHL	Dr. Nathan Fowler
TG-1101 & TGR-1202 in CLL	Dr. Anthony Mato
Q&A Session	Dr.'s O'Connor, Fowler & Mato
Closing Remarks	



Owen A. O'Connor, MD, PhD

Professor of Medicine and Experimental Therapeutics
Director of the Center for Lymphoid Malignancies
Columbia University Medical Center

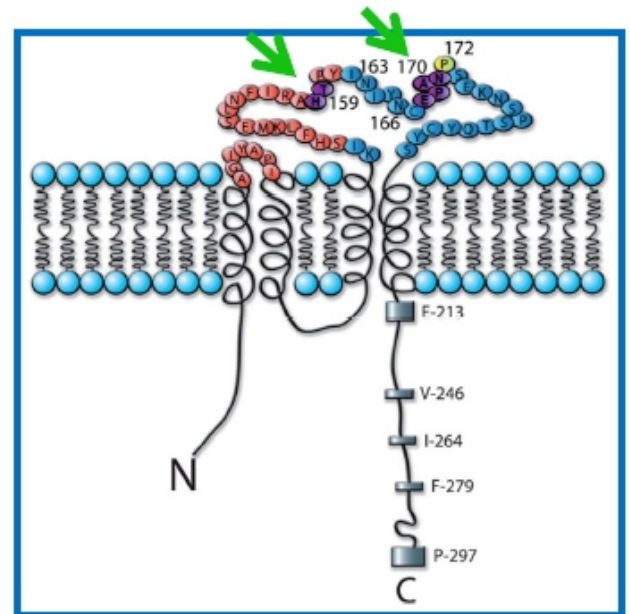
TG-1101 & TGR-1202 Single Agent



TG-1101
(UBLITUXIMAB)

Ublituximab: A Novel Glycoengineered Anti-CD20 mAb

- Unique protein sequence
- Type 1 Chimeric IgG1 mAb
- Potential advantages over current standard of care:
 - Glycoengineered for significantly enhanced ADCC
 - Activity in “low” CD20 expressing cell lines, a characteristic of rituximab resistance
 - Binds to a novel epitope on CD20



Safety of Ublituximab

- Day 1 Infusion Related Reaction most common adverse event
 - manageable with infusion interruptions only and recovered without sequelae
- Infusion times decreased to an average of 90 minutes for the 4th and all subsequent infusions

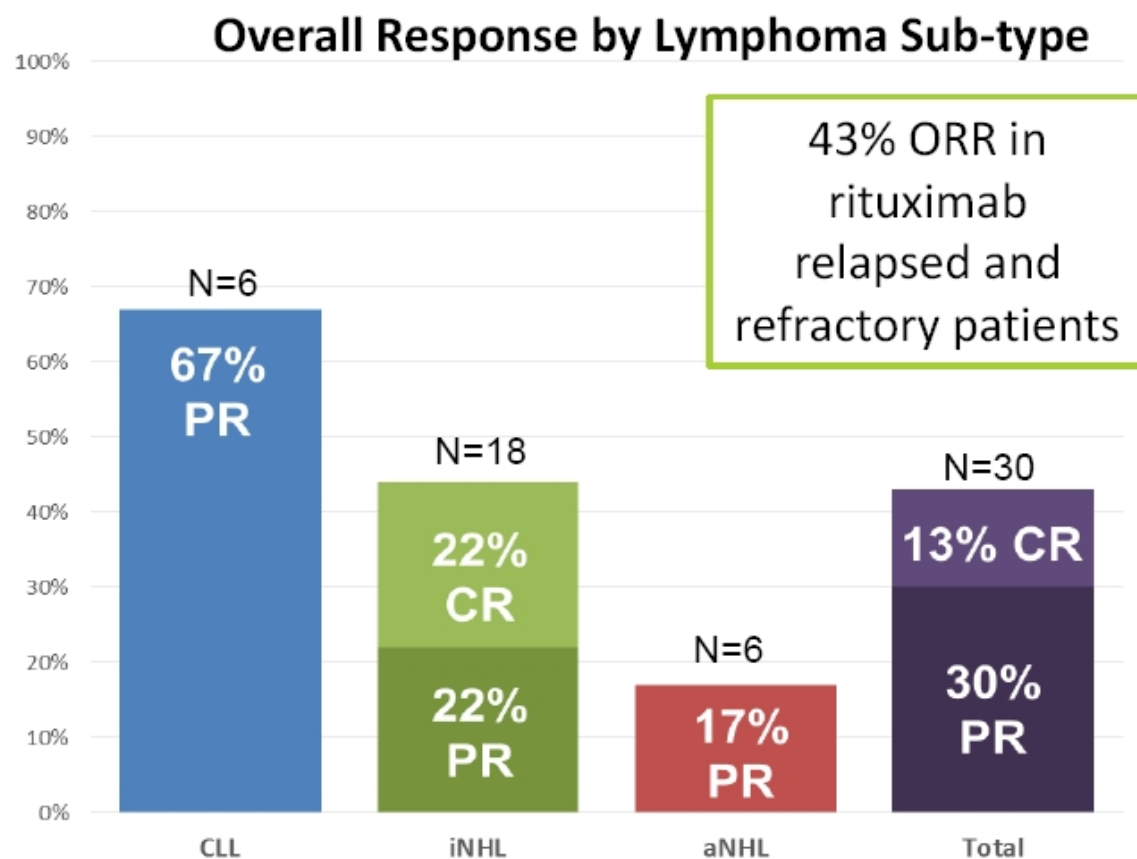
At Least Possibly Related AE's

All Patients (n = 35)		
AE	All Grades n (%)	Grade 3/4 n (%)
Infusion Related Reaction*	10 (29%)	0
Fatigue	5 (14%)	1 (3%)
Diarrhea	4 (11%)	0
Pain (General)	4 (11%)	0
Dysgeusia	3 (9%)	0
Bilirubin Increase	2 (6%)	0
Pruritus	2 (6%)	0

At Least Possibly Related Lab Abnormalities

AE	CLL (n=8)		NHL (n=27)	
	Grade 1/2 n	Grade 3/4 n	Grade 1/2 n	Grade 3/4 n
Neutropenia	1	3	0	0
Thrombocytopenia	1	1	0	0
Anemia	0	0	0	1

Demonstrated single agent activity: TG-1101 Phase 1 Efficacy Results ASCO/EHA 2014



Ublituximab – Take Home Messages

- Well tolerated with minimal IRR complications
- Promising activity in both rituximab relapsed and rituximab refractory patients across all histologies
 - Interesting activity in iNHL—e.g. one rituximab refractory MZL patient transition from hospice to durable (2+ year) Complete Response
- 11 of 30 evaluable patients remained on study >1 year with no complications (2 patients on study >2 years)



TGR-1202

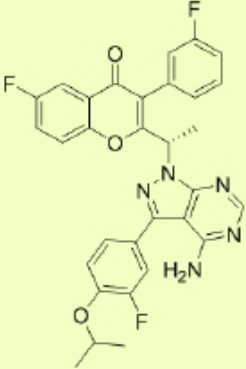
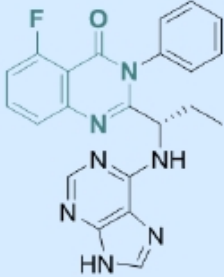
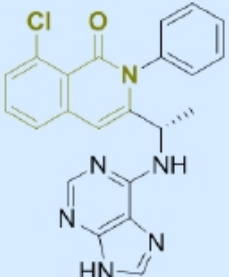
SINGLE AGENT

Clinical activity and safety profile of TGR-1202, a novel once daily PI3K δ inhibitor, in patients with CLL and B-cell lymphoma.

Howard A. Burris III, MD^{1,2}, Manish R. Patel, MD^{1,3}, Timothy S. Fenske, MD⁴, Owen A. O'Connor, MD, PhD⁵, Changchun Deng, MD, PhD⁵, Danielle M. Brander, MD⁶, Martin Gutierrez, MD⁷, Suzanne Jones, PharmD¹, John Kuhn, PharmD⁸, Hari P. Miskin, MS⁹, Peter Sportelli⁹, Swaroop Vakkalanka, PhD¹⁰ and Ian Flinn^{1,11}

¹Sarah Cannon Research Institute, Nashville, TN; ²Tennessee Oncology, PPLC, Nashville, TN; ³Florida Cancer Specialists, Sarasota, FL; ⁴Medical College of Wisconsin, Milwaukee, WI; ⁵Columbia University Medical Center, New York, NY; ⁶Duke University Medical Center, Durham, NC; ⁷John Theurer Cancer Center at Hackensack University Medical Center, Hackensack, NJ; ⁸University of Texas Health Science Center at San Antonio, San Antonio, TX; ⁹TG Therapeutics, Inc., New York, NY; ¹⁰Rhizen Pharmaceuticals SA, La Chaux-de-Fonds, Switzerland; ¹¹Tennessee Oncology, PLLC, Nashville, TN

TGR-1202: Novel PI3K delta Inhibitor

TGR-1202	Idelalisib (GS-1101)	Duvelisib (IPI-145)
		
<p>Delta</p>	<p>Delta</p>	<p>Delta/Gamma</p>
<p>QD</p>	<p>BID</p>	<p>BID</p>

- PK profile that allows once-daily oral dosing
- 93% nodal PR rate in patients with rel/ref CLL¹

¹Burris et al, ASCO 2015, Abstract # 7069

Demographics

Evaluable for Safety (n)	66	
Evaluable for Efficacy (n)	51	
Median Age, years (range)	66 (22 – 85)	
Male/Female	46/20	
Histology	20 CLL	5 MCL
	17 FL	3 MZL
	10 DLBCL	1 HCL
	9 HL	1 WM
ECOG 0/1/2	22/43/1	
Prior Therapies, median (range)	3 (1 – 14)	
Patients with \geq 3 Prior Therapies (%)	36 (55%)	
Patients Refractory to Prior Therapy	34 (52%)	

† Patient's evaluable for efficacy included only patients treated with 800 mg of initial formulation or higher, and any micronized dose level of which the following were excluded: 4 were Too Early To Evaluate, 2 Non-Compliant (both at 1800 mg Fasted), 1 removed per investigator discretion, and 1 Failed Inclusion/Exclusion (Richter's Transformation prior to entry)

Adverse Events in TGR-1202 Treated Patients

All Events in >10% of Pts (N=66)				
AE	All Grades		Gr. 3/4	
	N	%	N	%
Nausea	27	41%	0	0%
Diarrhea	21	32%	1	2%
Fatigue	21	32%	2	3%
Headache	15	23%	0	0%
Vomiting	15	23%	0	0%
Cough	14	21%	0	0%
Decreased Appetite	11	17%	0	0%
Rash	11	17%	3	5%
Constipation	9	14%	1	2%
Hypokalemia	9	14%	3	5%
Anemia	8	12%	5	8%
Dizziness	8	12%	0	0%
Dyspnea	8	12%	3	5%
Neutropenia	8	12%	7	11%
Pyrexia	8	12%	0	0%
Abdominal Pain	7	11%	0	0%

- ❖ Limited Gr. 3/4 events and no significant dose or time dependent trends in AEs observed with 31 patients on study 6+ months
- ❖ **3 patients (< 5%) have discontinued due to an adverse event, none of which for hepatic toxicity, colitis, or pneumonitis**

PI3K-Delta Class AE Profile

	Idela + Ofa (ASCO '15) ² (n=173)	Duvelisib (ASCO '15) ³ (n=18)	Idelalisib Label (CLL & NHL) ¹ (n=256)	TGR-1202 All Studies (ASCO 2015) ⁴ (n=137)
	All Grades (≥Gr 3)	All Grades (≥Gr 3)	All Grades (≥Gr 3)	All Grades (≥Gr 3)
Diarrhea/ Colitis	49% (20%)	78% (22%)	36% (10%)	26% (1%)**
Pneumonia	17% (13%)	N/A	24% (16%)	7% (4%)
ALT Elevations	N/A	N/A	43% (11%)	2% (2%)
AST Elevations	N/A	N/A	34% (7%)	4% (2%)
ALT/AST Elevations	35% (13%)	28% (17%)	N/A	3% (2%)
Discontinuations due to AE	31%	33%	12%	4%

¹Aggregated from Idelalisib Prescribing Information

²Jones et al, ASCO 2015

³Patel et al, ASCO 2015

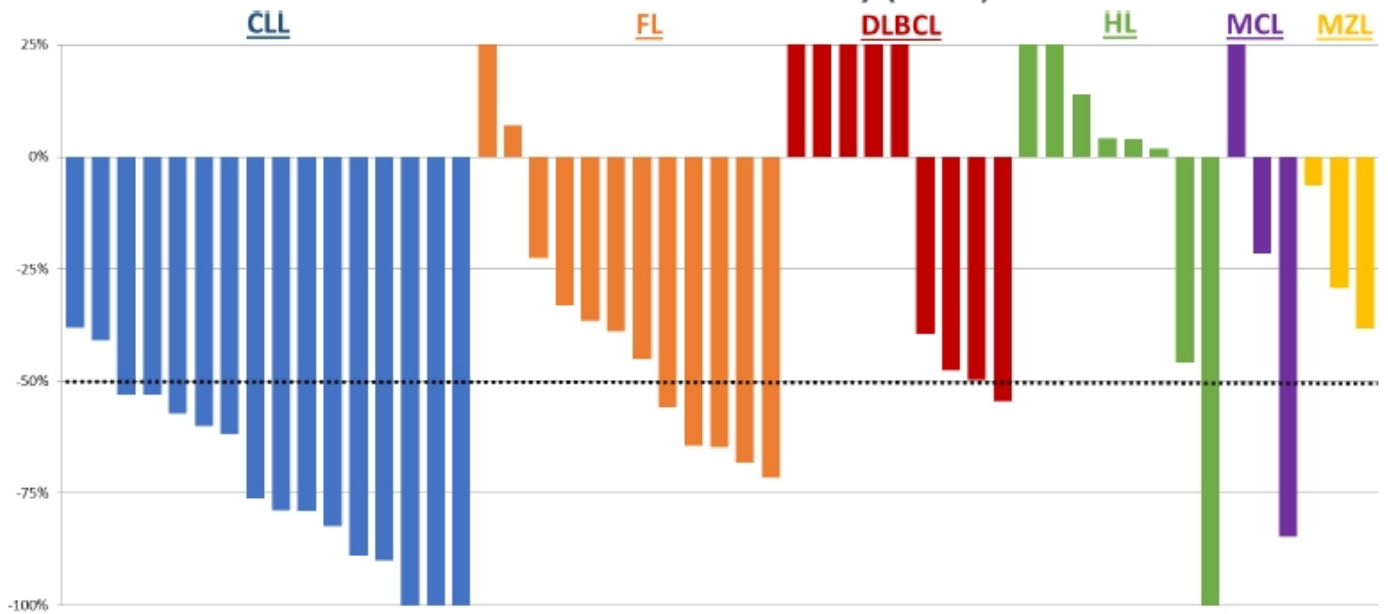
⁴ Aggregated from Burris et al, Lunning et al, Fowler et al, ASCO 2015

** No observed instances of colitis

Overall Efficacy

Best Percent Change from Baseline in Nodal Size

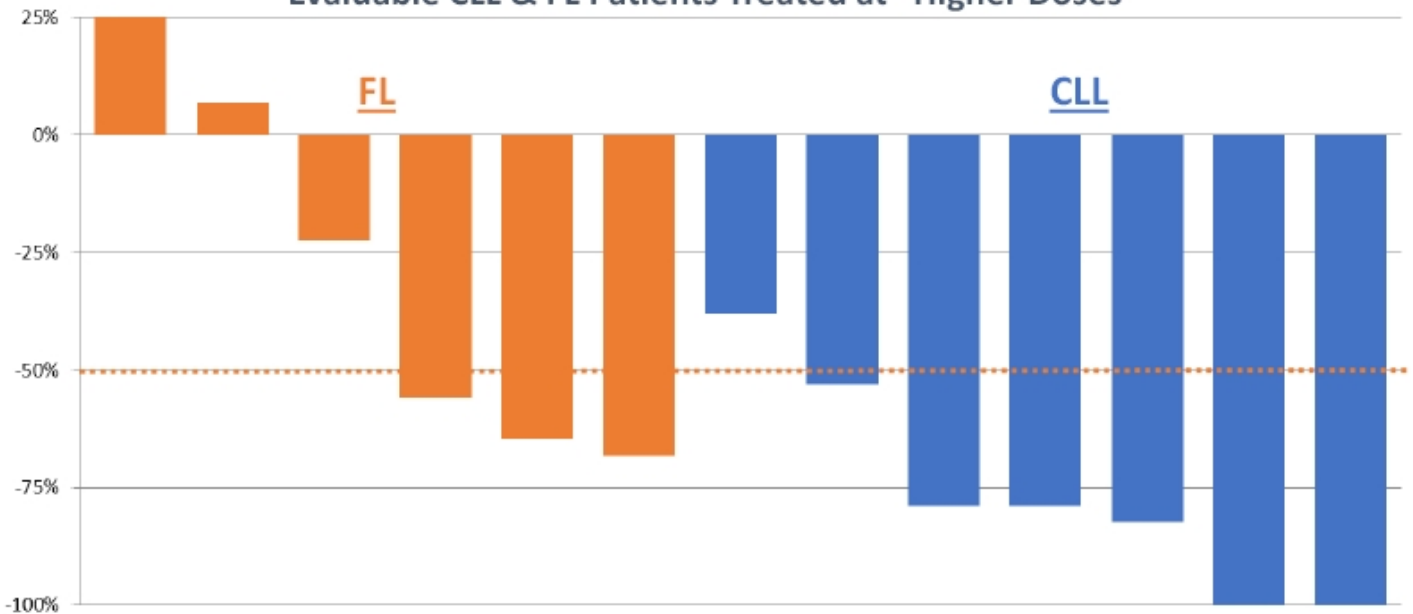
Patients Evaluable for Efficacy (N=51)



- ❖ High level of activity demonstrated across a wide variety of hematologic malignancies

Best Percent Change from Baseline in Nodal Size

Evaluable CLL & FL Patients Treated at “Higher Doses”



- ❖ “Higher Doses” of TGR-1202 (1200 mg initial formulation, or \geq 600 mg micronized) demonstrated rapid and profound responses

TGR-1202 Take Home Messages

- Once-daily PI3K δ inhibitor with single agent activity across B-cell malignancies
 - 88% nodal response rate in rel/ref CLL;
 - 42% ORR in rel/ref FL
 - Patients remaining on therapy pending further efficacy assessments
- Differentiated safety profile from other PI3K δ inhibitors
 - Hepatic toxicity
 - Diarrhea/colitis
 - Pneumonia/pneumonitis
 - Discontinuations due to AE's have been rare

Nathan Fowler, MD

Associate Professor
Lead, New Drug Development
MD Anderson Cancer Center

Combination of TG-1101 & TGR-1202
“TG-1303”

Ublituximab + TGR-1202 Demonstrates Activity and Favorable Safety Profile in Relapsed/Refractory B-Cell NHL and High-Risk CLL

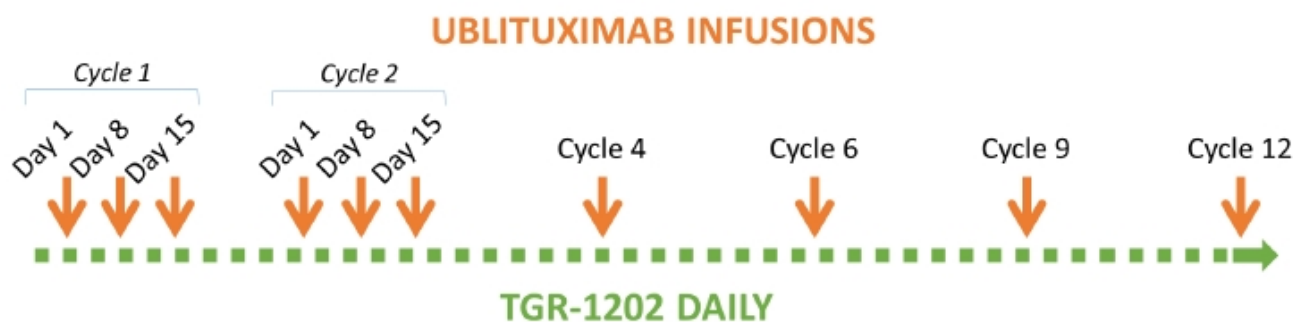
Matthew Lunning, DO¹, Julie Vose, MD¹, Nathan Fowler, MD², Loretta Nastoupil, MD², Jan A. Burger, MD², William G. Wierda, MD², Marshall T. Schreeder, MD³, Tanya Siddiqi, MD⁴, Christopher Flowers, MD⁵, Jonathon Cohen, MD⁵, Susan Blumel, RN, BSN¹, Myra Miguel, RN², Emily K. Pauli, PharmD³, Kathy Cutter, RN³, Brianna Phye, BS⁴, Peter Sportelli⁶, Hari P. Miskin, MS⁶, Michael S. Weiss⁶, Swaroop Vakkalanka, PhD⁷, Srikant Viswanadha, PhD⁸ and Susan O'Brien, MD⁹

¹University of Nebraska Medical Center, Omaha, NE; ²MD Anderson Cancer Center, Houston, TX; ³Clearview Cancer Institute, Huntsville, AL; ⁴City of Hope National Medical Center, Duarte, CA; ⁵Emory University/Winship Cancer Institute, Atlanta, GA; ⁶TG Therapeutics, Inc., New York, NY; ⁷Rhizen Pharmaceuticals S.A, La Chaux-de-Fonds, Switzerland; ⁸Incozen Therapeutics, Hyderabad, India; ⁹University of California Irvine, Orange, CA

Study Design

Cohort	Ublituximab NHL Dose	Ublituximab CLL Dose	TGR Dose (QD)
1	900 mg	600 mg	800 mg
2	900 mg	600 mg	1200 mg
3	900 mg	900 mg	400 mg (micronized)
4	900 mg	900 mg	600 mg (micronized)
5	900 mg	900 mg	800 mg (micronized)
6	900 mg	900 mg	1200 mg (micronized)
Expansion	<i>Currently Enrolling Expansion Cohorts with TGR-1202 at 800 mg and 1200 mg micronized</i>		

Treatment Schedule:



Demographics

Evaluable for Safety (n)	55	
Evaluable for Efficacy [†] (n)	39	
Median Age, years (range)	64 (29 – 86)	
Male/Female	36/19	
Histology	CLL/SLL	15
	DLBCL	16
	FL	16
	MZL	5
	MCL	2
	Richter's	1
ECOG, 0/1/2	17/37/1	
Prior Therapies, median (range)	3 (1 – 9)	
Patients with ≥ 3 Prior Therapies (%)	60%	
Prior RTX Based Therapies, median (range)	3 (1 – 7)	
Refractory to Prior Therapy, n (%)	28 (51%)	

[†]16 Patients not evaluable (13 too early, 1 non-related AE, 1 removed per investigator discretion, 1 ineligible)

Safety

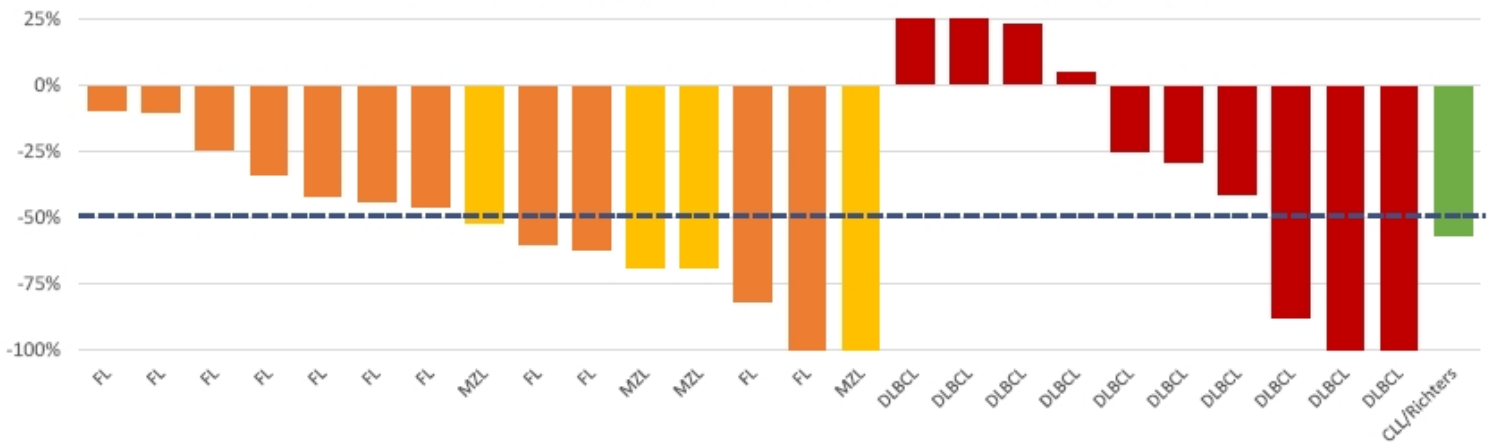
Related AE's Occurring in ≥ 5% of Patients (n = 55)

Adverse Event	All Grades		Grade 3/4	
	N	%	N	%
Infusion Related Reaction	16	29%	1	2%
Neutropenia	15	27%	13	24%
Nausea	15	27%	-	-
Diarrhea	11	20%	1	2%
Fatigue	10	18%	-	-
Vomiting	6	11%	-	-
Abd. Pain/Discomfort	4	7%	-	-
Muscle Cramping	4	7%	-	-
Anemia	3	5%	-	-
Bruising	3	5%	-	-
Hoarseness	3	5%	-	-
Thrombocytopenia	3	5%	-	-

- ❖ 3 patients (~5%) have come off study due to an adverse event, none related to hepatic toxicity or colitis

TG-1101 + TGR-1202 – NHL

Best Percent Change from Baseline in Nodal Size



Type	TGR-1202 Higher* Doses						Type	TGR-1202 Lower** Doses					
	Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)		Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)
CLL/SLL	6	-	5	5 (83%)	1	-	CLL/SLL	7	1	3	4 (57%)	3	-
DLBCL	7	2	1	3 (43%)	3	1	DLBCL	3	-	-	-	1	2
FL/MZL	11	2	5	7 (64%)	4	-	FL/MZL	4	-	1	1 (25%)	3	-
Richter's	1	-	1	1 (100%)	-	-	Richter's	-	-	-	-	-	-
Overall	25	4	12	16 (64%)	8	1	Overall	14	1	4	5 (36%)	7	2

*Higher Dose = 1200 original formulation and 600 or > micronized

**Lower Dose = 800 original formulation and 400 micronized

TG-1101 + TGR-1202 – Higher Doses NHL

Patients Treated at the “Higher Doses” of TGR-1202
Best Percent Change from Baseline in Nodal Size



Type	TGR-1202 Higher* Doses					
	Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)
CLL/SLL	6	-	5	5 (83%)	1	-
DLBCL	7	2	1	3 (43%)	3	1
FL/MZL	11	2	5	7 (64%)	4	-
Richter's	1	-	1	1 (100%)	-	-
Overall	25	4	12	16 (64%)	8	1

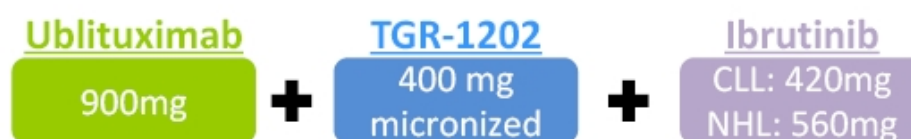
* Higher Dose = 1200 original formulation and 600 or > micronized

TG-1101 + TGR-1202 Take Home Messages

- Combination is well tolerated
 - Grade 3/4 AE's and discontinuations due to AE's have been limited (~5%)
- Activity of the combination has been observed in indolent NHL, and GCB-DLBCL
- Safety profile supports additional multi-drug combination regimens
 - TG-1101 + TGR-1202 + Ibrutinib, oral presentation
Monday, June 1, 2015

ASH 2014: TGR-1202 + Ublituximab + Ibrutinib

- Initial cohorts for both NHL and CLL (n=5)



Histology	Description	Prior # Rx	Prior Ibrutinib	Rel/Ref	Rituximab Refractory	Response	% ↓
Follicular	Stage IV	4	Refractory	Refractory	Yes	PR	74%
MCL	Advanced	2	No	rAuto txp	No	CR	PET -
Richter's	17p	3	No	Refractory	Yes	PD	N/A
CLL	17p	2	No	Refractory	Yes	Too Early	N/A
Follicular	Stage IV	1	No	Refractory	Refractory	Too Early	N/A

- Tomorrow's update to include additional patients evaluable for safety and efficacy



Anthony R. Mato, MD

**Director, Center for CLL
University of Pennsylvania**

**The GENUINE Phase 3 Study
&
TGR-1202 + TG-1101 Combination**

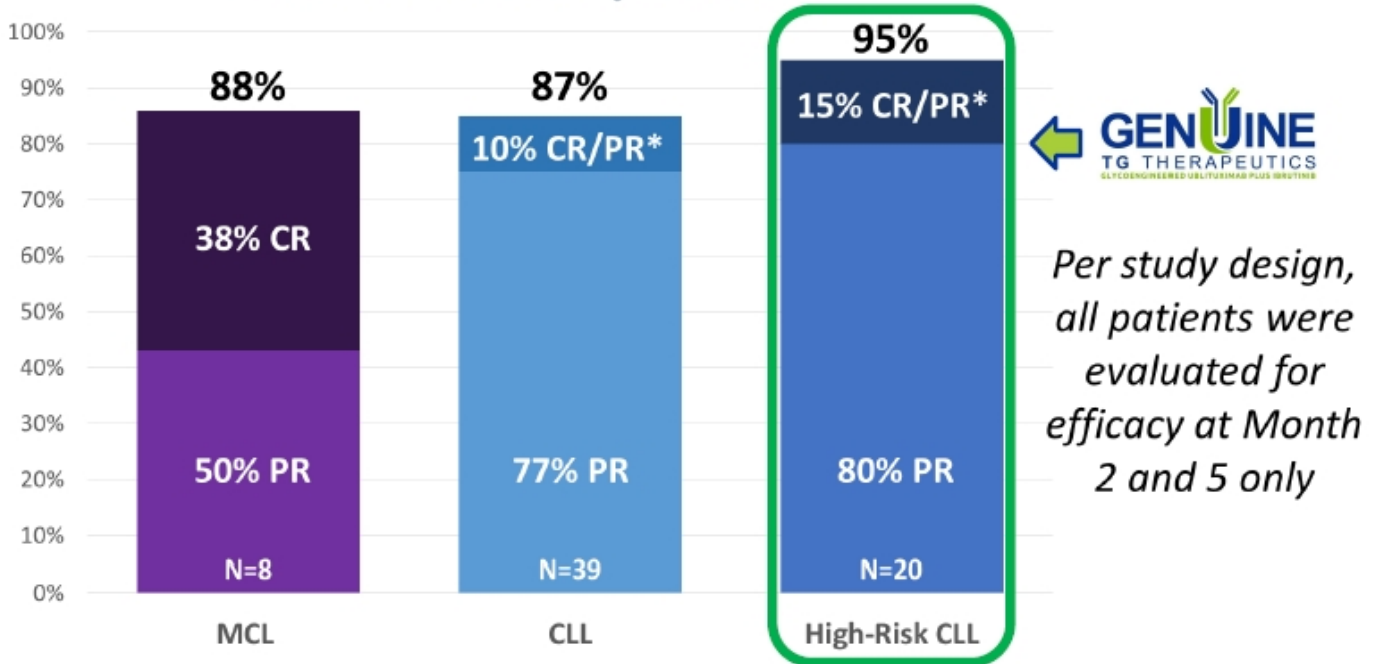


GENUINE PHASE 3 STUDY

Phase II: Ublituximab + Ibrutinib

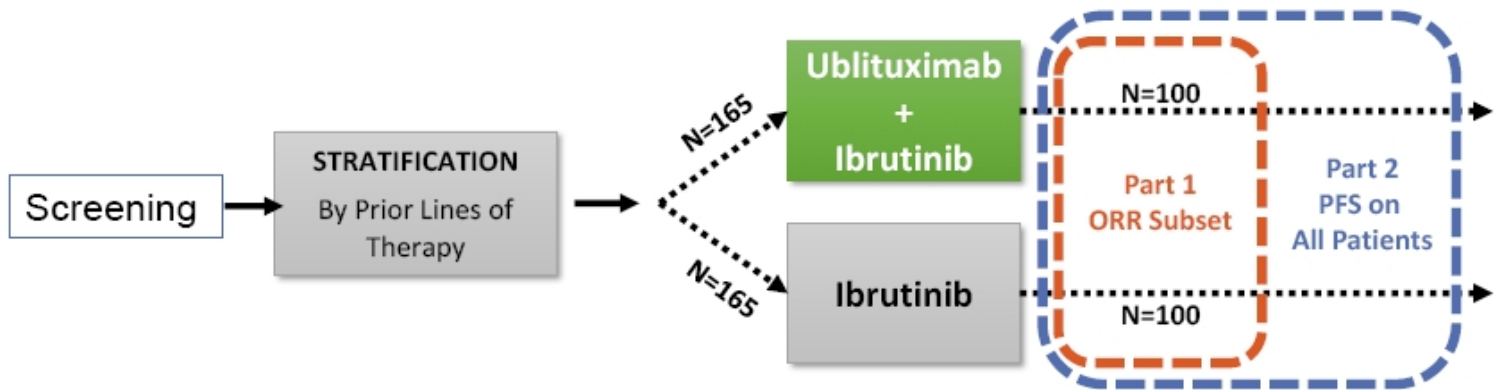
Overall Efficacy

Best Overall Response Rate



CLL assessed by iwCLL (Hallek 2008) Criteria; MCL/SLL assessed by Cheson, 2007 Criteria
 PR* = Complete Response per iwCLL criteria, pending bone marrow confirmation

The GENUINE Phase 3 Trial



- Design, Endpoints, and Statistics agreed to via Special Protocol Assessment (SPA)
- Enrolling ~330 patients with high-risk CLL
- **Part 1:** ORR among first 200 patients
- **Part 2:** PFS of all 330 patients
 - Part 1 to be analyzed following full enrollment of study



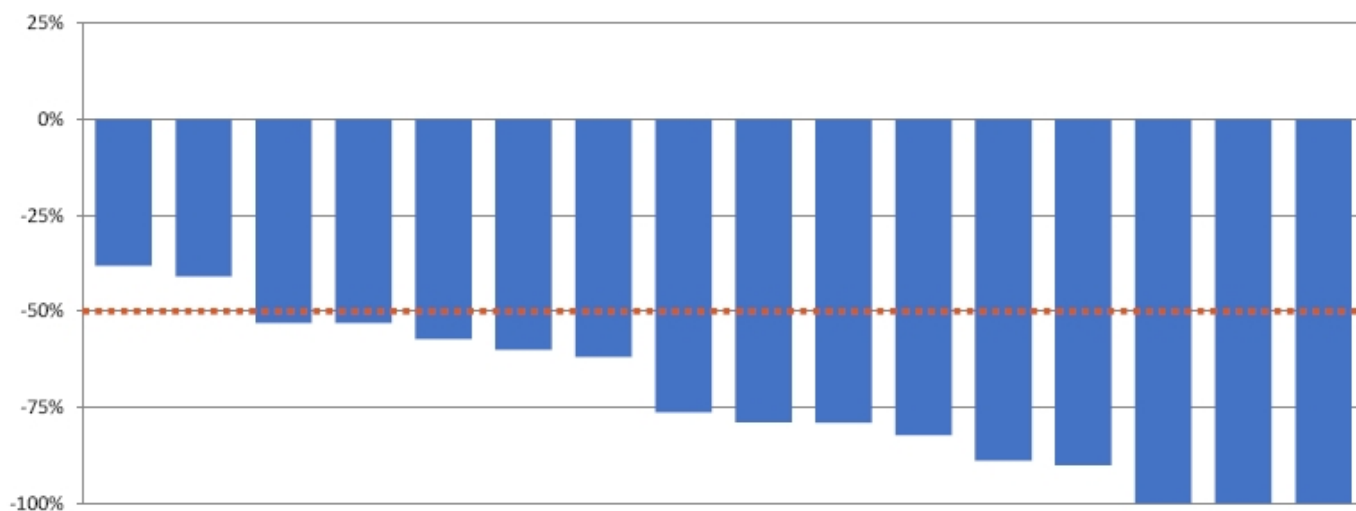


**TGR-1202 SINGLE
AGENT
&
TG-1101 + TGR-1202
IN CLL**



TGR-1202 Single Agent – CLL

Best Percent Change from Baseline in Nodal Size Patients Evaluable for Efficacy (N=16)

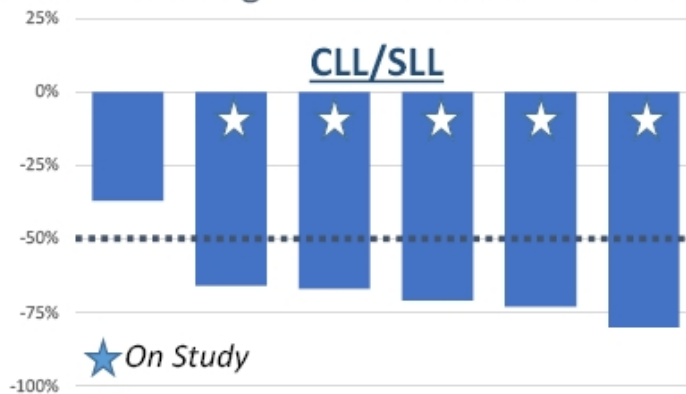


- 88% of CLL patients (14/16) achieved a nodal PR, remaining 2 patients still on study pending further evaluation
- 63% of CLL patients (10/16) achieved a response per iwCLL (Hallek 2008) criteria

TG-1101 + TGR-1202 – CLL

Patients Treated at the “Higher Doses” of TGR-1202

Best Percent Change from Baseline in Nodal Size



70% of CLL patients had high-risk cytogenetics (17p del and/or 11q del)

Type	TGR-1202 Higher* Doses						Type	TGR-1202 Lower** Doses					
	Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)		Pts (n)	CR (n)	PR (n)	ORR n (%)	SD (n)	PD (n)
CLL/SLL	6	-	5	5 (83%)	1	-	CLL/SLL	7	1	3	4 (57%)	3	-
DLBCL	7	2	1	3 (43%)	3	1	DLBCL	3	-	-	-	1	2
FL/MZL	11	2	5	7 (64%)	4	-	FL/MZL	4	-	1	1 (25%)	3	-
Richter's	1	-	1	1 (100%)	-	-	Richter's	-	-	-	-	-	-
Overall	25	4	12	16 (64%)	8	1	Overall	14	1	4	5 (36%)	7	2

*Higher Dose = 1200 original formulation and 600 or > micronized **Lower Dose = 800 original formulation and 400 micronized

TG-1101 + TGR-1202

Safety supports further combination studies

Related AE's Occurring in $\geq 5\%$ of Patients (n = 55)

Adverse Event	All Grades		Grade 3/4	
	N	%	N	%
Infusion Related Reaction	16	29%	1	2%
Neutropenia	15	27%	13	24%
Nausea	15	27%	-	-
Diarrhea	11	20%	1	2%
Fatigue	10	18%	-	-
Vomiting	6	11%	-	-
Abd. Pain/Discomfort	4	7%	-	-
Muscle Cramping	4	7%	-	-
Anemia	3	5%	-	-
Bruising	3	5%	-	-
Hoarseness	3	5%	-	-
Thrombocytopenia	3	5%	-	-

- ❖ ~5% have come off study due to an adverse event
- ❖ No patients at ≥ 800 mg micronized TGR-1202 have discontinued due to an AE

Newest Triple Combination Study

Phase I/II study of pembrolizumab in combination with TG-1101 (ublituximab) and TGR-1202 in patients with relapsed-refractory CLL

A unique opportunity to correct immunological defects which allow CLL to escape immune surveillance

A research collaboration between University of Pennsylvania, Center for CLL and TG Therapeutics

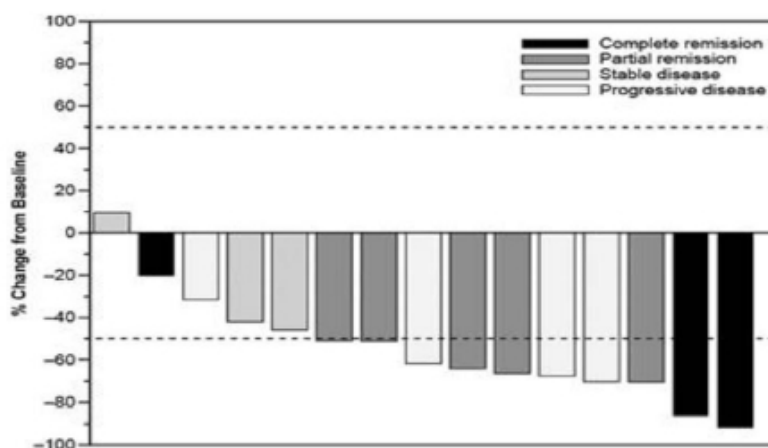
Study Rationale: PD-1 Blockade and CLL

- Malignant cells utilize PD-1 receptor-ligand pathway to evade immune surveillance by inactivating cytotoxic T cells via PD-L1 expression.
- CLL: Preclinical data demonstrates the importance PD-1 / PD-L1 signaling
 - PD-1 expression is significantly higher in CLL patients (T cells) vs. healthy donors.
 - CLL cells expresses higher PD-L1 and PD-1 vs. circulating B lymphocytes from healthy donors.
 - CD4+/PD-1+ T lymphocytes are found to be in close contact with PD-L1+ CLL cells.
 - In vivo data demonstrate that early PD-L1 blockade effectively controls CLL development in TCL1 murine model for CLL.

Pembrolizumab is a highly selective, humanized IgG4/kappa monoclonal antibody that binds PD-1, and prevents its interaction with its ligands.

Recent data highlight the activity and immense potential of anti PD-1 antibodies in patients with Hodgkin lymphoma and B cell lymphoproliferative disorders.

Response Rates	Objective Response Rate, n (%)	Complete Responses, n (%)	Partial Responses, n (%)	Stable Disease n (%)
B-Cell Lymphoma* (n=29)	8 (28)	2 (7)	6 (21)	14 (48)
Follicular Lymphoma (n=10)	4 (40)	1 (10)	3 (30)	6 (60)
Diffuse Large B-Cell Lymphoma (n=11)	4 (36)	1 (9)	3 (27)	3 (27)



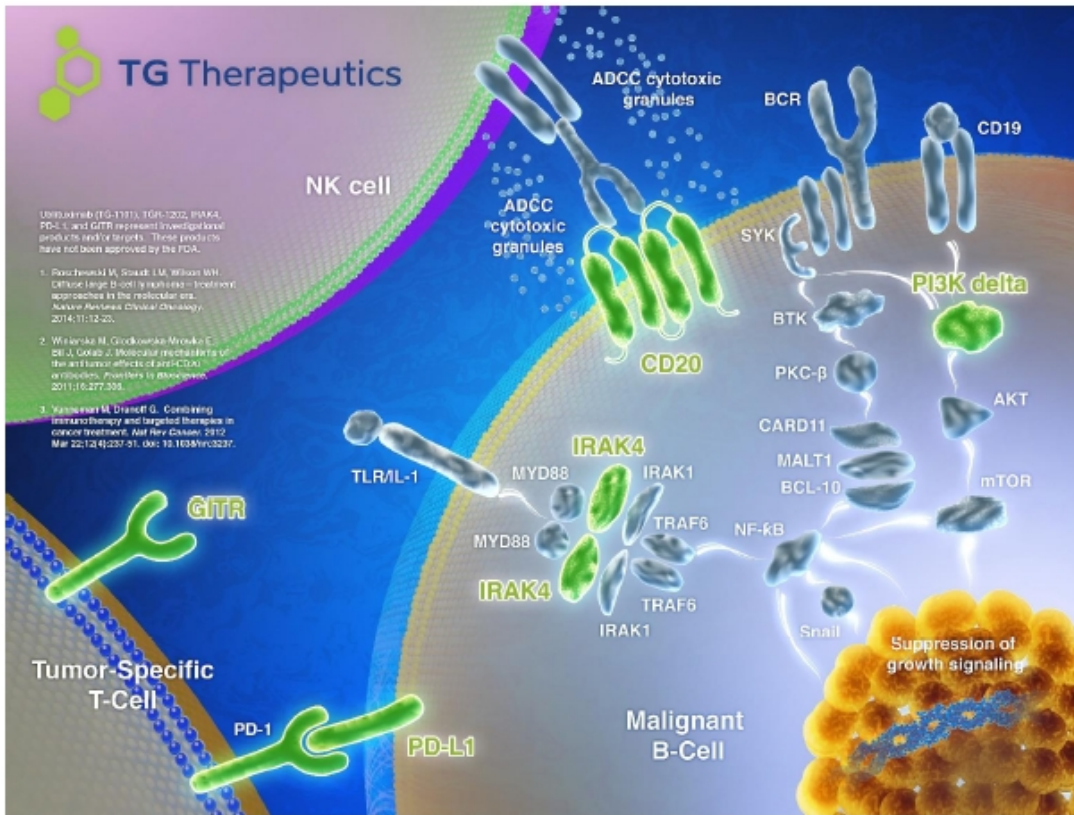
Response rate in HD

- 3 patients (20%) = CR
- 5 patients (33%) = PR
- Best ORR = 53%

Lesokhin et al. ASH 2014, Abstract 291.

Moscowitz et al, Blood. 2014;124(21):290-290.

Hypothesis



TG1101 + TG1202 doublet is an ideal platform for combination with anti-PD1 therapy based on clinical activity and non overlapping safety profile.

Pembrolizumab will enhance the efficacy of host T cells to induce apoptosis in CLL patients following TG-1101 and TGR-1202 induction.

Objectives

Primary objective:

Determine the safety of pembrolizumab + ublituximab + TGR-1202 following ublituximab and TGR-1202 in patients with relapsed-refractory CLL.

Secondary objectives:

- Describe the clinical efficacy of pembrolizumab triplet combination therapy in patients with relapsed-refractory CLL.
- Describe changes T cell repertoire and PD-1 / PD-L1 expression in subjects at planned time points pre and post pembrolizumab

Questions?



TG Therapeutics

2015 ASCO Analyst & Investor Event

May 31, 2015