

# Corporate Presentation

October 2020

### **Forward Looking Safe Harbor Statement**

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### **Fearless Pursuit**

- Founded 8 years ago with one goal in mind... to create the best possible treatment options for patients with B-Cell diseases
- Focused on cancer & autoimmune disease with registration programs ongoing in:
  - Chronic Lymphocytic Leukemia (CLL)
  - Marginal Zone Lymphoma (MZL)
  - Follicular Lymphoma (FL)
  - Multiple Sclerosis (MS)



# **B-Cell Focused Platform** Clinical Stage Portfolio Overview

Drug Candidate	Mechanism of Action	Stage of Development	
Umbralisib (TGR-1202)	ΡΙ3Κδ/ϹΚ1ε	Phase 3	
<b>Ublituximab</b> (TG-1101)	Anti-CD20	Phase 3	
<b>Cosibelimab</b> (TG-1501)	Anti-PD-L1	Phase 1b	
TG-1701	BTKi	Phase 1	
TG-1801	Anti-CD47/CD19	Phase 1	

## 2020: Transformational Year w/ Multiple Pivotal Data Sets

#### UNITY-NHL Rel/Ref MZL and FL

– Umbralisib Monotherapy –

Positive Topline ORR Data

ODD Granted for MZL & FL and BTD granted for MZL

Rolling NDA Submission accepted by the US FDA August 2020 UNITY-CLL Front Line & Rel/Ref

– Umbralisib + Ublituximab (U2) –

Trial Conduced Under SPA

Enrolled ~420 patients

Positive topline results announced May 2020

#### ULTIMATE I & II Relapsing MS

– Ublituximab Monotherapy –

Trials Conducted under SPA

Enrolled Over 1100 Patients

Awaiting topline results, Target 4Q 2020

• Potential for FDA Approvals in MZL, FL, CLL, SLL and MS from 2020 to 2022

• Commercial Preparations Underway



# **Umbralisib:**

Investigational dual PI3k-delta & CK1-epsilon inhibitor



- Demonstrated activity across NHL and CLL
- Potentially differentiated tolerability profile over 1<sup>st</sup> generation compounds
- Once daily v. twice daily for 1<sup>st</sup> generation compounds



## **UNITY-NHL -** *Umbralisib Monotherapy Cohorts Relapsed/Refractory MZL* & *FL*

- MZL & FL Cohort's Met Primary End Point of Overall Response Rate (ORR)
  - Exceeding 40% ORR hurdle
  - Interim efficacy analysis of MZL cohort, n=42, showed 52% ORR, including 19% Complete Response (CR) rate
- Umbralisib monotherapy appeared to be well tolerated in both cohorts, with a safety profile consistent with previous reports
- Rolling NDA submission for umbralisib to treat R/R MZL and FL accepted by the US FDA August 2020
  - MZL PDUFA goal date of February 15, 2021
  - FL PDUFA goal date of June 15, 2021
- Targeting presentation of full data by year-end 2020

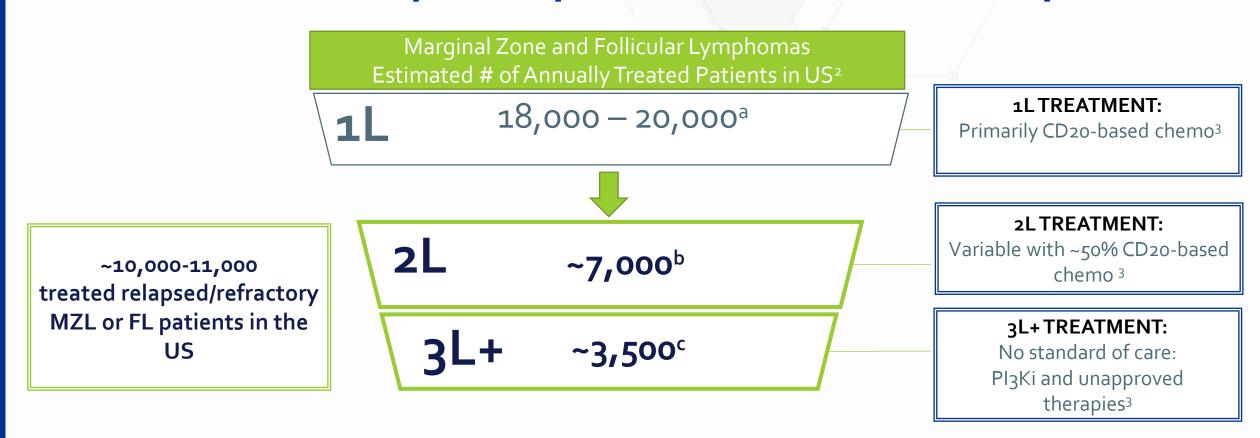
UNITY-NHL Ph2b Trial FL & MZL Cohorts

> Umbralisib (TGR-1202) Monotherapy

<b>Positive Topline ORR Results</b>						
Target ORR Achieved	>40%					
Enrollment Complete MZL (n=69) FL (n=118)	Aug 2018 Oct 2018					
Targeting Full Data Presentation	YE 2020					



## MZL and FL are chronic and often incurable diseases characterized by multiple recurrences and relapses<sup>1</sup>



#### Response and remission duration decline with subsequent treatments, and cumulative toxicities increase<sup>3,4</sup>

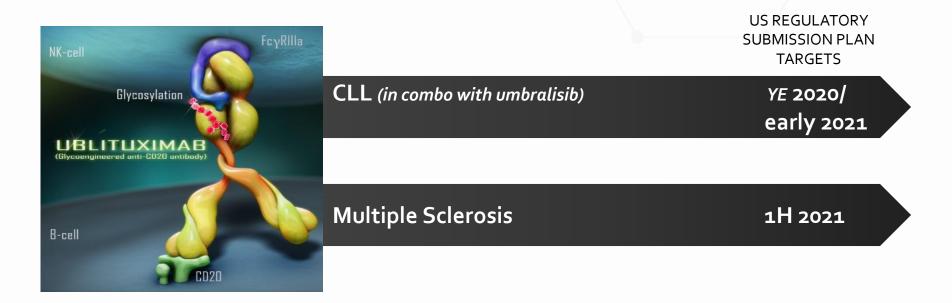
#### Continued need for active, well-tolerated treatment options for R/R MZL & FL



a=FL: 12,000 treated; MZL: 6,000 treated; b= FL: 5,000 treated, MZL: 2,500 treated; c=FL: 2,500 treated, MZL: 1,000 treated. (expect FDA approval in 2L+ MZL and 3L+FL) (1) Denlinger NM, et al. Cancer Manage Res 2018; Rivas-Delgado A, et al. Brit J Haematology 2019; (2) Putnam Associates, 2018; (3) Putnam Associates, 2019; (4) Kritharis A, et al. Cancer Treatment and Research, 2015; 5. Morrison V, et al. Clin Lymphoma, Myeloma, and Leukemia. 2019]

# **Ublituximab:**

#### Investigational Next Generation Anti-CD20 Monoclonal Antibody



#### Ublituximab

Glycoengineered for enhanced potency over 1<sup>st</sup> generation

Activity in rituximab refractory patients

Shorter infusion time than approved anti-CD20s

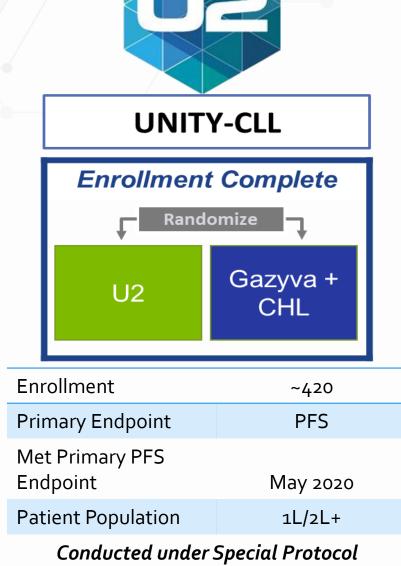


# **UNITY-CLL Phase 3 Trial of U2 in CLL**



#### **POSITIVE TOPLINE RESULTS – MAY 2020**

- **UNITY-CLL** met the primary endpoint of improved PFS (p<.0001)
- Trial will be stopped early for superior efficacy observed at the interim analysis
- PFS benefit seen across both treatment naïve & relapsed/refractory patient populations
- Full data presentation and regulatory submission targeted by year-end 2020/early 2021





Assessment

10

### **CLL Market Opportunity**

## One of the Fastest Growing Global Hematology Markets

- ~115,000 Americans living with CLL
- ~20,000 newly-diagnosed patients each year
- ~20,000 previously treated patients seeking treatment each year



## U2 Has the Potential to Address Unmet Needs in CLL

- **Over 60,000 patients** in the US have been treated with a BTK-inhibitor creating a large population in the post-BTK setting in need of treatment options
- ~20% of treatment naïve patients will be deemed poor candidates for BTK inhibitors due to potential safety/tolerability concerns
- **Up to 40% of patients will discontinue** BTK inhibitors for efficacy/tolerability issues at median of 17 months from starting therapy in recent real-world analysis
- Venetoclax represents a challenge for community practices due to enhanced monitoring and potential need for hospitalization to avoid TLS

#### > Substantial need for additional treatments for CLL remains

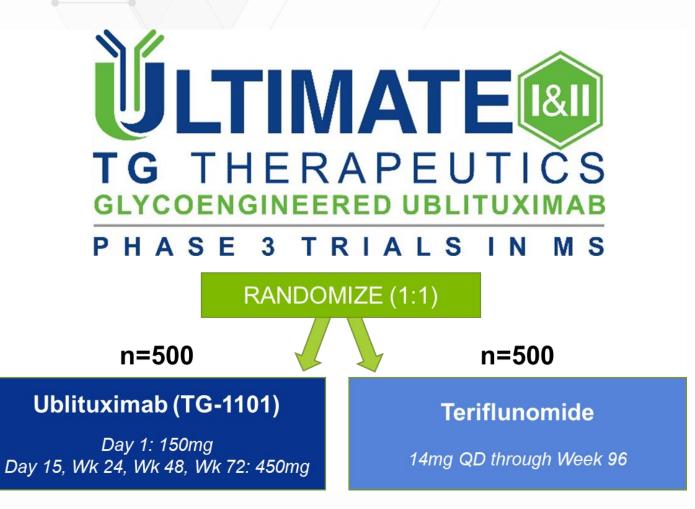


## **U2-Based Triplets Currently Enrolling**

U2 + Venetoclax		U2 + Ibrutinib		U2 + 1701 (BTKi)	
		Phase 1 Study in rel/ref B-cell malignances		Phase 1 Study in rel/ref B-cell malignances	
Target Enrollment: Rel/Ref CLL BTK Refractory CLL Front line CLL Completion	~60 patients ~30 patients ~60 patients Q1 2021	Enrolled:	~50 patients	Target Enrollment:	Up to 100 patients
		Published:	Lancet Oncology, Jan. 2019	Target Determination of Ph 3 Dose:	Q4 2020
Primary Endpoint(s):	ORR and CR @ 12 months	Primary Endpoint(s)	Safety, Efficacy	Primary Endpoint(s)	Safety
Phase 1 U2+Ven ASH `19 Update (Barr et al)	CLL Patients: ORR= 100% (n=9) CR= 44% PB MRD-= 100% BM MRD-= 78%	<b>Lancet Jan 2019</b> (Nastoupil et al)	CLL/SLL Patients: ORR= 100% (n=22) CR= 36% (8/22) MZL Patients: ORR= 100% (3/3)	<b>EHA '20 Update</b> (Cheah et al)	Triple U2 +1701: All Patients ORR= 77% (n=13) CLL ORR= 100% (3/3) MZL ORR= 100% (2/2) Single Agent 200mg:
					CLL ORR= 92% (11/12)

# **Ublituximab in Relapsing Forms of Multiple Sclerosis**

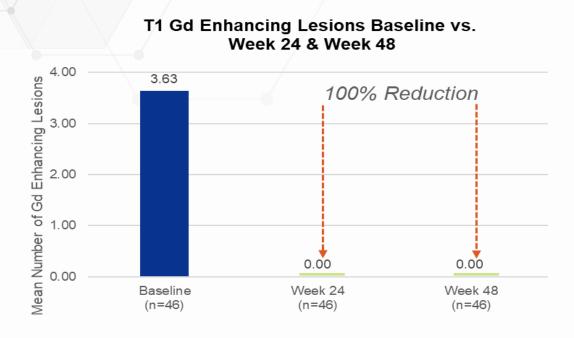
- ~1M Americans living with MS
- Completed Phase 2, data presented at multiple conferences
- Fully Enrolled Phase 3
  ULTIMATE Trials
  - Special Protocol Assessment (SPA)
  - Topline Data Targeted for Q4 2020





# Final Ublituximab Phase 2 Data in RMS

- Ublituximab was well tolerated across all patients (n=48)
- No study drug related discontinuations occurred
- Median B cell depletion was >99% at the primary analysis point of Week 4 (n=48) and maintained at Week 24 and Week 48
- No T1 Gd-enhancing lesions were detected in any subjects at Week 24 or Week 48 (100% reduction; p=0.003)
- An Annualized Relapse Rate (ARR) of 0.07 was observed with 93% of subjects relapse free at Week 48



#### Subject T1 Gd MRI at Baseline, Week 24 & Week 48





Fox E et al., ECTRIMS 2018



## Significant Opportunity for Ublituximab in MS

Global MS Market 2018 - 2025

#### Billions US US Ex-US (Japan, France, Germany, Italy, Spain & UK)

**Estimated Global Sales** 

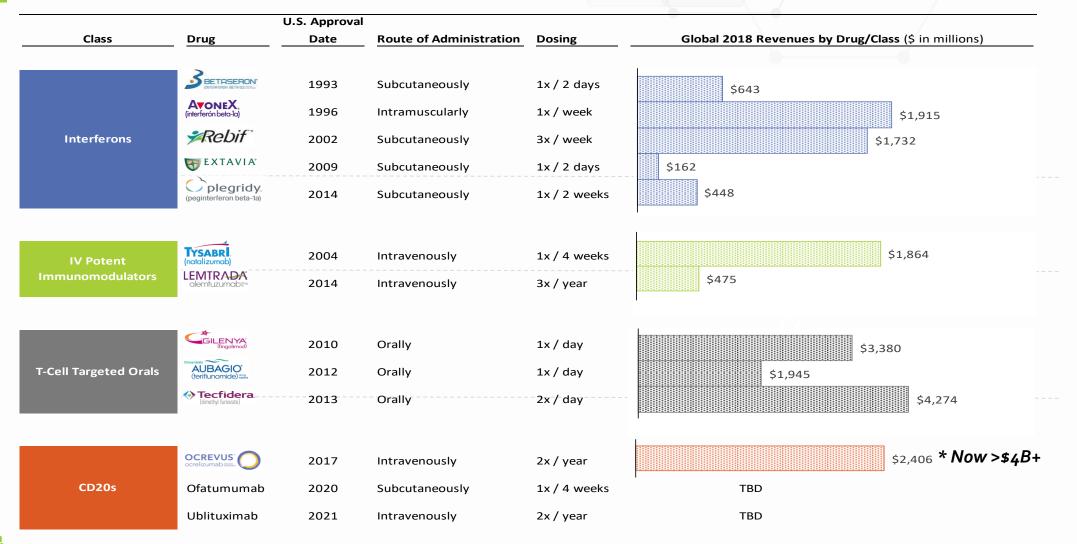
Global Prevalence = ~2.3Million

Global Market Size >\$30Billion by 2025

• Ocrelizumab >\$2 Billion in 2018 annual sales; achieved ~\$4B in 2019



## Multiple Treatment Options Coexist & Account for Meaningful Market Share



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17

## **Ublituximab Potential Value Proposition in MS**

- Significant activity and manageable safety profile in Phase 2 study
- Convenience of 1 hour infusion every 6 months v. 3-4 hours for ocrelizumab
- Potential to strategically price to optimize patient access
- Estimate \$1-2B annual market opportunity in the US alone for ublituximab in MS



## **Target Milestones**

#### 1H 2020

Report topline UNITY-NHL FL results

Initiate rolling NDA submission for umbralisib to treat relapsed/refractory MZL & FL

Report topline UNITY-CLL results

Present updated data at major medical meetings

Complete NDA submission for umbralisib to treat relapsed/refractory MZL & FL

#### 2H 2020 – Q1 2021

NDA submission for umbralisib to treat MZL & FL accepted by US FDA & PDUFA goal dates set

- Report topline Phase 3 ULTIMATE MS data
- Present final data from UNITY-CLL & UNITY-NHL umbralisib monotherapy MZL & FL cohorts
- Submit NDA/BLA for U2 to treat CLL
- Complete enrollment in ULTRA-V Phase 2b trial



#### **Key Financial Statistics**

