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Verastem, Inc. (NASDAQ:VSTM) is a biopharmaceutical company focused on developing and commercializing drugs to improve survival and quality of life for patients with cancer. Verastem's product candidates seek to treat cancer by modulating the local tumor microenvironment and enhancing anti-tumor immunity.

Duvelisib, a dual inhibitor of PI3K-delta and PI3K-gamma, has successfully met its primary endpoint in a Phase 2 study in indolent Non-Hodgkin Lymphoma (iNHL) and a Phase 3 clinical trial in patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Duvelisib NDA has been accepted by the FDA with Priority Review for the Treatment of Patients with Relapsed/Refractory CLL/SLL and Accelerated Approval in Relapsed/Refractory Follicular Lymphoma.
FDA Target Action Date: October 5, 2018

Verastem is also developing the FAK inhibitor defactinib, which is currently being evaluated in three separate clinical collaborations in combination with immunotherapeutic agents for the treatment of several different cancer types, including pancreatic cancer, ovarian cancer, non-small-cell lung cancer (NSCLC), and mesothelioma.

Verastem is focused on establishing a commercial infrastructure in the U.S. for the potential launch of duvelisib in hematologic malignancies as an oral monotherapy for patients needing additional lines of therapy following previous treatment and exploring ex-U.S. partnering opportunities for duvelisib in parallel, and plan to file a European Marketing Application in 2018.

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Duvelisib and Defactinib:
Key Clinical Trials Ongoing to Evaluate Safety and Efficacy

Verastem

DUVELISIB	
Mechanism	Dual inhibitor of PI3K-δ (delta) and PI3K-γ (gamma)
RP2D	25 mg BID. Oral
IP	COM 2030 before extensions
Orphan designation	CLL/SLL and FL in the US and EU
FDA Fast Track Designation	• Patients with follicular lymphoma who have received at least two prior therapies • Patients with CLL or PTCL who have received at least one prior therapy • **NDA Accepted with Priority Review FDA** **Target Action Date: October 5, 2018**

Dual PI3K-δ,γ inhibitor with positive Phase 2 data in iNHL and Phase 3 data in CLL; Potential applicability in other lymphoid malignancies

DEFACTINIB	
Mechanism	Dual inhibitor of FAK and PYK2
RP2D	400 mg BID. Oral
IP	COM 2028 before extensions
Orphan designation	Ovarian and mesothelioma in the US and EU

FAK inhibitor in combination studies with leading immuno-oncology agents for the treatment of multiple solid tumors

DUVELISIB in iNHL

PHASE 2 STUDY, FULLY ENROLLED WITH FINAL ANALYSIS COMPLETED

DYNAMO™

Double refractory* iNHL patients *N=129*

Duvelisib 25 mg BID

Study Points

Primary: Overall response rate (ORR) by Independent Review Committee (IRC)

Key secondary:
- Safety
- Duration of response (DOR)
- Progression-free survival (PFS)
- Overall survival (OS)

✓ Accrual complete November 2015

✓ Final analysis (April 2016) presented at ASH 2016

✓ Mature follow up (March 2017) presented at ICML 2017

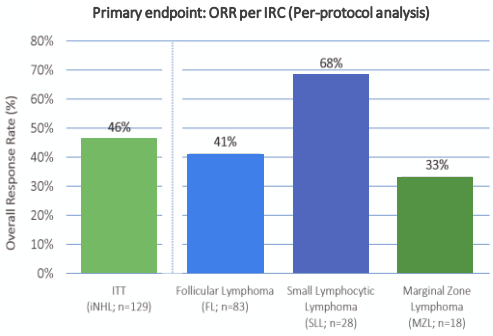
*** Heavily pretreated patient population:**
- Median number of prior treatments = 3
- Inclusion criteria: Refractory to both rituximab (R) and a chemotherapy regimen or radioimmunotherapy (RIT)

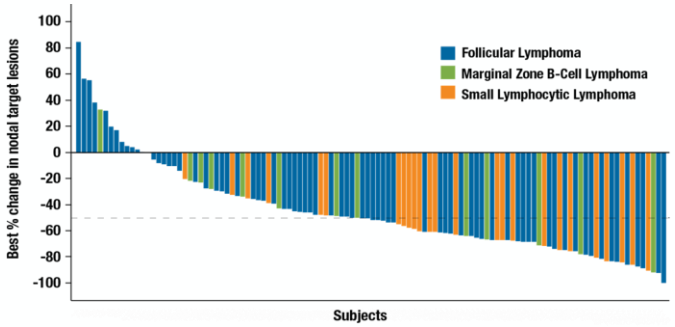
Primary endpoint:

- ORR by IRC at per-protocol final analysis: **(p=0.0001)**

Secondary endpoints:

- Median PFS on duvelisib: **8.4 months**
- Median DOR: **10 months**





DUVELISIB in CLL/SLL

DUO™

Relaspsed or Refractory CLL/SLL patients *319 patients Randomized 1:1*

Duvelisib 25 mg BID continuously * *N=160*

Ofatumumab IV 300 mg IV infusion on Day 1 2000 mg IV weekly (x7) then monthly (x4) *N=159*

Optional Crossover Study

Ofatumumab IV Administration same as DUO *N=8*

Duvelisib 25 mg BID continuously *N=89*

DUO™ met its primary endpoint of PFS by IRC in both the ITT and del(17p) subpopulation

DUO™ TOP LINE DATA

	Duvelisib	Ofatumumab
PRIMARY ENDPOINT: PROGRESSION-FREE SURVIVAL (PFS) BY IRC		
ITT population, median	13.3 months	9.9 months
	HR = 0.52; p < 0.0001	
del(17p) subset, median	12.7 months	9.0 months
	HR = 0.41; p = 0.0011	

Duvelisib monotherapy had a manageable safety profile, with results from this study consistent with the well-characterized safety profile of duvelisib monotherapy observed to date in patients with advanced hematologic malignancies.

Full data presented at ASH 2017

DEFACTINIB in I-O COMBINATIONS

FAK inhibition **boosts immune attack**, supporting combination with immunotherapies

Cell
Nuclear FAK Controls Chemokine Transcription, Tregs, and Evasion of Anti-tumor Immunity
Serrels et al. (2015) Cell 163: 160-173

FAK inhibition **reduces stromal density**, enabling therapies & immune cells to penetrate tumors

nature medicine
Targeting focal adhesion kinase renders pancreatic cancers responsive to checkpoint immunotherapy
Jiang et al. (2016) Nature Medicine 163: 851-860

Pfizer MERCK — Ongoing combination trial with avelumab (Ovarian)

MERCK — 2 combination trials with pembrolizumab (NSCLC, pancreatic, mesothelioma)

CANCER RESEARCH UK — First cross-company deal as part of Experimental Cancer Medicine Centre (ECMC) Combinations Alliance

Washington University in St Louis — Active pre-clinical to clinical translation of I-O combinations