

**REGENERON**  
*SCIENCE TO MEDICINE®*

**ONCOLOGY  
STRATEGY**

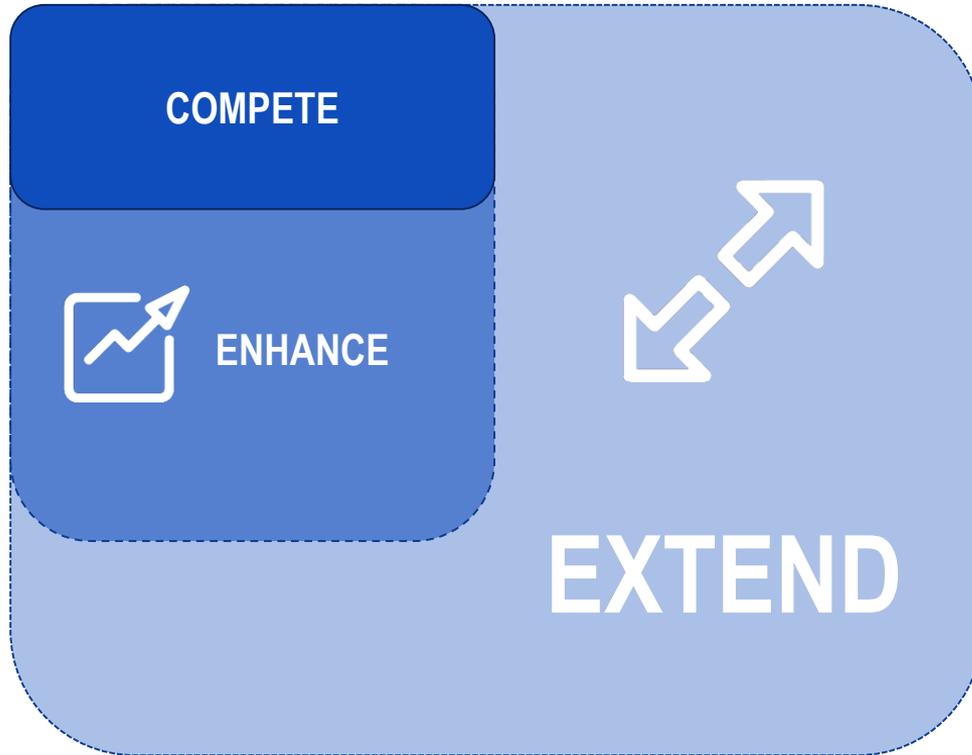
NOVEMBER 2019



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# ONCOLOGY STRATEGY: COMPETE, ENHANCE, EXTEND



**Compete:** Libtayo in tumors “responsive” to PD1 checkpoint inhibition (e.g., skin & lung)

- PD-(L)1 market: >\$15Bn in 2018, +65% YoY growth\*

**Enhance:** Even for “responsive” tumors, more than half patients do not respond to IO treatment

- Add novel therapeutics to Libtayo to “*enhance*” responsiveness for these tumors

**Extend:** For tumor settings with limited response to checkpoint inhibition

- Novel therapeutics to “*extend*” responsiveness to these tumor settings – e.g. bispecifics

\*Based on annual sales data for approved PD-(L)1 agents in 2018 and 2017

# OUR ONCOLOGY TOOLKIT CONSISTS OF INTERNALLY DEVELOPED AND EXTERNALLY PARTNERED THERAPEUTIC CANDIDATES

T and NK cell  
activators  
(CD3 bispecifics)

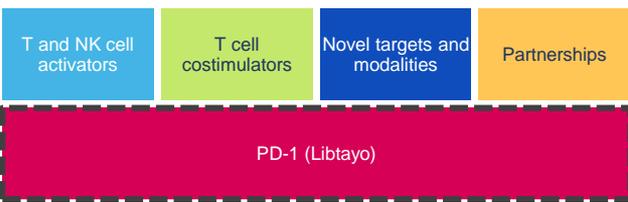
T cell  
costimulators  
(CD28 bispecifics)

Novel targets  
and modalities

Partnerships  
(CAR-Ts; Vaccines)

PD-1 (Libtayo)

# LIBTAYO STORY: ESTABLISH LIBTAYO AS THE FOUNDATION TO COMPETE, ENHANCE AND EXTEND TREATMENT BENEFITS IN MONOTHERAPY AND IN COMBINATIONS



Fast to CSCC market

- First PD-(L)1 approval for CSCC
  - Nearly 50% ORR in late-stage metastatic & locally-advanced CSCC
- From Ph1 trial initiation to FDA approval: ~3.5 years

Expand dermatology

- Moving to earlier lines of therapy and to other skin cancers:
- CSCC:
    - Adjuvant CSCC trial started
    - Neoadjuvant pilot has 70% ORR with 55% CRs – larger study initiating
  - BCC: Registrational study reading out 2020
  - Melanoma: Libtayo combinations with novel agents initiating

Position in NSCLC

- Become competitive in the major anti-PD1 opportunity, i.e. Lung Cancer:
- Libtayo Monotherapy in PD-L1-high 1<sup>st</sup> Line NSCLC:
    - 700 patient study is 90% enrolled
    - Based on early OS interim, IDMC recommended to continue as planned
    - ORR for first 361 patients: 42% for Libtayo vs. 22% for Chemo
  - 2<sup>nd</sup> major Ph3 study in combination with Chemo: full enrollment by 2H20

Induce responsiveness to Libtayo with bispecifics

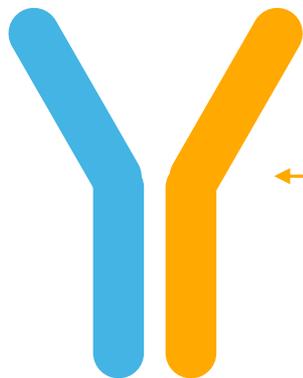
- Enhance and Extend Responsiveness to anti-PD-1 class:
- Combinations with PSMAxCD28 in Prostate Cancer
  - Multiple combinations with CD3 and CD28 bispecifics
  - Novel combinations with Vaccines & Viruses

NSCLC		
Monotherapy study preliminary investigator read response data		
N=361	Libtayo	Chemo
ORR*	42%	22%

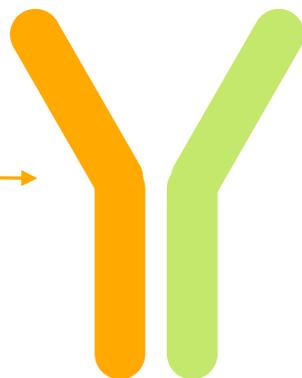
\*ORR – Objective Response Rate; in NSCLC, regulatory authorities do not consider ORR a validated surrogate endpoint; CSCC – Cutaneous Squamous Cell Carcinoma; BCC – Basal Cell Carcinoma; NSCLC – Non-Small Cell Lung Cancer

# REGENERON CAN CREATE AND DEVELOP HIGH-QUALITY BISPECIFICS OF ANY DESIRED SPECIFICITY

Anti-CD3



Anti-CD28



## VELOCISUITE®

- VG + VI technologies are fundamental – allowing us to compete and partner
- First- and/or best-in-class reagents
- Foundation for Dupixent, Libtayo, and Praluent; poised to continue to deliver
- REGN can make several distinct classes of bispecifics using next generation VI mice

T cell activators

T cell costims

VI – VelocImmune®; VG – VelociGene®

# BISPECIFICS VISION: ENHANCE ACTIVITY VS TUMORS ALREADY RESPONSIVE TO ANTI-PD-1, AND EXTEND ACTIVITY TO IO-UNRESPONSIVE TUMORS

T and NK cell activators

T cell costimulators

Novel targets and modalities

Partnerships

PD-1 (Libtayo)



CD20xCD3

- CD20xCD3 with potential best-in-class activity, to be updated at ASH'19
  - Initiated Pivotal Phase 2 study

BCMAxCD3

- BCMAxCD3: encouraging single-agent data to be presented at ASH'19

MUC16xCD3

- MUC16xCD3 ongoing in ovarian cancer, more solid tumors to come
  - Combinations with Libtayo and other bispecifics to increase activity

PSMAxCD28

- PSMAxCD28 is first “costimulatory” bispecific
  - In combination with Libtayo, to induce activity in Prostate Cancer

Several in Preclinical Pipeline

- Several CD3 and CD28 bispecifics in Preclinical Pipeline
  - Can be combined together or with Libtayo to enhance activity
  - Also includes “non-IO” bispecifics such as METxMET

# BISPECIFICS STORY, CHAPTER 1: CD20xCD3 IN LYMPHOMA

T and NK cell  
activators

T cell  
costimulators

Novel targets and  
modalities

Partnerships

PD-1 (Libtayo)



- REGN1979 links CD20 on tumor cells to CD3 on killer T cells
- First bispecific in our portfolio: required careful approach to safely escalate doses of a potent immunostimulatory agent to provide benefit to patients

**REGN1979 POC EHA data (June 2019)**

Anti-CD3    Anti-CD20



**REGN1979**

## Late-Stage Follicular Lymphoma

- Strong monotherapy activity
- N=14, doses 5mg–320 mg
- ORR=93%, CR=71%

## Late-Stage DLBCL

- Encouraging monotherapy activity
- N=7, doses 80mg–160 mg
- ORR=57% (4/7, all CRs)
  - 2/4 ORR in post-CAR-T responders

**ORR and Durability to be updated at ASH 2019  
(~20 patients treated at target doses in both FL & DLBCL)**

DLBCL – Diffuse Large B Cell Lymphoma

# BROADENING OUR ONCOLOGY PIPELINE

■ LIBTAYO ■ CD3 BISPECIFICS ■ CD28 BISPECIFICS ■ OTHER

## EARLY DEVELOPMENT

**REGN5458 (BCMAxCD3)**  
Multiple myeloma

**REGN5678 (PSMAxCD28)**  
Prostate cancer

**REGN5093 (METxMET)**  
MET-altered NSCLC

**REGN5459 (BCMAxCD3)**  
Multiple myeloma

**REGN4659 (CTLA-4)**  
NSCLC

**REGN4018 (MUC16xCD3)**  
Ovarian cancer

**REGN3767 (LAG-3)**  
Solid/hematologic cancers

## APPROVED

**LIBTAYO**  
CSCC

## PRECLINICAL

**TSAxCD3**  
TBA cancer

**GITR**  
Solid tumors

**PiG (Peptide in HLA Groove)**  
Solid tumors

**TSAxCD28**  
B cell malignancies

**And More To Come**

## POTENTIALLY PIVOTAL

**LIBTAYO**  
NSCLC, BCC, Cervical, Adjuvant CSCC

**REGN1979 (CD20xCD3)**  
B cell NHL

TSA = Tumor Specific Antigen

This slide includes pipeline drug candidates currently undergoing clinical testing in a variety of diseases. The safety and efficacy of these drug candidates have not been evaluated by any regulatory authorities for the disease categories described here.

# ONCOLOGY R&D COLLABORATIONS

T and NK cell  
activators

T cell  
costimulators

Novel targets and  
modalities

Partnerships

PD-1 (Libtayo)



Cell  
therapy:



Vaccine  
-like:



Other:



VSV – Vesicular Stomatitis Virus; HSV – Herpes Simplex Virus

# REGENERON ONCOLOGY ACCOMPLISHMENTS AND NEXT STEPS

## Accomplishments

- ✓ Approval of LIBTAYO (anti-PD-1) as sole anti-PD-(L)1 in late-stage CSCC
- ✓ LIBTAYO launched in U.S. and initial ex-U.S. markets
- ✓ Positive early LIBTAYO neoadjuvant data in CSCC
- ✓ 5 registration-enabling LIBTAYO studies ongoing
- ✓ Compelling initial REGN1979 (CD20xCD3) data
- ✓ REGN1979 potentially pivotal Ph2 initiated
- ✓ REGN5458 (BCMAxCD3) in POC trial
- ✓ REGN5678 (PSMAxCD28) First costim in clinic
- ✓ Three additional bispecifics entered clinic (MUC16xCD3, second BCMAxCD3, METxMET)

## Looking ahead 2019/2020

- LIBTAYO: Launch in >15 additional EU countries
- LIBTAYO: 2<sup>nd</sup> OS interim analysis in Ph3 NSCLC study
- LIBTAYO: Report pivotal BCC data
- LIBTAYO: Initiate larger neoadjuvant CSCC
- REGN1979: Update results of POC study in NHL (ASH)
- REGN1979: Expand potentially pivotal Ph2 program
- REGN5458: Report initial POC data in multiple myeloma (ASH)
- Additional bispecifics to enter the clinic