

**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): January 9, 2020

**MERUS N.V.**

(Exact name of registrant as specified in its charter)

**The Netherlands**  
(State or other jurisdiction of  
incorporation or organization)

**001-37773**  
(Commission  
File Number)

**Not Applicable**  
(I.R.S. Employer  
Identification No.)

**Yalelaan 62**  
**3584 CM Utrecht**  
**The Netherlands**  
(Address of principal executive offices) (Zip Code)

**+31 85 016 2500**  
(Registrant's telephone number, including area code)

**N/A**  
(Former Name or Former Address, if Changed Since Last Report)

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 (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, €0.09 nominal value per share	MRUS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On January 9, 2020, Merus N.V. (the "Company") posted an updated corporate slide presentation in the "Investors and Media" portion of its website at [www.merus.nl](http://www.merus.nl) including updates to its clinical program for MCLA-158. A copy of the slide presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibit

The following exhibit relates to Item 7.01, which shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Merus N.V. Corporate Slide Presentation as of January 9, 2020</a>

**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.

**MERUS N.V.**

Date: January 9, 2020

By: /s/ Sven A. Lundberg  
Name: Sven (Bill) Ante Lundberg  
Title: President, Chief Executive Officer and Principal Financial Officer

# Merus

## Closing In On Cancer

January 9, 2020



## Disclaimer

This presentation (including any oral commentary that accompanies this presentation) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the impact our Biconics® platform can have on cancer, our product candidates' potential to treat certain types of tumors, the timing of regulatory filings and the timing and anticipated data read outs or results from our clinical trials and our collaborations. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding, which may not be available and which may require us to restrict our operations or require us to relinquish rights to our technologies or bispecific antibody candidates; potential delays in regulatory approval, which would impact our ability to commercialize our product candidates and affect our ability to generate revenue; the unproven approach to therapeutic intervention of our Biconics® technology; our limited operating history; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; the unpredictable nature of our

early stage development efforts for marketable drugs; potential adverse public reaction to the use of cancer immunotherapies; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; failure to obtain marketing approval internationally; failure to compete successfully against other drug companies; potential competition from other drug companies if we fail to obtain orphan drug designation or maintain orphan drug exclusivity for our products; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; protection of our proprietary technology; our patents being found invalid or unenforceable; potential lawsuits for infringement of third-party intellectual property; our ability to attract and retain key personnel; managing our growth could result in difficulties; and we may lose our foreign private issuer status and incur significant expenses as a result.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on April 3, 2019, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

# Merus: pioneering bispecific antibodies since 2006

4 clinical-stage bispecific antibodies in oncology







Sophisticated proprietary bispecific and trispecific technology platforms

Multiple clinical milestones anticipated in the next 12 months

Discovery of novel modes of action based on target combinations and functional screening

Fully integrated discovery-to-manufacturing bi-/tri-specific technology platforms

# Merus clinical pipeline, near term milestones and program status

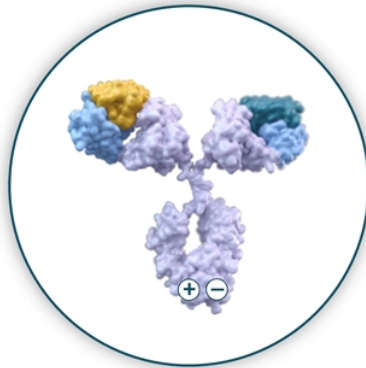
PROGRAM	TARGETS	INDICATION / DRUG COMBINATION	PRE-IND	PHASE 1	PHASE 2	MILESTONE/STATUS
MCLA-128	HER3 x HER2	NRG1 Solid tumors (monotherapy)				Update expected around end of 2020
		Metastatic Breast (combination in 2 cohorts)				Phase 2 Results in 2020
MCLA-117	CLEC12A x CD3	Acute Myeloid Leukemia (AML)				Initial Data 1H 2020
MCLA-158	Lgr5 x EGFR	Solid tumors				Phase 1 Trial Ongoing
MCLA-145	CD137 x PD-L1	Solid tumors  (ex- U.S.)				Phase 1 Trial Ongoing
MCLA-129	EGFR x c-MET	Solid tumors  (China)				IND Enabling Studies Ongoing
ONO-4685	PD-1 x CD3	Autoimmune disease 				Phase 1 Trial Ongoing
....	Undisclosed	Autoimmune disease 				

# Biclomics® — designed to look and perform like natural human antibodies

**BICLONICS®** - leveraging the attractive characteristics of natural antibodies  
Merus' Bispecific Antibodies are produced by a single cell

**Common Light Chain**  
for 'unforced', natural pairing  
with 2 different heavy chains

**Electrostatic attraction**  
to efficiently drive  
formation of Biclonics®



**IgG Format**  
for efficient manufacturing and  
predictable *in vivo* behavior

**Fc Modifications**  
for Improved functionality  
(ADCC or silencing)



# Biclomics® — Selected in functional assays for differentiated activity

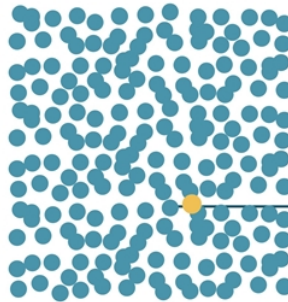
## HUMAN ANTIBODY GENERATION



**MeMo®**  
Transgenic Mouse

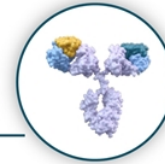
We use a proprietary transgenic mouse to generate panels of high-quality human antibodies

## PANEL GENERATION




We can create up to 1,000 Biclomics® against any target pair of choice

## FUNCTIONAL SCREENING



We use large-scale functional screening in cell-based assays to identify Biclomics® with novel modes of action



# Clinical Programs

## MCLA-128

**HER2 x HER3 Biclomics®**

# Blocks primary tumor cell growth and escape to HER2/EGFR targeted therapy

**Unique DOCK & BLOCK<sup>®</sup> mechanism of action potently inhibits neuregulin (NRG)-driven tumor growth**

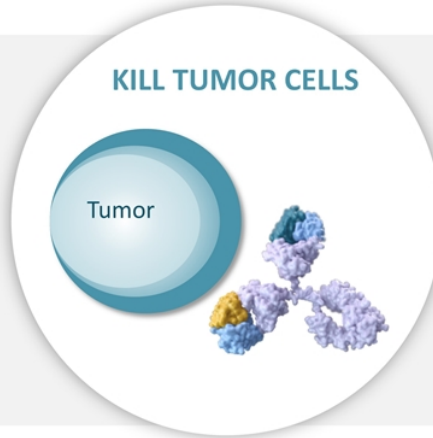
### Block HER3

Blocks HER3 signaling even in high neuregulin tumor environments

### Enhanced ADCC

Mediates tumor elimination by immune killer cells

### KILL TUMOR CELLS



### Dock HER2

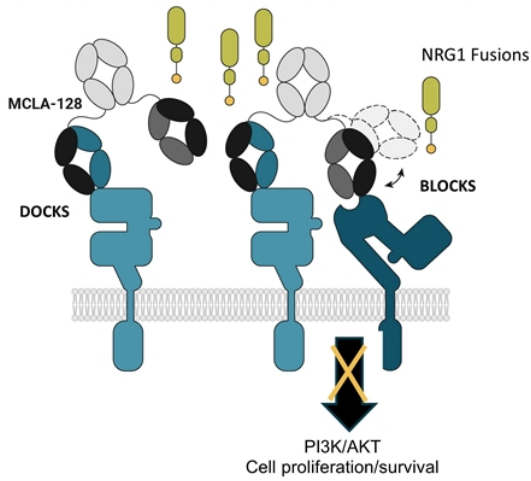
Docks to HER2 expressed on tumor cells to efficiently block HER2:HER3 dimer formation

### Combination

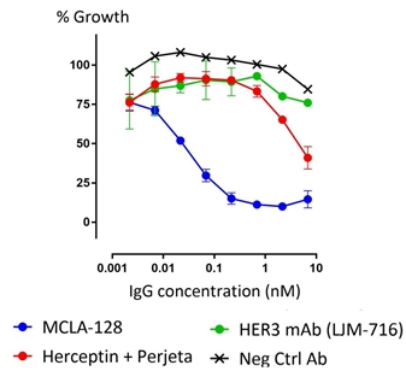
Combinations with HER2 targeted therapies possible

# Preclinical efficacy demonstrated, well-tolerated in patients

## DOCK ONTO HER2 & BLOCK NRG1 -DRIVEN HER/HER3 DIMER FORMATION



## SUPERIOR ACTIVITY SHOWN IN PRECLINICAL MODELS



## SAFETY AND TOLERABILITY IN PHASE 1/2 TRIAL

### 117 PATIENTS EVALUATED\*

MCLA-128 Dosing: 750 mg ranging from q1w-q3w

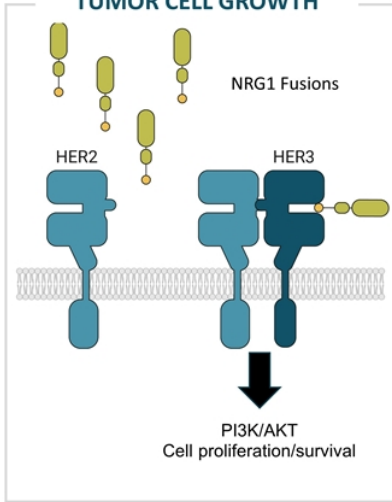
- Single agent well tolerated
- Low risk for immunogenicity

Please Refer to <https://merus.nl/publications/> for full data presented. Refer to ASCO poster 2018 and AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019

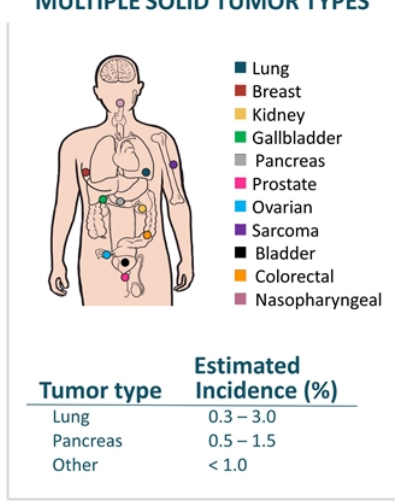
\* As of Jan. 2019

# Novel therapeutic paradigm for *NRG1* Fusion cancers

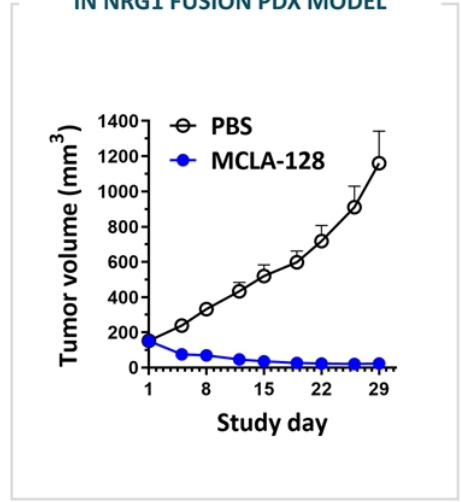
## NRG1 FUSIONS STIMULATE TUMOR CELL GROWTH



## NRG1 FUSIONS ARE FOUND ACROSS MULTIPLE SOLID TUMOR TYPES



## MCLA-128 BLOCKS TUMOR GROWTH IN NRG1 FUSION PDX MODEL



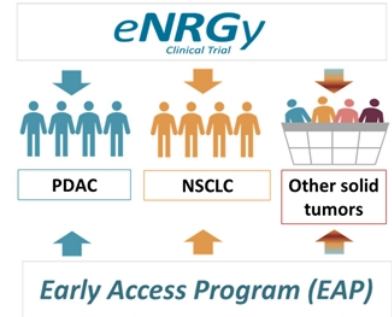
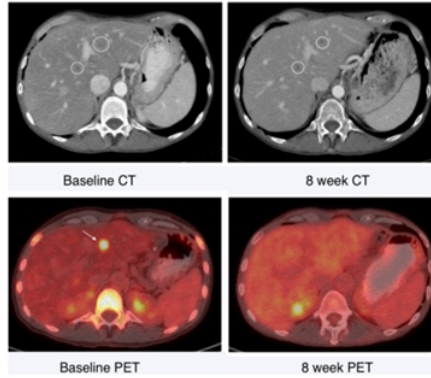
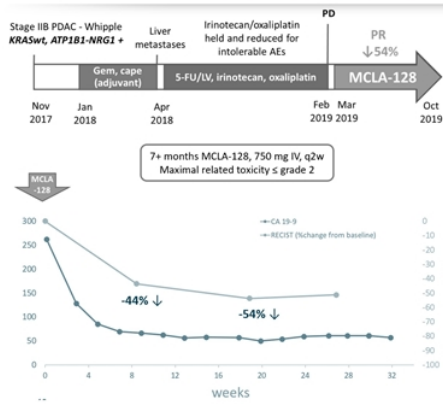
Projections of *NRG1* Fusions occurrence (incidence) are based on limited published information

# Active in NRG1 fusion<sup>POS</sup> cancers

Clinical Proof of Concept Established

Clinical Trial Ongoing

PDAC (ATP1B1-NRG1): 52-year-old male\*



\* Data was presented on October 27, 2019, at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics by investigators from the Memorial Sloan Kettering Cancer Center in a presentation titled "Clinical proof-of-concept for MCLA-128, a bispecific HER2/3 antibody therapy, in NRG1 fusion-positive cancers"

# Phase 1/2 in NRG1 solid tumors, Phase 2 in metastatic breast cancer (combo)

WHOLLY-OWNED	TARGETS	INDICATION / DRUG COMBINATION	PRE-IND	PHASE 1	PHASE 2
MCLA-128	HER3 x HER2	NRG1 Solid tumors (monotherapy)			
		Metastatic Breast (2 cohorts)			

MRUS Fully Owned

DESIGN		ENDPOINTS	STATUS
<b>NRG1 Solid Tumors (Monotherapy)</b>	<b>Phase 1/2 Study</b> Cohort 1: NRG1+ Pancreatic cancer Cohort 2: NRG1+ NSCLC Cohort 3: NRG1+ Other solid tumors Dose: 750mg every 2 weeks	<ul style="list-style-type: none"> <li>Safety</li> <li>Anti-tumor activity</li> </ul>	<ul style="list-style-type: none"> <li>Enrollment ongoing</li> </ul>
<b>Metastatic Breast Cancer (MBC)</b>	<b>Phase 2 Study in combination with 2 cohorts in MBC</b> Cohort 1: HER2+ (MCLA-128 + Herceptin + Chemo) Cohort 2: ER+/HER2 <sup>low</sup> (MCLA-128 + Hormone Therapy) Dose: 750mg every 3 weeks	<ul style="list-style-type: none"> <li>Clinical benefit at 24 weeks</li> </ul>	<ul style="list-style-type: none"> <li>To be presented at a medical conference in 2020</li> </ul>



Clinical Programs  
MCLA-117

**CD3 x CLEC12A Biclomics®**



# T cell engager for acute AML addressing a potential first-in-class target

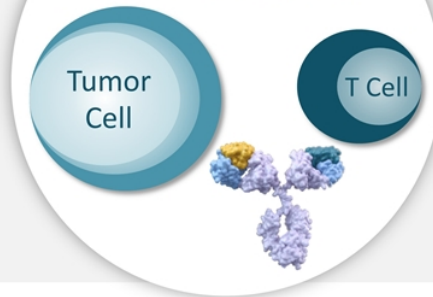
**MCLA-117 efficiently activates and redirects T cells to kill  
CLEC12A-expressing acute myeloid leukemia (stem) cells**

## CLEC12A

Expressed by tumor (stem) cells in  
~ 90-95% of AML patients

Expression restricted to  
hematopoietic system =  
potential less off-tumor toxicity

## ENGAGE T CELLS AND KILL TUMOR CELLS



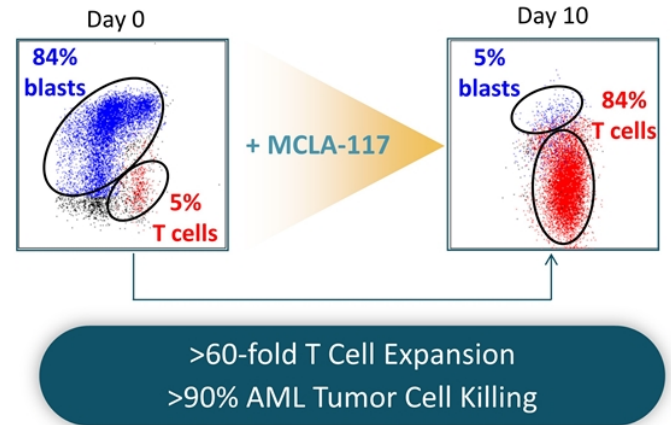
## CD3

Low affinity CD3 arm and silenced  
Fc for controlled T cell activation  
to reduce toxicity and improve  
biodistribution

## Potent activation of T cells in preclinical studies

- MCLA-117 efficiently activates and redirects T cells to kill CLEC12A-expressing AML(stem) cells
- Designed to spare the formation of platelets and red blood cells during therapy
- Active across AML patient subpopulations

### MCLA-117 MEDIATED ACTIVATION OF T CELLS AND KILLING OF TUMOR CELLS

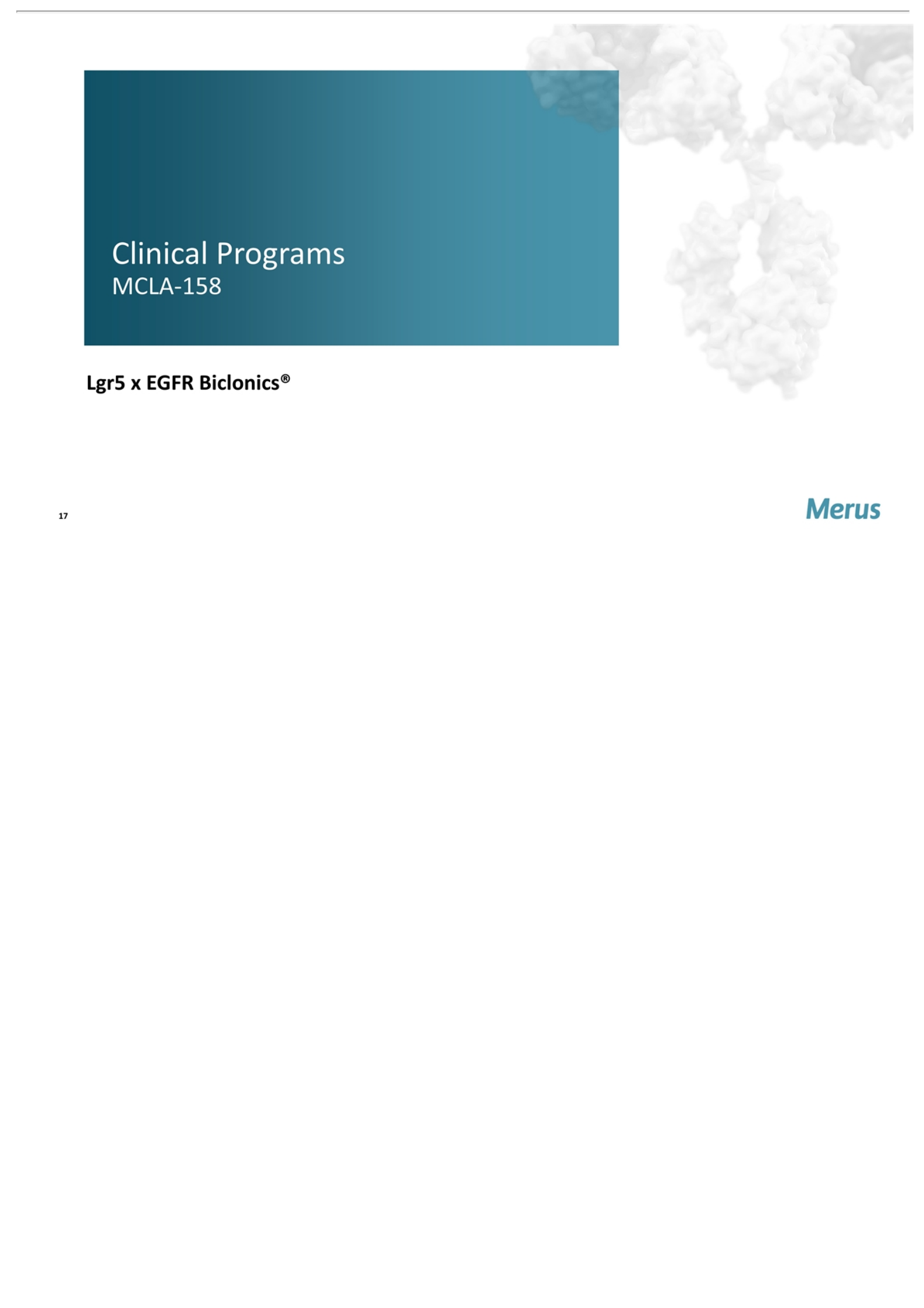


## Phase 1 Trial

	TARGETS	INDICATION / DRUG COMBINATION	PRE-IND	PHASE 1	PHASE 2
MCLA-117	CLEC12A x CD3	Acute Myeloid Leukemia (AML)			

MRUS Fully Owned

DESIGN	ENDPOINTS	STATUS
<p><b>Single-arm, open-label, dose escalation w/ safety dose expansion</b></p> <ul style="list-style-type: none"> <li>Up to 50 patients with relapsed / refractory AML</li> <li>Starting dose determined using MABEL dose escalation requirements</li> <li>Protocol amended July 2019 to allow for the exploration of higher doses</li> </ul>	<ul style="list-style-type: none"> <li><b>Primary Endpoints:</b> safety, tolerability</li> <li><b>Secondary Endpoints:</b> PK/PD, anti-tumor response, clinical benefit</li> </ul>	<ul style="list-style-type: none"> <li>Ongoing in Europe and the U.S.</li> <li>Preliminary anti-tumor activity has been observed</li> <li>Initial data expected at medical conference 1H 2020</li> </ul>



# Clinical Programs

## MCLA-158

**Lgr5 x EGFR Biclomics®**

# Potently blocks EGFR signaling in Wnt dysregulated solid tumors

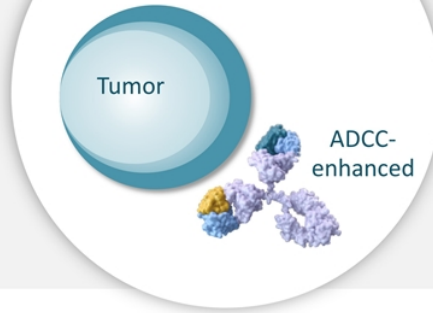
**Potential to be first colorectal cancer treatment to block growth of tumors with RAS mutations (~50% of patients), a high unmet need**

## Lgr5

Expressed by intestinal cancer initiating cells

Identified through Merus functional screening and organoid discovery methods

## KILL TUMOR CELLS



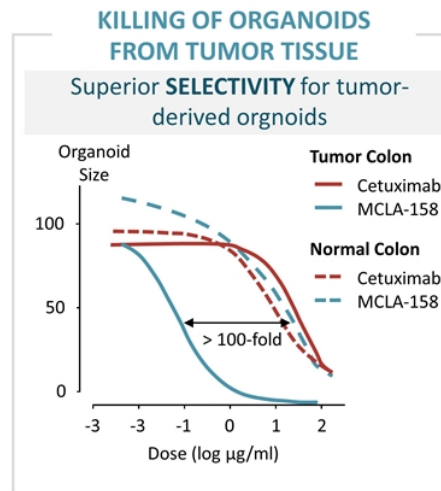
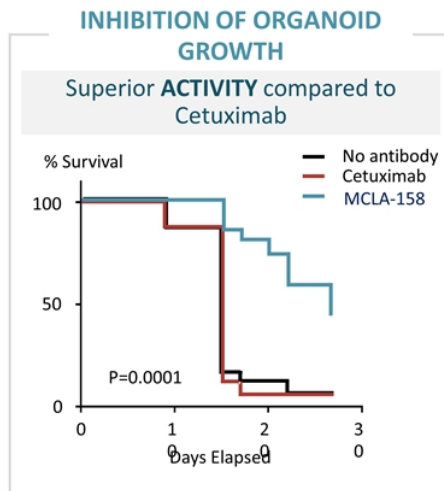
## EGFR

Blocks growth in Wnt dysregulated tumors including RAS<sup>mut</sup>

Preclinical data shows higher potency than Cetuximab

# Superior growth inhibition and selectivity of tumor versus healthy tissue

- MCLA-158 is active in xenograft models that are resistant to treatment with Cetuximab
- Unlike Cetuximab, MCLA-158 discriminates between organoids derived from tumor and healthy tissue




# Phase 1 Trial

	TARGETS	INDICATION / DRUG COMBINATION	PRE-IND	PHASE 1	PHASE 2
MCLA-158	Lgr5 x EGFR	Solid tumors			

MRUS Fully Owned

DESIGN	ENDPOINTS	STATUS
<p><b>Global open-label, multicenter dose escalation w/ safety dose expansion phase</b></p> <ul style="list-style-type: none"> <li>Patients with solid tumors</li> <li>Initial focus on metastatic colorectal cancer</li> </ul>	<ul style="list-style-type: none"> <li><b>Primary endpoint:</b> safety and tolerability of defined dose</li> <li><b>Secondary endpoint:</b> single-agent preliminary anti-tumor activity</li> </ul>	<ul style="list-style-type: none"> <li>Dose escalation is ongoing.</li> <li>Amended protocol to allow for the exploration of higher dose cohorts.</li> <li>Acceptable safety profile with no observed dose limiting toxicities to date.</li> </ul>



Clinical Programs  
MCLA-145

**CD137 x PD-L1 Biclomics®**



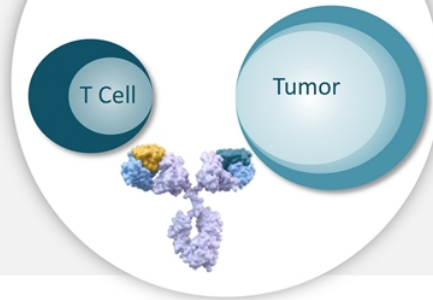
# Recruit, activate and prevent exhaustion of tumor-infiltrating T cells

## Triple action for potent and durable T cell activation in the tumor micro-environment

### CD137

Potent activation of tumor infiltrating T cells dependent on PD-L1 expressing tumor cells and macrophages

### TUMOR-INFILTRATING T CELL REVIVAL



### PD-L1

Targeting to PD-L1 positive cells in the tumor

Blocking of T cell inhibitory PD-1/PD-L1 interactions in tumor

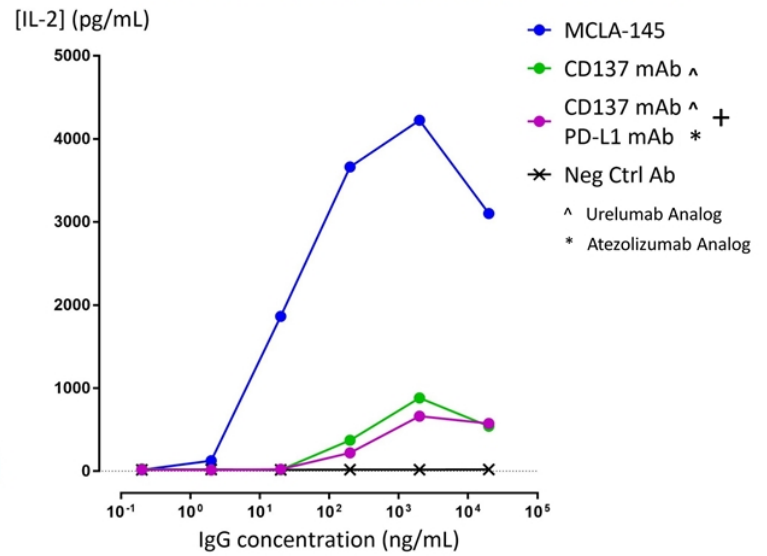
Attracting T cells into the tumor

# Demonstrated Potent T Cell Activation

- Binds to PD-L1 and CD137
- Preclinical work demonstrates
  - recruitment of T cells into the tumor
  - blocking of inhibitory PD-1/PD-L1 axis
  - potent T cell activation
- Potential to overcome the known side effects of CD137 agonists in development

MCLA-145 preclinical data presented at  
AACR 2019

## PRIMARY T CELL TRANSACTIVATION ASSAY



# Phase 1 trial initiated in May 2019

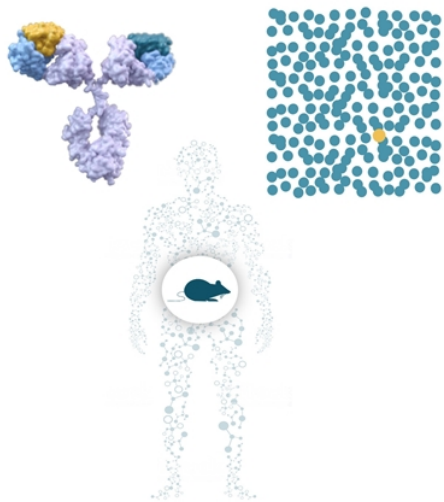
	TARGETS	INDICATION / DRUG COMBINATION	PRE-IND	PHASE 1	PHASE 2
MCLA-145	CD137 x PD-L1	Solid tumors			

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Incyte ex-US Rights

DESIGN	ENDPOINTS	STATUS
<p><b>Global open-label, multicenter dose escalation with dose expansion phase</b></p> <ul style="list-style-type: none"> <li>Patients with advanced solid tumors</li> </ul>	<ul style="list-style-type: none"> <li><b>Primary endpoint:</b> dose finding, safety and tolerability</li> <li><b>Secondary endpoint:</b> single-agent preliminary activity</li> </ul>	<ul style="list-style-type: none"> <li>IND cleared January 2019</li> <li>First patient dosed May 9, 2019</li> </ul>

# The new Triclomics™ platform for additional differentiated modes of action

The BICLONICS® Beginning  
*Our existing foundation...*



**Designed by nature.  
Improved by Merus.**

Next Generation TRICLONICS™ Platform  
*for 2 or 3 different targets*



Common light chain for unforced pairing with 3 (different) V<sub>H</sub> regions



Linker diversity for added functionality

1:1:1 or 2:1 format for new biology/modes of action

**Merus**

# Merus

## Closing In On Cancer

