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): August 5, 2021

Neoleukin Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36327**	**98-0542593**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

188 East Blaine Street, Suite 450
Seattle, Washington 98102
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (866) 245-0312

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 (see General Instruction A.2. below):

☐ 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 Stock, $0.000001 par value	**NLTX**	**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.

o

Item 2.02 Results of Operations and Financial Condition

On August 5, 2021, Neoleukin Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the quarter ended June 30, 2021. The full text of the press release announcing such results is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

The Company has prepared investor presentation materials with information about the Company, which it intends to use as part of investor presentations. A copy of the investor presentation materials to be used by management for presentations is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this current report on Form 8-K and in Exhibits 99.1 and 99.2 attached hereto is being furnished, but shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and is not incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Number	Description
99.1	Press Release of Neoleukin Therapeutics, Inc. dated August 5, 2021
99.2	Presentation of Neoleukin Therapeutics, Inc. dated August 2021
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 5, 2021

Neoleukin Therapeutics, Inc.
By: /s/ Robert Ho
Name: Robert Ho
Title: Chief Financial Officer

Neoleukin Therapeutics Announces Second Quarter 2021 Financial Results & Provides Corporate Update

SEATTLE, Washington, August 5, 2021 – Neoleukin Therapeutics, Inc., "Neoleukin" (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced financial results for the second quarter ended June 30, 2021 and provided a midyear corporate update.

"Our progression to a clinical stage company is a significant milestone, and we remain focused on execution of our clinical development strategy and pipeline expansion as we advance and explore the potential of our *de novo* protein technology platform," said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin.

Recent Updates

NL-201

NL-201 is Neoleukin's lead *de novo* protein therapeutic candidate, designed to mimic the therapeutic activity of natural cytokines IL-2 and IL-15, while potentially reducing the toxicities associated with high-dose IL-2.

In May 2021, Neoleukin announced dosing of the first patient in a Phase 1 trial of NL-201. The Phase 1 study, underway at clinical sites in the U.S. and Australia, is enrolling patients with advanced, relapsed, or refractory solid tumors. Patients will receive NL-201 as intravenous monotherapy to assess safety, pharmacokinetics, pharmacodynamics, immunogenicity, and antitumor activity. While certain factors, including COVID-19, have had an impact on site activation for our Phase 1 trial of NL-201, we are accelerating site start-up activities to increase the pace of enrollment. Interim data from the ongoing systemic Phase 1 trial of NL-201 is currently anticipated in 2022.

In addition, Neoleukin is assessing plans for a local administration study of NL-201 while prioritizing the NL-201 systemic trial. Management will update timing for future trials as appropriate.

NL-CVX1

NL-CVX1 is a *de novo* protein that binds to the spike protein of SARS-CoV-2, the virus that causes COVID-19 and blocks infection of human cells. The design and characterization of NL-CVX1 in under three months underscores the speed and versatility of Neoleukin's *de novo* protein platform.

In June 2021, in response to the evolving COVID-19 therapeutic landscape, including the widespread availability of effective vaccines, Neoleukin suspended plans to advance this research program into clinical trials.

Other Research Updates

Neoleukin has multiple research projects underway evaluating the applications of *de novo* protein technology to develop agonists and antagonists of immune pathways. Neoleukin currently plans to discuss its *de novo* protein pipeline during the second half of 2021.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled $164.2 million as of June 30, 2021, compared to $192.6 million as of December 31, 2020.

Based upon current internal infrastructure and pipeline initiatives, Neoleukin believes it has sufficient cash to fund operations into 2023.

R&D Expenses: Research and development expenses for the second quarter of 2021 increased to $9.8 million from $4.8 million for the second quarter of 2020. The increase was primarily due to increased expenses incurred from IND-enabling and clinical trial activities related to Neoleukin's lead product candidate, NL-201, and in connection with the advancement of other Neoleukin technologies.

G&A Expenses: General and administrative expenses for the second quarter of 2021 increased to $5.3 million from $4.9 million for the second quarter of 2020. The increase in general and administrative expenses was primarily due to increases in personnel-related costs as Neoleukin continues to grow its operations. The increase was partially offset by higher costs incurred in the second quarter of 2020 associated with the termination of its Vancouver, Canada office lease.

Net Loss: Net loss for the second quarter of 2021 was $15.1 million compared to a net loss of $9.7 million in the second quarter of 2020.

About Neoleukin Therapeutics, Inc.

Neoleukin is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Neoleukin's lead product candidate, NL-201, is a combined IL-2 and IL-15 agonist designed to improve tolerability and activity by eliminating the alpha receptor binding interface. For more information, please visit the Neoleukin website: www.neoleukin.com.

Safe Harbor / Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the therapeutic properties and potential of the company's *de novo* protein design technology, the results of the clinical trial for NL-201, expectations regarding cash forecasts, and planned clinical and development activities and timelines. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to the company's cash forecasts, the company's ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, the timing and results of preclinical and clinical trials, the timing of announcements and updates relating to the company's clinical trials and related data market conditions and further impacts of COVID-19, that could cause actual results to differ materially from what Neoleukin expects. Further information on potential risk factors that could affect Neoleukin's business and its financial results are detailed under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. Neoleukin undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Contacts:

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Investors
Solebury Trout
Alexandra Roy
617-221-9197
aroy@soleburytrout.com

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated balance sheet data

(In thousands of U.S. dollars)

	June 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 164,235	$ 192,556
Other current assets	3,261	1,966
Non-current assets	19,527	15,997
Total assets	$ 187,023	$ 210,519
Liabilities		
Current liabilities	$ 7,584	$ 7,889
Non-current liabilities	12,368	11,414
Total liabilities	19,952	19,303
Stockholders' equity	167,071	191,216
Total liabilities and stockholders' equity	$ 187,023	$ 210,519

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated statements of operations

(In thousands of U.S. dollars, except per share and share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
Research and development	$ 9,824	$ 4,843	$ 19,506	$ 10,341
General and administrative	5,300	4,926	10,566	8,499
Total operating expenses	15,124	9,769	30,072	18,840
Other income (loss), net	(5)	23	(7)	452
Net loss	$ (15,129)	$ (9,746)	$ (30,079)	$ (18,388)
Net loss per common stock – basic and diluted	$ (0.27)	$ (0.20)	$ (0.55)	$ (0.37)
Basic and diluted weighted average common shares outstanding	55,026,404	49,392,533	54,985,639	49,280,492

Exhibit 99.2

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THERAPEUTICS

August 5, 2021

Forward Looking Statements

Certain of the statements made in these slides and the accompanying oral presentation are forward looking, including those relating to Neoleukin's business, strategy, future operations, advancement of its product candidates and product pipeline, clinical development of its product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, properties of its product candidates, availability of data, the use and sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "expect," "may," "plan," "project," "potential," "will," "would," "could," "continue," and similar expressions. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials; our ability to identify or acquire additional clinical candidates, our ability to obtain and maintain regulatory approval for any product candidates and the potential safety, efficacy or clinical utility of or any product candidates; further impacts of COVID-19 on our operations; and other factors discussed in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. More information about the risks and uncertainties faced by the Company is contained in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, Annual Report on Form 10-K for the year ended December 31, 2020, and subsequent reports, filed with the Securities and Exchange Commission. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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Leader in Therapeutic Protein Design

First Program: Cancer Immunotherapy

Platform technology: computational protein design methods for creating *de novo* Neoleukin™ cytokine mimetics

NL-201 program: highly potent, non-alpha, combined IL-2 and IL-15 receptor agonist for cancer immunotherapy

2018 FOUNDED — SEATTLE WA

2019 PUBLIC — NASDAQ: NLTX

2020 IND SUBMISSION — NL-201

2021 CLINICAL TRIALS — FPI

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Functional De Novo Proteins

Better Immunotherapies by Design

nature **2019**

Article | Published: 09 January 2019

De novo design of potent and selective mimics of IL-2 and IL-15

Daniel-Adriano Silva ✉, Shawn Yu, Umut Y. Ulge, Jamie B. Spangler, Kevin M. Jude, Carlos Labão-Almeida, Lestat R. Ali, Alfredo Quijano-Rubio, Mikel Ruterbusch, Isabel Leung, Tamara Biary, Stephanie J. Crowley, Enrique Marcos, Carl D. Walkey, Brian D. Weitzner, Fátima Pardo-Avila, Javier Castellanos, Lauren Carter, Lance Stewart, Stanley R. Riddell, Marion Pepper, Gonçalo J. L. Bernardes, Michael Dougan, K. Christopher Garcia ✉ & David Baker ✉

Science **2020**

CORONAVIRUS Article | Published: 4 December 2020

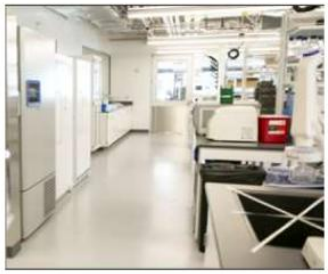
De novo design of potent and resilient hACE2 decoys to neutralize SARS-CoV-2

Thomas W. Linsky[1,*], Renan Vergara[1,*], Nuria Codina[1,*], Jorgen W. Nelson[1,*], Matthew J. Walker[1], Wen Su[2], Christopher O. Barnes[3], Tien-Ying Hsiang[4], Katharina Esser-Nobis[4], Kevin Yu[1], Z. Beau Reneer[5], Yixuan J. Hou[4], Tanu Priya[1], Masaya Mitsumoto[1], Avery Pong[1], Uland Y. Lau[1], Marsha L. Mason[1], Jerry Chen[1], Alex Chen[1], Tania Berrocal[1], Hong Peng[1], Nicole S. Clairmont[1], Javier Castellanos[1], Yu-Ru Lin[1], Anna Josephson-Day[1], Ralph S. Baric[6], Deborah H. Fuller[7], Carl D. Walkey[1], Ted M. Ross[5,8], Ryan Swanson[1], Pamela J. Bjorkman[3], Michael Gale Jr.[4], Luis M. Blancas-Mejia[1], Hui-Ling Yen[2], Daniel-Adriano Silva[1]†

- Scientific founders are world leaders in *de novo* protein design
- Technology originated at University of Washington Institute for Protein Design, led by David Baker, PhD
- Exclusive license obtained for commercialization of NL-201 and other *de novo* protein assets

Neoleukin™ Progress in 2021

- Initiated Phase 1 clinical trial for NL-201
- Announced hiring Priti Patel, MD as Chief Medical Officer
- Occupied new lab and headquarters in Seattle, WA
- ~90 FTE; added expertise in CMC and Clinical
- Continuing to build our pipeline and technology



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Leadership Team

Jonathan Drachman, M.D.
Chief Executive Officer
Prior: CMO, EVP R&D, Seattle Genetics

Robert Ho
Chief Financial Officer
Prior: Morgan Stanley & Co., DaVita

Priti Patel, M.D., M.S.
Chief Medical Officer
Prior: AstraZeneca, Acerta Pharma

Holly Vance, J.D., Pharm.D.
General Counsel
Prior: Gates Foundation Strategic Investment Fund

Carl Walkey, Ph.D.
Senior VP, Corporate Development
Prior: Postdoctoral Fellow, UW-IPD

Samantha Willing
VP, People
Prior: Seattle Genetics, Microsoft

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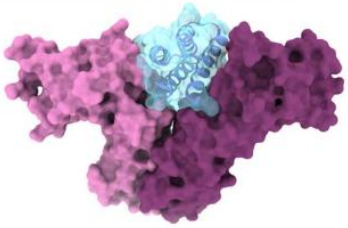
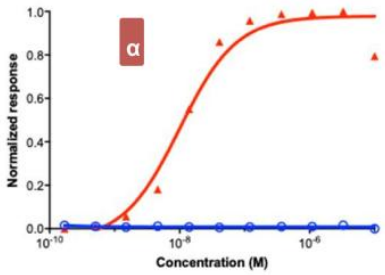
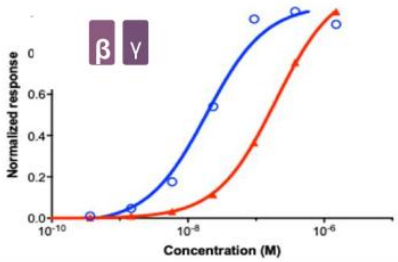
NL-201: *De Novo* IL-2/IL-15 Agonist

Designed to retain benefits of IL-2 without drawbacks

- 100% non-alpha: no residual alpha subunit binding
- No bias toward T-regulatory or endothelial cells
- More potent than IL-2 *and* IL-15
- Activates CD8+ naïve T-cells *and* NK cells
- Hydrophilic, compact, increased thermal stability







Neoleukin-2/15 — hIL-2

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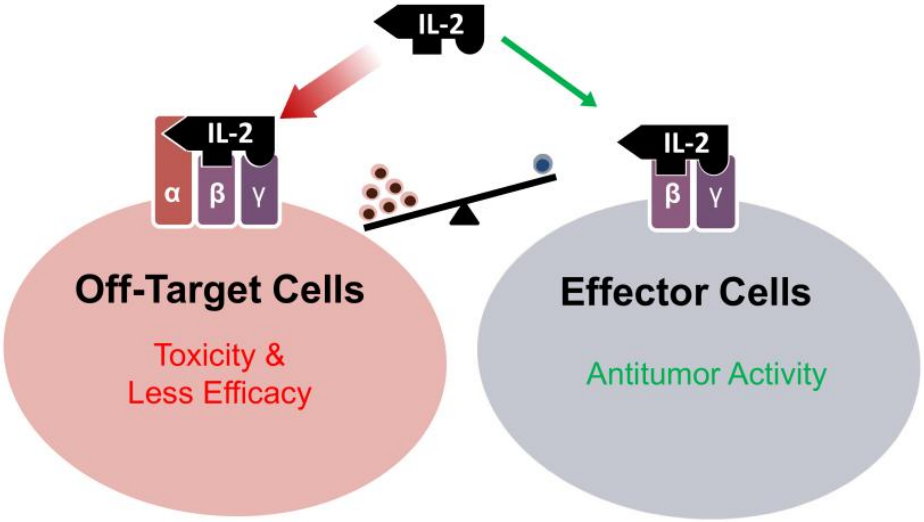
Source: Silva et al. *Nature*, 565, 186-191 (2019)

IL-2 Binds Strongly to Non-Target Cells, Causing Toxicity and Limiting Efficacy



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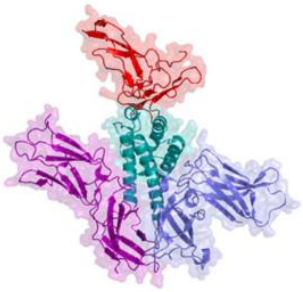
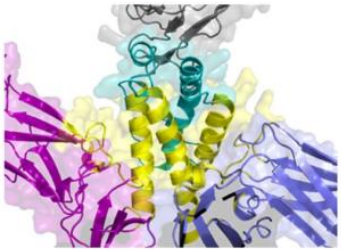
Building a Neoleukin™ Cytokine Mimetic in 4 Steps

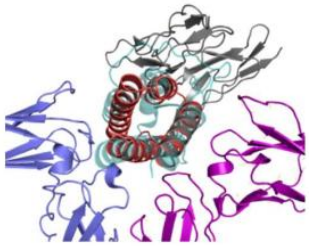
1. Develop an accurate structural model of the target



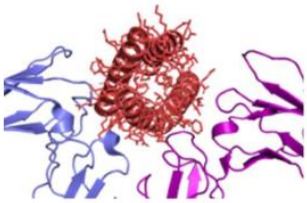
2. Identify regions of intermolecular contact



3. Design an idealized topology



4. Assign optimal amino acid sequence



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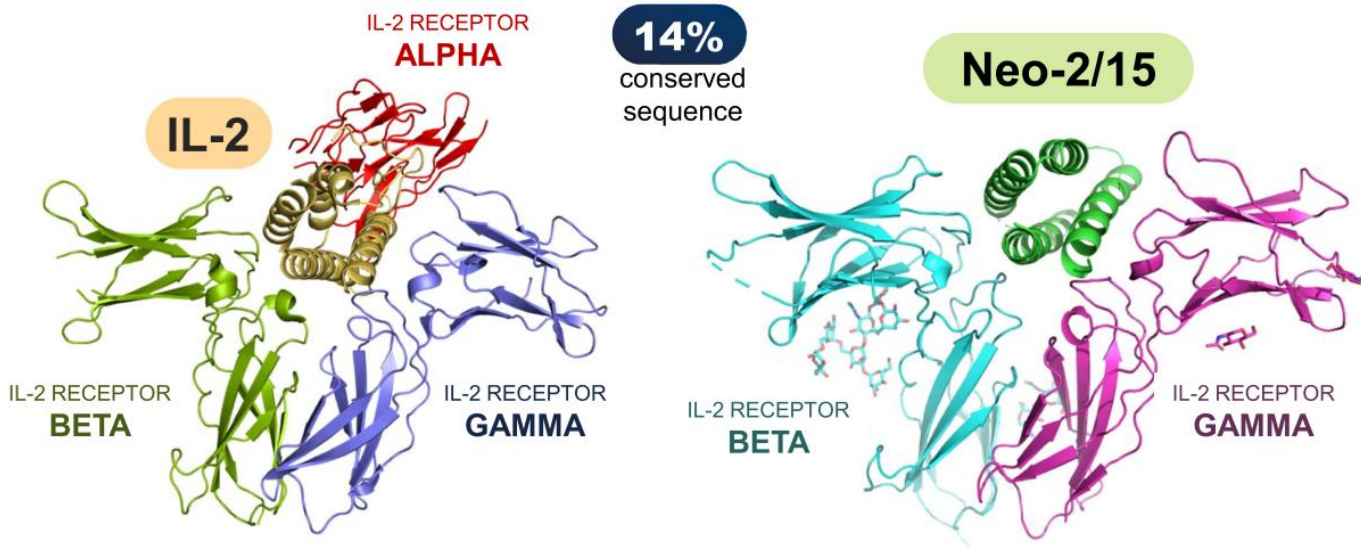
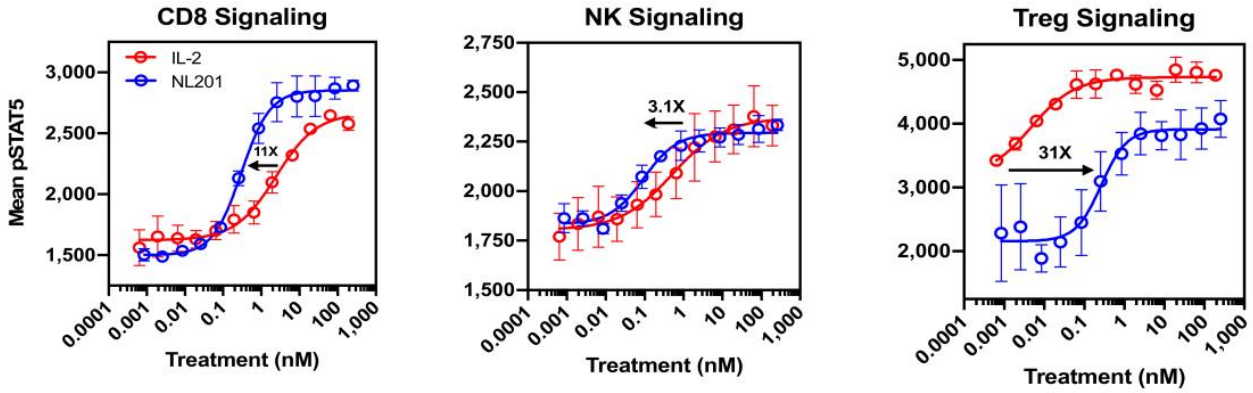
Crystal Structure Shows Neo-2/15 Binding Beta/Gamma as Predicted



Source: Silva et al. *Nature*, 565, 186-191 (2019)

NL-201 Stimulates CD8 Effector T and NK Cells More Selectively Than IL-2



- NL-201 is ~330-fold and ~90-fold more selective for CD8+ T and NK cells (vs. Tregs) than IL-2, respectively

Walkey et. al, AACR Virtual Annual Meeting II, Abstract #4518, June 2020

1) STAT5 phosphorylation in CD8+ T cells, NK cells, and Tregs was measured by flow cytometry using PBMCs from 10 healthy human donors. Proliferation was evaluated using Ki67.

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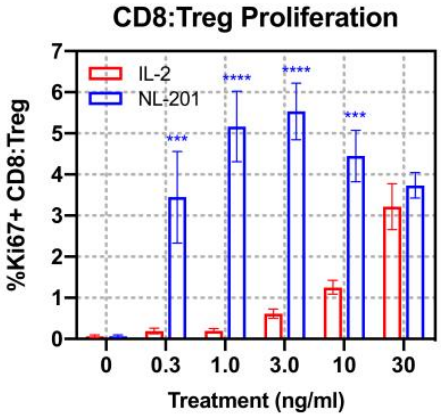
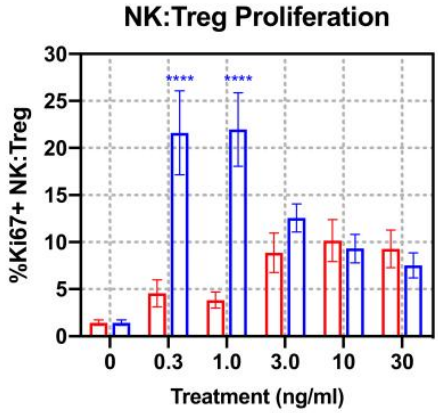
NL-201 Stimulates Dose-Dependent CD8:Treg and NK:Treg Proliferation More Potently Than IL-2





Walkey et. al, AACR Virtual Annual Meeting II, Abstract #4518, June 2020

1) NL-201 vs IL-2: * p<0.05; ** p<0.01; *** p<0.001; **** p<0.0001

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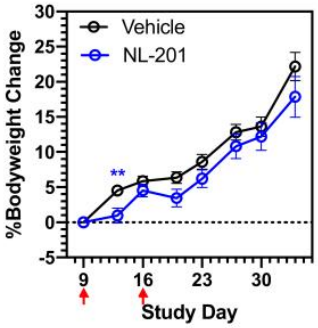
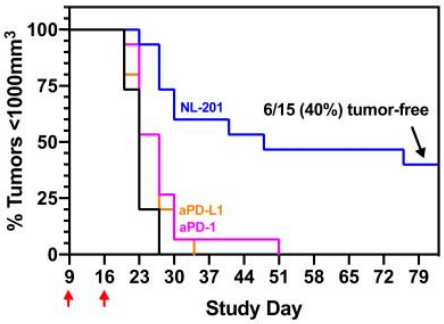
NL-201 is Well Tolerated and Promotes Durable Anti-tumor Activity

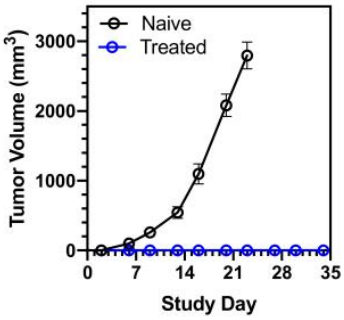
Tolerability



Tumor Growth Inhibition



Re-Challenge



- NL-201 is well-tolerated at therapeutic doses
- NL-201 treatment exhibits single-agent activity
- NL-201 promotes durable anti-tumor immunity

Walkey et. al, AACR Virtual Annual Meeting II, Abstract #4518, June 2020

1) Study in a checkpoint inhibitor-resistant CT26 colon cancer murine model.

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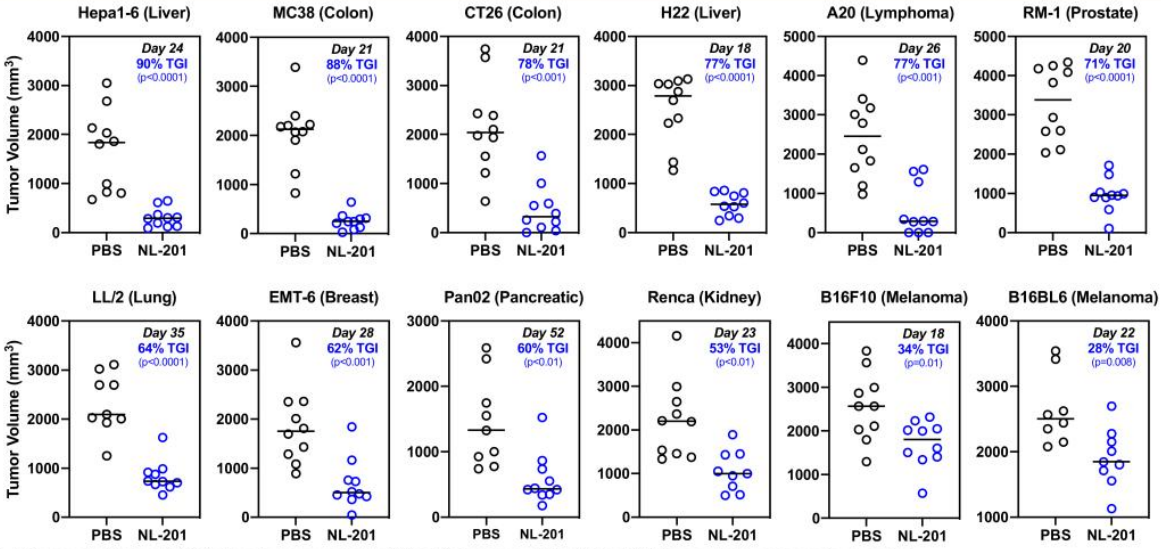
NL-201 Demonstrates Robust Single-Agent Activity in Multiple Tumor Models



1) NL-201 was administered QWx2 when tumors reached ~100mm3. Tumor growth inhibition (TGI) is reported in each graph vs. control.
2) NL-201 treatment inhibited tumor growth in all models: NL-201 significantly inhibited tumor growth in models that are typically refractory to anti-PD-1 checkpoint inhibitors.

Walkey et. al, AACR Virtual Annual Meeting II, Abstract #4518, June 2020

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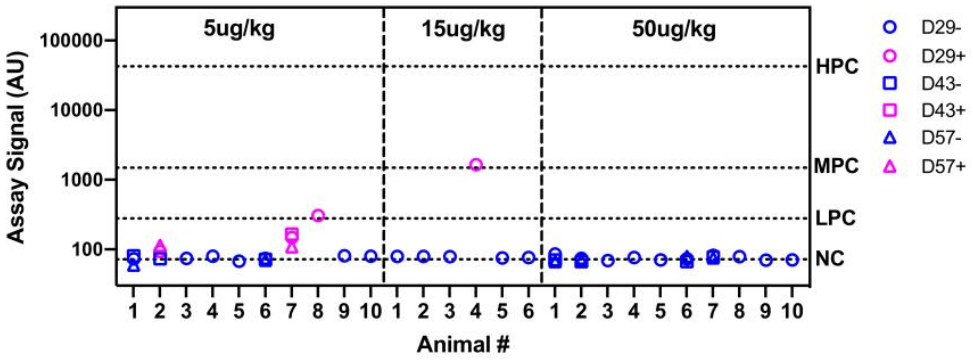
NL-201 Shows Minimal Immunogenicity in NHPs



- ADAs were detectable in: 3/10 NHPs at 5µg/kg; 1/6 NHPs at 15µg/kg; 0/10 NHPs at 50µg/kg NL-201
- 3 of 4 ADA+ NHPs were at or below the low positive control (LPC) level

Abstract #4518, Walkey et. al, AACR Virtual Annual Meeting II, June 2020

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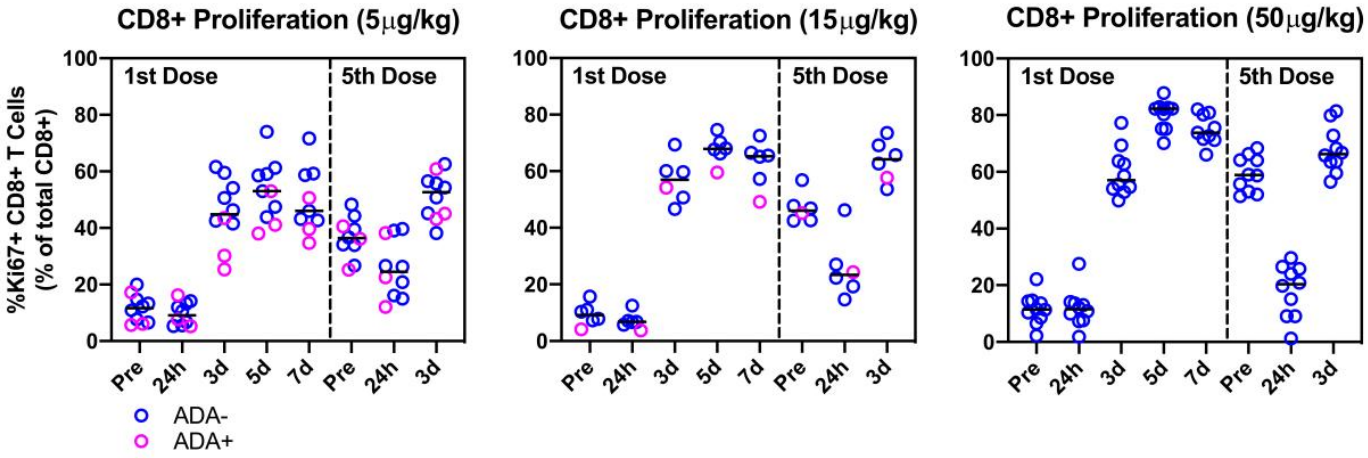
Similar Pharmacodynamics and Tolerability Observed in ADA+ vs ADA- NHPs



Adapted from Abstract #4518, Walkey et. al, AACR Virtual Annual Meeting II, June 2020

NL-201 Phase 1 Clinical Trial

- IV, monotherapy in patients with advanced, relapsed or refractory solid tumors
- Multiple schedules and dose levels to assess safety, PK, PD, and antitumor activity
- Indication-specific expansion cohorts, including renal cell carcinoma and melanoma
- Trial will be conducted at multiple sites in Australia and North America
- Targeted enrollment up to 120 patients
- Interim data expected in 2022

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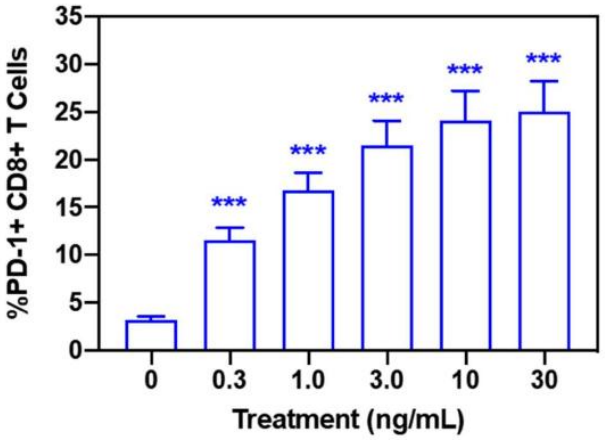
NL-201 Upregulates PD-1 Expression by CD8+ T Cells



- NL-201 induces concentration-dependent PD-1 expression by CD8+ T cells
- Combining NL-201 with a checkpoint inhibitor may overcome PD-L1 mediated T cell inhibition

Walkey et. Al, SITC 2020, Abstract #576, November 2020

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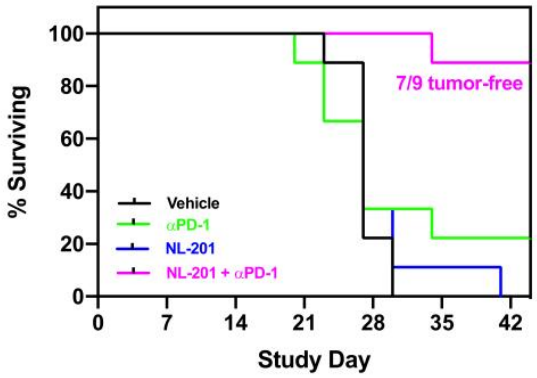
NL-201 Enhances Activity of Checkpoint Inhibitors in Preclinical Models

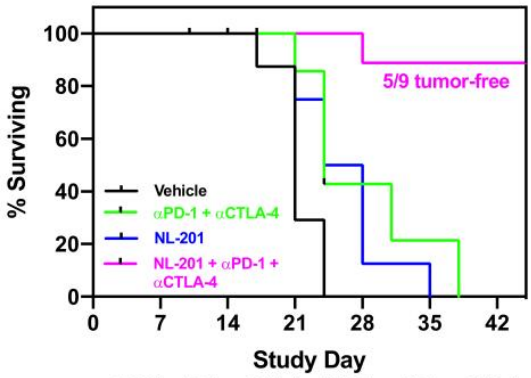
- NL-201 enhances activity of CPIs in breast and kidney cancer models
- Combination with NL-201 beneficial in CPI-resistant syngeneic tumors

EMT-6 (Breast)



p=0.0029: αPD-1 vs NL-201 + αPD-1
p<0.0001: NL-201 vs NL-201 + αPD-1

Renca (Kidney)



p=0.0001: αPD-1 + αCTLA-4 vs NL-201 + αPD-1 + αCTLA-4
p=0.0006: NL-201 vs NL-201 + αPD-1 + αCTLA-4

NL-201: 90µg/kg QWx2
αPD-1: 10mg/kg BiWx6
αCTLA-4: 10gm/kg BiWx6
Treatment began when tumors reached ~90mm³

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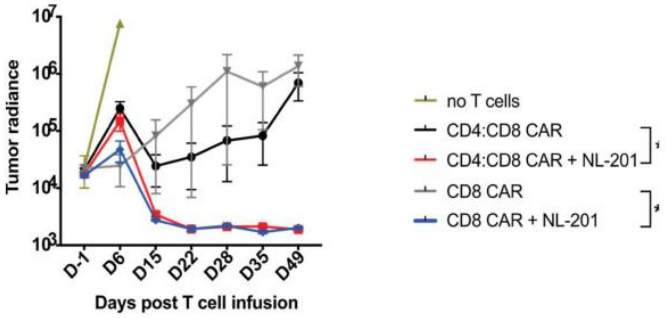
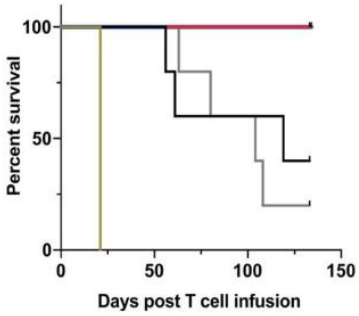
NL-201 Potently Expands CAR-T Cells and Promotes Antitumor Activity

Subcurative doses of CAR-T cells combined with NL-201 induce deep tumor control and achieve 100% survival.

NL-201 greatly enhances intratumoral CD8: Treg ratios (approximately 1000x compared to 50x for IL-2).





Leung et. al, AACR Virtual Annual Meeting II, Abstract #2222, June 2020

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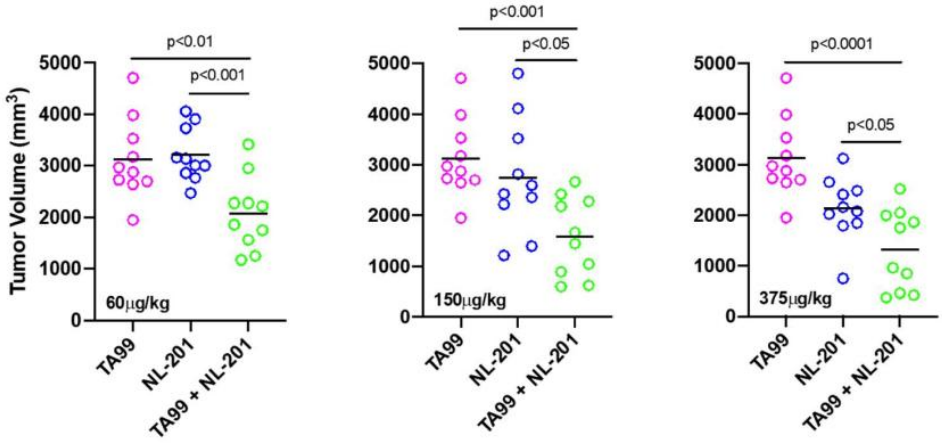
NL-201 Enhances Activity of Tumor-Targeting Antibodies in Multiple Preclinical Models

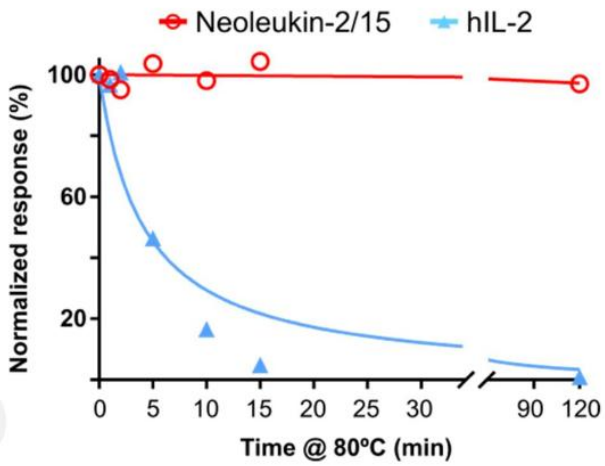
NL-201 + TA99 significantly improved tumor growth inhibition compared to TA99 or NL-201 alone



Walkey et. Al, SITC 2020, Abstract #576, November 2020

Neoleukin™ Cytokine Mimetics are Hyperstable and Easily Modified

- Able to withstand extreme conditions
- Able to adjust half-life or tune affinity
- Can use with targeting domain to improve biodistribution
- Can be conditionally activated in the tumor microenvironment
- Can be modified to make cytokine antagonists for inflammatory and autoimmune diseases



Source: Silva et al. *Nature*, 565, 186-191 (2019)

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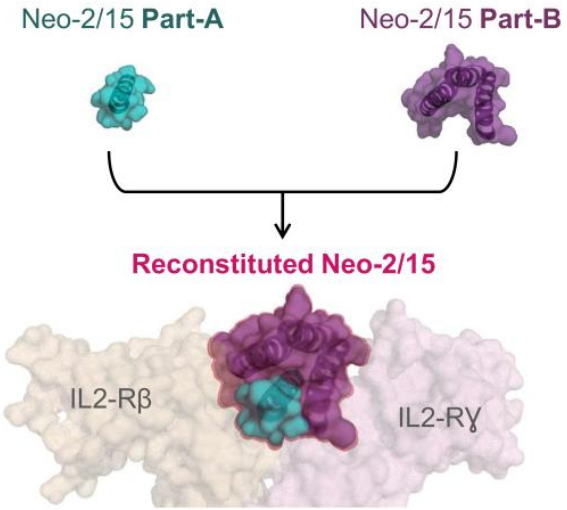
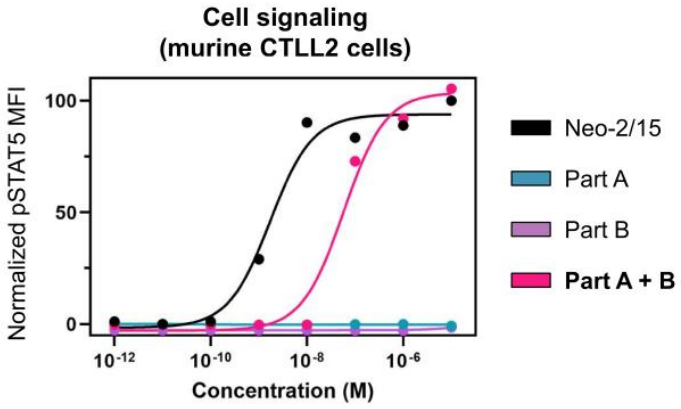
De Novo Split Technology - Conditionally Active IL-2 Mimetic





Quijano-Rubio et. Al., AACR Virtual Annual Meeting II, Abstract #1075, Jun/2020

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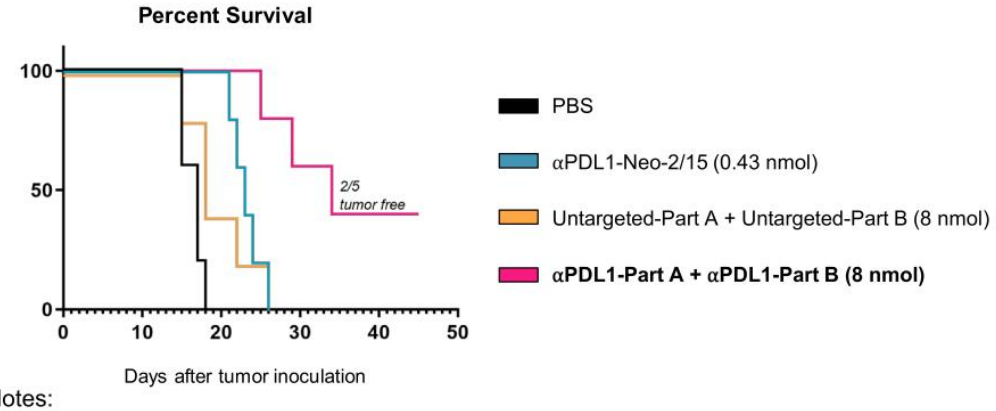
Targeted Split Neo-2/15 Increases Therapeutic Window



Notes:

1) C57BL/6J mice bearing B16 PDL1Hi melanoma cells in flank.
2) All groups were co-treated biweekly with Ta99 mAb (150µg/mice)
3) Targeted Neo-2/15 variants and Part-A fusions administered i.p.; Part-B fusions administered s.c. opposite flank of tumor

Quijano-Rubio et. Al., AACR Virtual Annual Meeting II, Abstract #1075, Jun/2020

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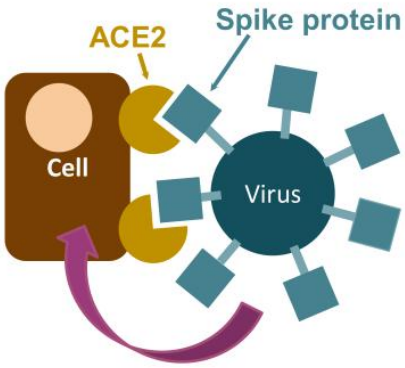
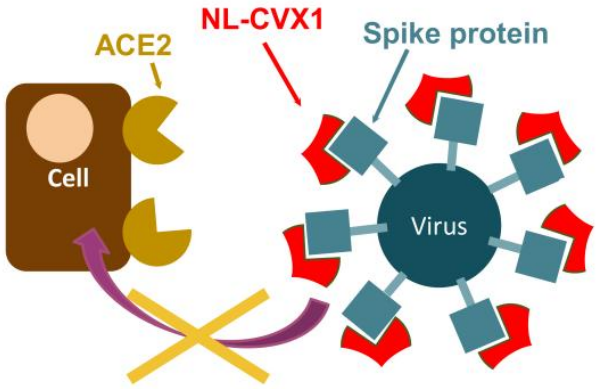
De Novo Platform Potential – COVID-19

SARS-CoV-2 uses **ACE2** as a receptor to gain access to and infect cells



NL-CVX1 - *de novo* ACE2 decoy:

- *Binds to SARS-CoV2 spike protein*
- *Inhibits viral infection in vitro*
- *Designed, tested, optimized in ~10 weeks*



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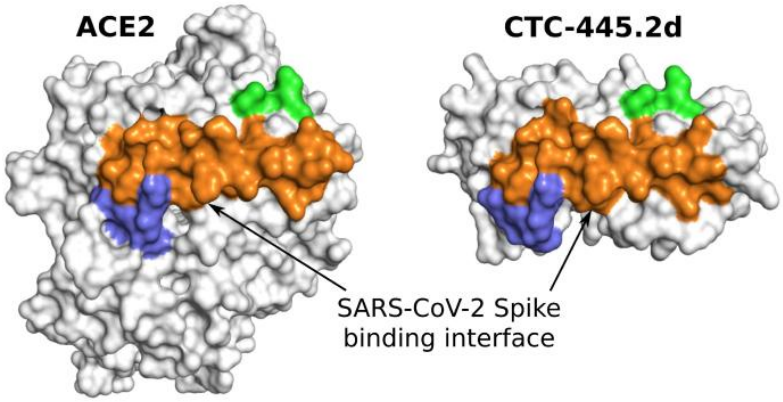
NL-CVX1 – *De Novo* Protein Decoy

De novo design of potent and resilient hACE2 decoys to neutralize SARS-CoV-2



Science AAAS

T. W. Linsky et. al. Science. 10.1126/science.abe0075 (2020)

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Financial Highlights

- $164.2 million cash & cash equivalents as of June 30, 2021
- Cash and cash equivalents expected to fund operations into 2023
- 42.3M common shares outstanding and 12.7M pre-funded warrants[1]

[1] Warrants to purchase common shares 1:1 with an exercise price of $0.000001 as of June 30, 2021.


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Designing for life.