

**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): September 2, 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 September 2, 2020, Merus N.V. (the “Company” or “Merus”) posted an updated corporate slide presentation (the “Presentation”) in the “Investors and Media” portion of its website at www.merus.nl including updates to its clinical program for zenocutuzumab (“Zeno”, also known as MCLA-128). A copy of the Presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

As set forth in the Presentation, the Company now plans to present efficacy data at a major medical conference in the second quarter of 2021 on more than 30 patients with neuregulin-1 (NRG-1) gene fusion positive (NRG1+) pancreatic, lung and other cancers with the opportunity for four or more months of follow up. At that time, Merus plans to also discuss details of the program and overall strategy. Merus previously expected to provide a clinical update of the Zeno Phase 1/2 eNRGy trial in patients with NRG1+ cancers by the end of the year.

As previously reported, enrollment and clinical operations activities in this trial have continued, albeit at a slower pace, through the COVID-19 pandemic. The decision to revise the timing of the data presentation was made following a recent review of the available dataset, which revealed that trial site restrictions have resulted in not only slower than anticipated enrollment but also insufficient source verification of clinical data required for the presentation of a mature dataset in 2020. Consequently, the Company expects to provide clinical data and a program update at a major medical conference in the second quarter of 2021.

Merus believes that Zeno continues to demonstrate encouraging single agent activity in NRG1+ cancers. Zeno also continues to be well tolerated, which is consistent with previously reported safety data in the overall patient population treated with Zeno monotherapy.

Site activation, patient identification and enrollment, and clinical operations activities have increased since the second quarter of 2020. Thirty clinical trial sites are now open globally, with additional sites being added monthly. Merus expects patient identification and enrollment to continue to accelerate through the Company’s ongoing patient screening and patient identification collaborations.

The Company’s cash, cash equivalents and marketable securities balance as of June 30, 2020 was \$197.4 million, as previously reported. Based on Merus’ current operating plan, Merus continues to expect its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the second half of 2022.

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.

Forward-Looking Statements

This Current Report on Form 8-K (the “Report”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in the Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the sufficiency of our cash, cash equivalents and marketable securities, our enrollment in our clinical trial concerning Zeno; the content and timing of potential milestones, updates, guidance, information, clinical trials and data readouts with respect to the Phase 1/2 eNRGy trial and our strategy; and our expectation that patient identification and enrollment will continue to accelerate through the Company’s ongoing patient screening and patient identification 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 duration and severity of the COVID-19 pandemic and the duration and scope of government recommendations and/or mandates regarding social distancing and limitation of public exposure.

These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 filed with the Securities and Exchange Commission, or SEC, on August 6, 2020, 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 Report. Any such forward-looking statements represent management’s estimates as of the date of this Report. 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, except as required under applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

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	Merus N.V. Corporate Slide Presentation as of September 2, 2020

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.

Date: September 2, 2020

MERUS N.V.

By: /s/ Sven A. Lundberg

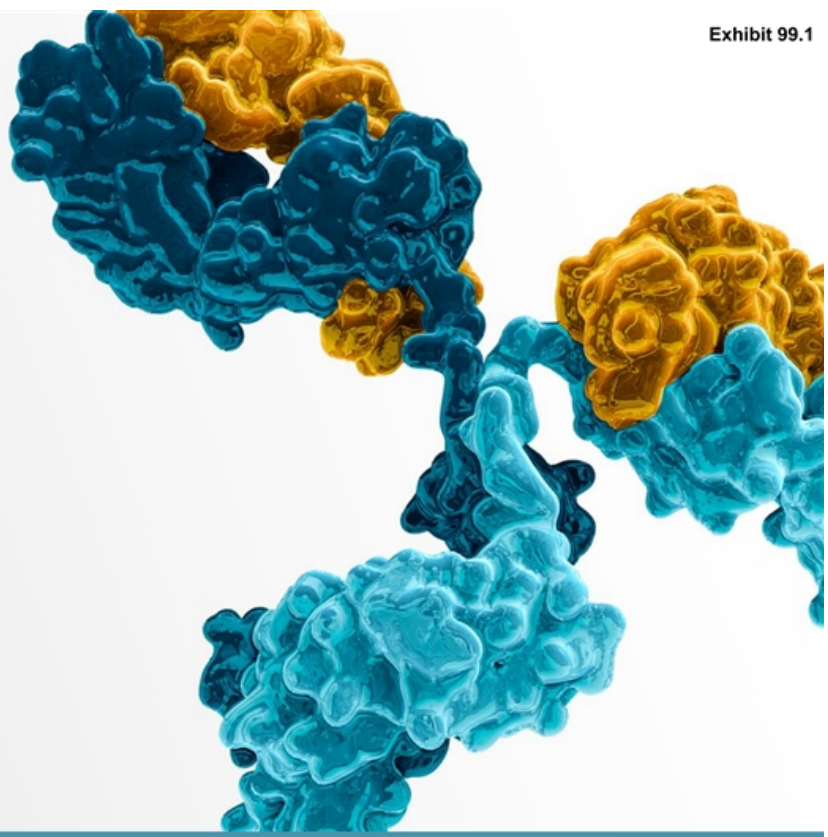
Name: Sven (Bill) Ante Lundberg

Title: President, Chief Executive Officer and Principal Financial Officer

Merus

Closing In On Cancer

September 2020



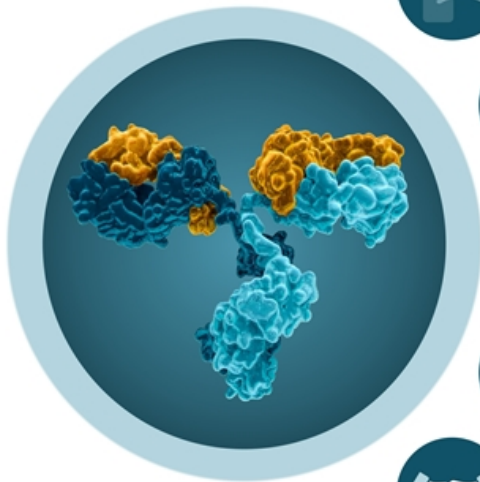
Disclaimer

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 Biclomics® 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 and impacts of the COVID-19 pandemic, 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 Biclomics®, and Triclomics™ 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 in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 filed with the Securities and Exchange Commission, or SEC, on August 6, 2020, 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 Overview



Oncology-focused Company Developing Multispecific Antibody Therapies
Bispecific and trispecific cancer therapeutic candidates based on the human IgG format



Established Clinical Pipeline

Clinical proof-of-concept with zenocutuzumab ("Zeno") in patients with neuregulin 1 (NRG1) positive gene fusion (NRG1+) cancers



Near Term Data Readouts and Strong Cash Position into 2H 2022

Zeno NRG-1 phase 1/2 clinical data 2Q 2021



Leading Multispecific Antibody (Multiclomics®) Platforms

Common light chain format permits broad high throughput Biclomics® and Triclomics™ discovery

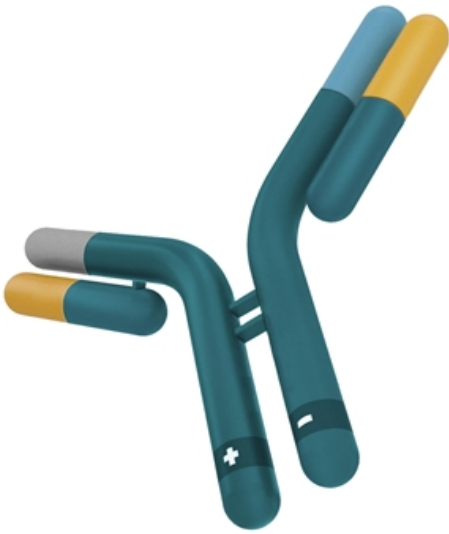


Strategic Collaborations to Unlock Platform Value

Multiple strategic collaborations and license agreements

Merus Multiclronics®

Bispecific and Trispecific Cancer Therapeutic Candidates in Human Monoclonal Antibody Formats



- Large-scale screening to select from up to 1,000s of candidates
 - Potential to identify best and new biological combinations
- Fully human IgG format allows for:
 - Ease of manufacturing
 - Low immunogenicity risk
 - Predictable *in vivo* behavior
 - Durable, consistent half life
 - Potential for ADCC enhancement and Fc silencing
- Robust IP portfolio: patents covering Multiclronics® technology, including common light chain antibody generation and dimerization by charge engineering

Merus Clinical Pipeline

PROGRAM	BISPECIFIC TARGETS	INDICATION(S)	PRECLINICAL	PHASE 1	PHASE 1/2	STATUS
Zenocutuzumab (Zeno) (MCLA-128)	HER3 x HER2	NRG1+ Pancreatic				Phase 1/2 trial ongoing
		NRG1+ Lung				Clinical data and program update planned 2Q 2021
		NRG1+ Other solid tumors				
MCLA-158	Lgr5 x EGFR	Solid tumors				Phase 1 Trial Ongoing Update planned YE 2020
MCLA-145	CD137 x PD-L1	Solid tumors				Phase 1 Trial Ongoing
MCLA-129	EGFR x c-MET	Solid tumors				IND Enabling Studies Ongoing
ONO-4685*	PD-1 x CD3	Autoimmune disease				Phase 1 Trial Ongoing
...*	Undisclosed	Autoimmune disease				

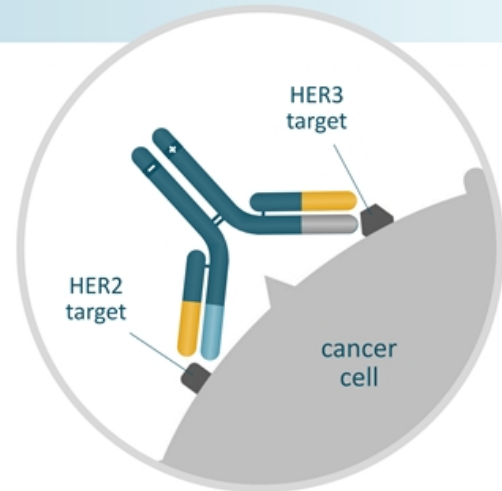
* If commercialized, Merus to receive royalties

***Promising early clinical activity
in patients with NRG1+ cancers***

Zenocutuzumab

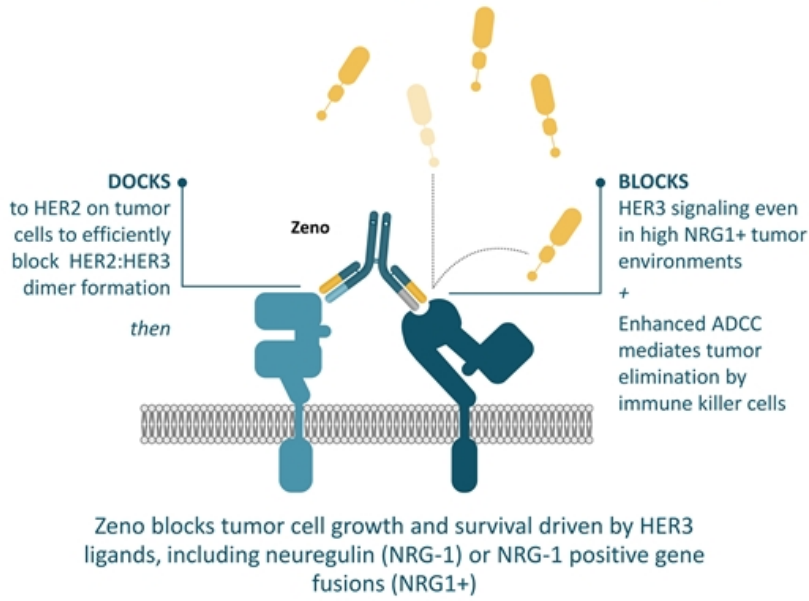
MCLA-128 or "Zeno"
HER2 x HER3 bispecific

- NRG-1 positive gene fusions (NRG1+) are rare genetic events occurring in lung, pancreatic and other solid tumors
- Unique DOCK & BLOCK® mechanism of Zeno potently inhibits NRG1+-driven tumor growth
- Enhanced ADCC mediates tumor elimination by immune effector cells
- eNRGy Trial enrolling and Early Access Program ongoing
- Clinical data and program update expected 2Q 2021

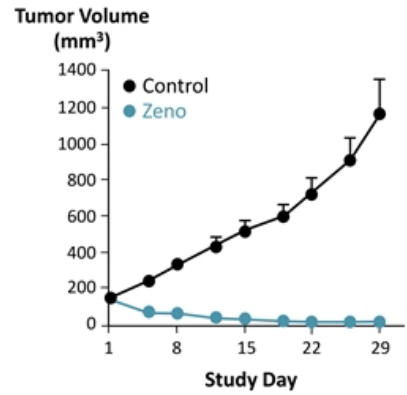


Zeno DOCK & BLOCK® Mechanism of Action

Uniquely Suited to Target NRG1+ Cancers



Zeno Blocks Tumor Growth in NRG1+ PDX Model



Zeno Safety Profile for Single Agent Use

Safety Data in Over 100 Patients in Phase 1/2 Trials



Safety and Tolerability in Phase 1/2 Trial

OVER 100 PATIENTS EVALUATED*

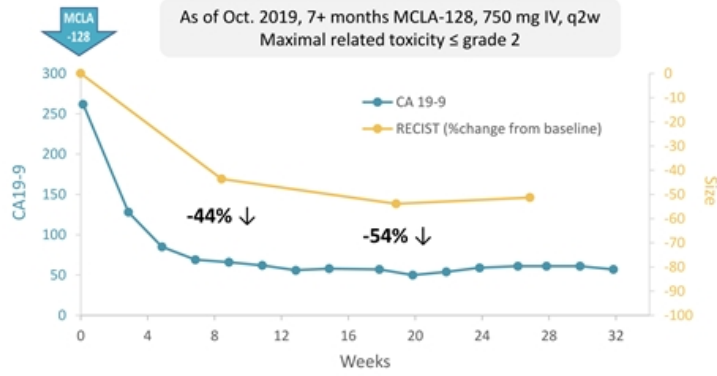
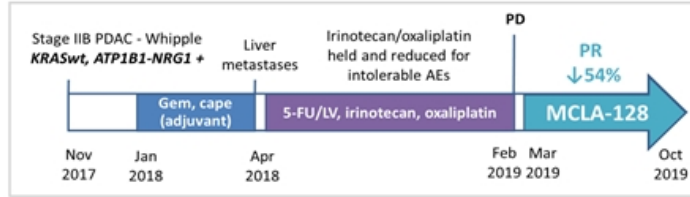
Zeno Dosing: 750 mg ranging from q1w-q3w

- Single agent well tolerated
- Low risk for immunogenicity
- Most AEs were grade 1-2

Zeno Clinical Response in NRG1+ Cancers

Patient Data Presented at 2019 AACR-NCI-EORTC International Conference

Example pancreatic cancer patient:



Source: AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019
https://merus.nl/app/uploads/2019/10/AACR-NCI-EORTC_Poster-LB-B12_NRG1-MCLA-128_10252019_FINAL.pdf/

Zeno Activity and Promising Durability Observed in Patients

Zeno NRG1+ Clinical Activity Reported by MSKCC at 2019 AACR-NCI-EORTC International Conference

	PANCREATIC CANCER		LUNG CANCER
Tumor size reduction	54% (PR)	25% (SD)	41% (PR)
PET scan	Neg	Neg	nd
Decline in tumor marker	~75%	~90%	N/A
Duration of treatment (mo)	>7*	>7*	~ 5*

Source: AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019
https://merus.nl/app/uploads/2019/10/AACR-NCI-EORTC_Poster-LB-B12_NRG1-MCLA-128_10252019_FINAL.pdf

Overall Experience with Zeno in NRG1+ Tumors as of October 2019

	N	PANCREATIC CANCER	LUNG CANCER
Evaluable	6	PR 7 mo*; SD 7 mo	PR 5 mo*; SD 7 mo; PD; PD
Non-evaluable	3	Died of progressive disease prior to first evaluation	2 Pts not yet at first evaluation

5 patients enrolled on the eNRGy trial; 4 patients treated under Early Access Program

Source: Merus Press Release Oct 27, 2019 <https://ir.merus.nl/news-releases/news-release-details/merus-bispecific-antibody-mcla-128-shows-encouraging-early>
 *Indicates treatment was ongoing at the time of the conference; nd, no data; N/A, not applicable

Zeno Clinical Programs in NRG1+ Cancers

eNRGy Clinical Trial and Early Access Program Ongoing

eNRGy
Clinical Trial

- Phase 1/2 global single arm trial of Zeno in NRG1+ cancers
- Cohorts include Pancreatic, NSCLC, and other solid tumors
- Majority of clinical trial sites open and enrolling
- Ongoing Phase 1/2 trial update expected 2Q 2021






Early Access Program

- For eligible patients who do not enroll on the eNRGy trial
- Allows patients with NRG1+ cancers to receive treatment with Zeno
- Evaluations and patient follow up may be similar to eNRGy protocol
- May provide additional clinical data in support of Zeno NRG1+ program

Identifying and Recruiting NRG1+ Patients

NRG1+ Cancers are Found Across Multiple Solid Tumor Types

TUMOR TYPE	ESTIMATED INCIDENCE (%)
 LUNG	0.3 – 3.0
 PANCREAS	0.5 – 1.5
 OTHER	< 1.0

Comprehensive Effort to Identify and Recruit NRG1+ Patients



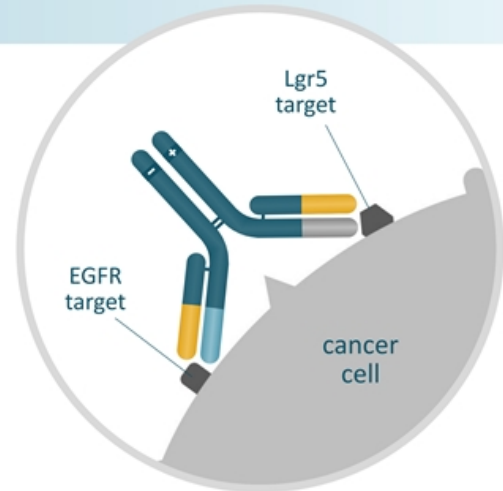
Note: Projections of NRG1+ estimated incidence based on limited published information, including Jonna S et al. Clinical Cancer Research (2019); independent epidemiology review <https://ir.merus.nl/news-releases/news-release-details/merus-announces-acceptance-six-abstracts-upcoming-medical>; and Wang (2015); Duruisseau (2017); Trombetta (2018); McCoach (2018); Karlsson (2019); Drilon (2018); Fernandez-Cuesta (2014); Seto (2018); and Scheel (2015)

Designed to potently block signaling and growth in Wnt-dysregulated solid tumors

MCLA-158

Lgr5 x EGFR bispecific

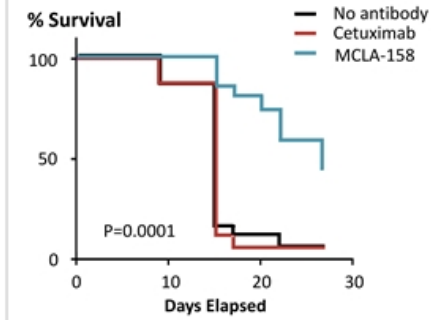
- Binds to EGFR and Lgr5, an intestinal cancer-initiating cell antigen
- Potential to address significant unmet need in colorectal cancers and a variety of other solid tumors
- Blocks growth in Wnt-dysregulated tumor models including Ras^{mut}
- Modifications to enhance ADCC
- Phase 1 trial update planned for year end 2020



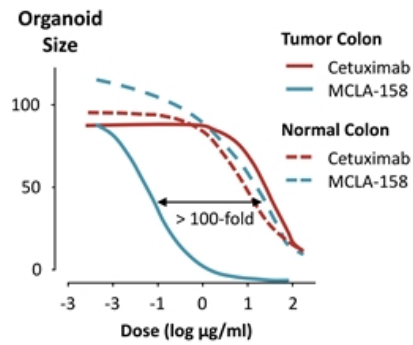
MCLA-158 — Novel Target and Innovative MoA

Superior Growth Inhibition and Selectivity of Tumor Versus Healthy Tissue

Superior **ACTIVITY** compared to Cetuximab



Superior **SELECTIVITY** for tumor-derived organoids



ONGOING PHASE 1 TRIAL

- Global Phase 1 dose escalation and cohort expansion trial
- Protocol includes dose expansion phase at RP2D
- Update planned year end 2020

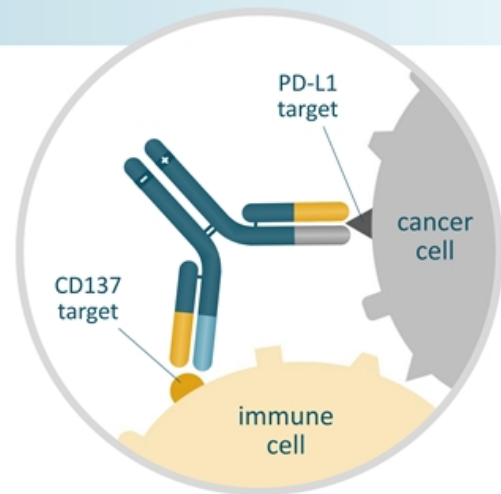
- Activity observed in xenograft models resistant to treatment with Cetuximab
- MCLA-158 discriminated between organoids derived from tumor and healthy tissue

Designed to recruit and activate tumor infiltrating T-cells

MCLA-145

PD-L1 x CD137 bispecific

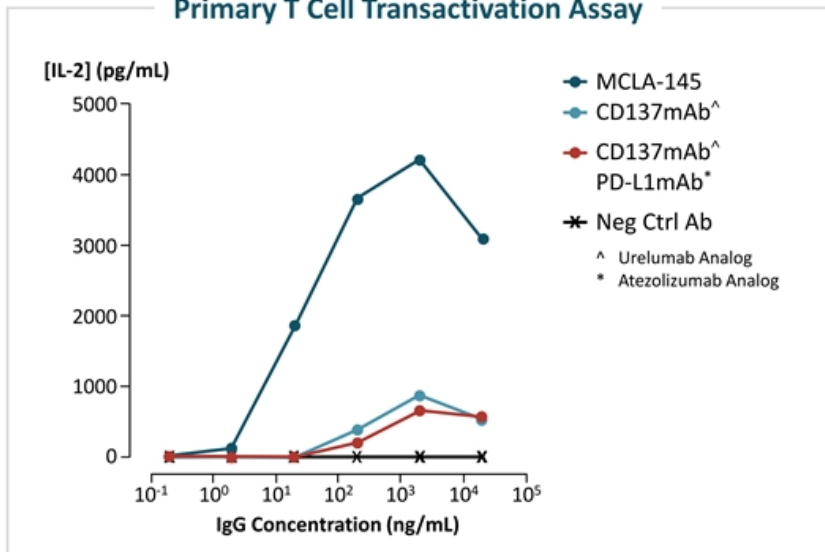
- Binds to PD-L1 on tumor cells and CD137 (4-1BB), a potent activator of tumor infiltrating T-cells, on activated T-cells
- Targeting to PD-L1 positive cells in the tumor and blocking the PD-1/PD-L1 inhibitory signal
- Potential in a variety of solid tumors and hematological malignancies
- Global phase 1 trial ongoing in collaboration with Incyte



MCLA-145 — Targets PD-L1 Positive Tumor Cells

Demonstrated Potent T Cell Activation in Preclinical Studies

Primary T Cell Transactivation Assay



Ongoing Phase 1 Trial

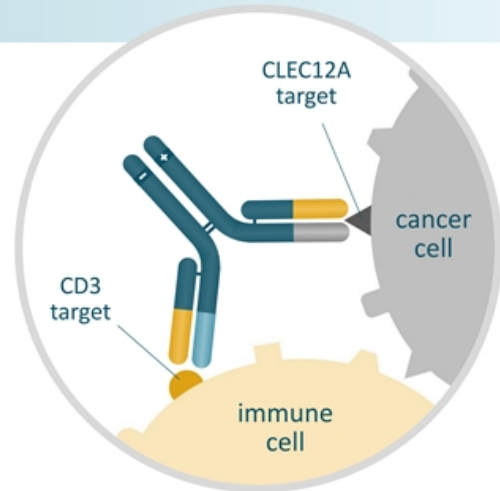
- Global open-label Phase 1 dose escalation trial ongoing
- Clinical trial co-developed in collaboration with Incyte Corporation

Source: 2019 AACR Presentation A bispecific Fc-silenced IgG1 antibody (MCLA-145) requires PD-L1 binding to activate CD137
https://merus.nl/app/uploads/2019/04/IC171-19E-AACR19-Mayer-MCLA-145-MoA-Poster_MT06_for-approval-032019.pdf

Interim phase 1 trial results of novel T-cell engager at EHA 2020

MCLA-117 CLEC12A x CD3 bispecific

- Designed with lower CD3 affinity binding to potentially reduce the risk of cytokine release syndrome
- Acceptable safety profile in clinical trial
- Active in acute myeloid leukemia (AML) with T-cell activation, cytokine elevation and AML blast reductions in some patients
- Insufficient clinical activity in escalation to continue to enroll dose expansion cohorts
- Findings from this trial expected to inform further development of our extensive proprietary T-cell engager platform

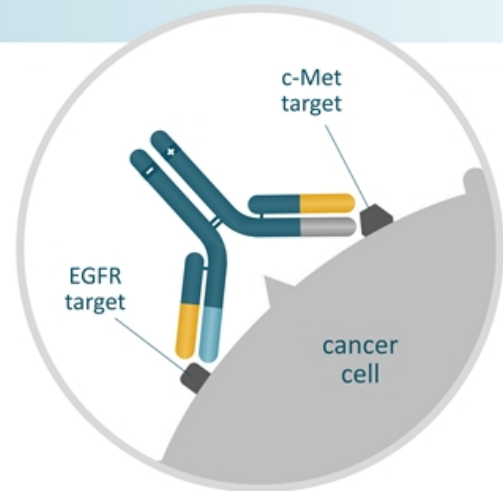


***Designed to target lung cancer
and other solid tumors***

MCLA-129

c-MET x EGFR Bispecific

- Targets both c-Met and EGFR on cancer cells as well as resistance mechanism
- Preclinical program directed at a target-pair combination with clinical validation
- Significant opportunity in lung cancer and other solid tumors



Merus Collaborations & Licensing Agreements

Expanding Merus pipeline through development of innovative therapeutics



Global collaboration of up to 11 Bionics® programs

\$200mm at signing and research funding, Merus retains full U.S. rights to develop, commercialize MCLA-145



MCLA-129 EGFR x C-MET collaboration

Betta conducting IND-enabling studies; Merus retains global rights ex-China



Collaboration with 3 immuno-oncology Bionics® programs

Simcere responsible for IND-enabling and China studies; Merus retains global rights ex-China



Bionics® Licensing Agreement for Auto-immune diseases

Phase 1 trial in Japan for ONO-4685, a PD-1 x CD3 bispecific antibody

Our Platform – Unparalleled Capabilities in Multispecific Antibodies



Patented discovery engine including the “Merus Mouse” (MeMo®) generates diverse, high quality common light chain (cLC) antibody panels



Proprietary inventory of thousands of cLC antibodies, each with distinct purposes and unique features



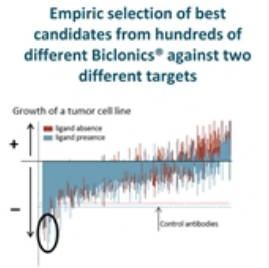
Robotics generate thousands of Multiconics® for functional screening



CH3 domain variations “DEKK” drives preferential, efficient pairing of different antibody chains to create multispecific functionality



In-format, unbiased functional screening with high throughput cellular assays



Empiric selection of best candidates from hundreds of different Biconics® against two different targets

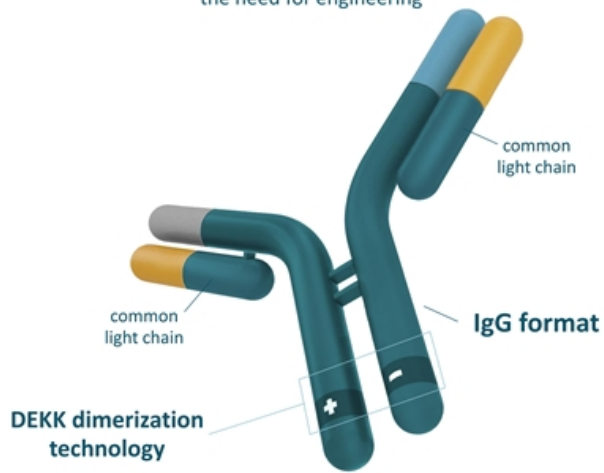
Merus

Our Science — Multiclronics® Technology

Leading the Next Generation of Multispecific Antibody Therapies

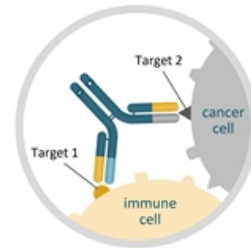
Common Light Chain (cLC) Antibodies

to prevent heavy/light chain mispairing without the need for engineering

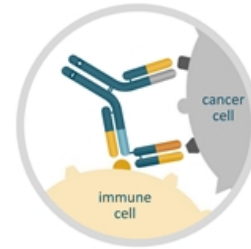


Multiclronics® Format

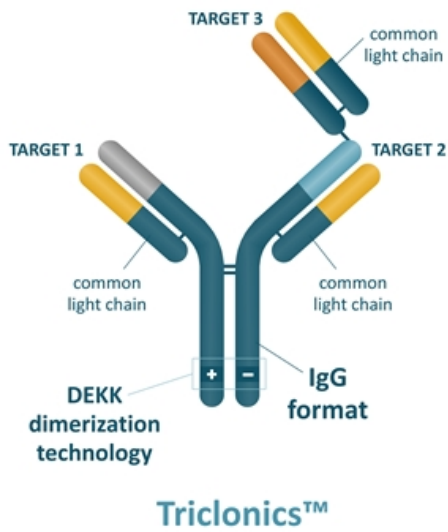
Biclomics®



Triclomics™



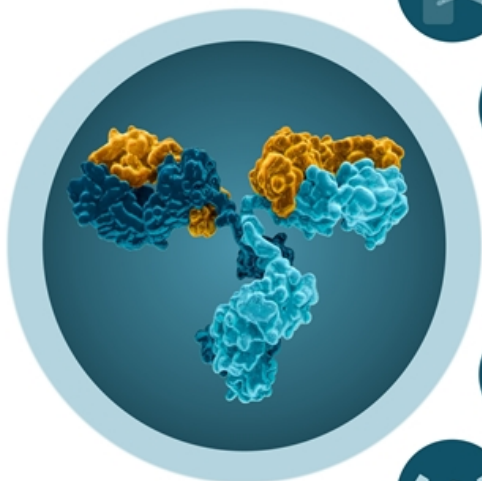
Our Research — Triclronics™ and Beyond



Triclronics™ Opportunity

- High throughput production, purification and screening in the trispecific format
- Stable format with predictable behavior that can be produced as if it were a normal monoclonal antibody
- Allows for 3 specificities without the need to engineer each individual Fab
- Leverages Merus' extensive library of established antibody panels that bind tumor antigens and engage and modulate the immune system to explore combinations and novel biology

Merus Overview



Oncology-focused Company Developing Multispecific Antibody Therapies

Bispecific and trispecific cancer therapeutic candidates based on the human IgG format



Established Clinical Pipeline

Clinical proof-of-concept with zenocutuzumab ("Zeno") in patients with neuregulin 1 (NRG1) positive gene fusion (NRG1+) cancers



Near Term Data Readouts and Strong Cash Position into 2H 2022

Zeno NRG-1 phase 1/2 clinical data 2Q 2021



Leading Multispecific Antibody (Multiclronics®) Platforms

Common light chain format permits broad high throughput Biclronics® and Triclronics™ discovery



Strategic Collaborations to Unlock Platform Value

Multiple strategic collaborations and license agreements