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): **November 19, 2018**

SYNLOGIC, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37566**	**26-1824804**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

301 Binney St., Suite 402 **Cambridge, MA** (Address of principal executive offices)	**02142** (Zip Code)

Registrant's telephone number, including area code: **(617) 401-9975**

Not applicable
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

Synlogic, Inc. ("Synlogic") has prepared an investor presentation to be used in connection with general corporate presentations. A copy of the presentation is furnished with this Current Report on Form 8-K as Exhibit 99.1.

The information in Item 7.01 of this Current Report on Form 8-K and 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 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Investor presentation provided by Synlogic dated November 19, 2018

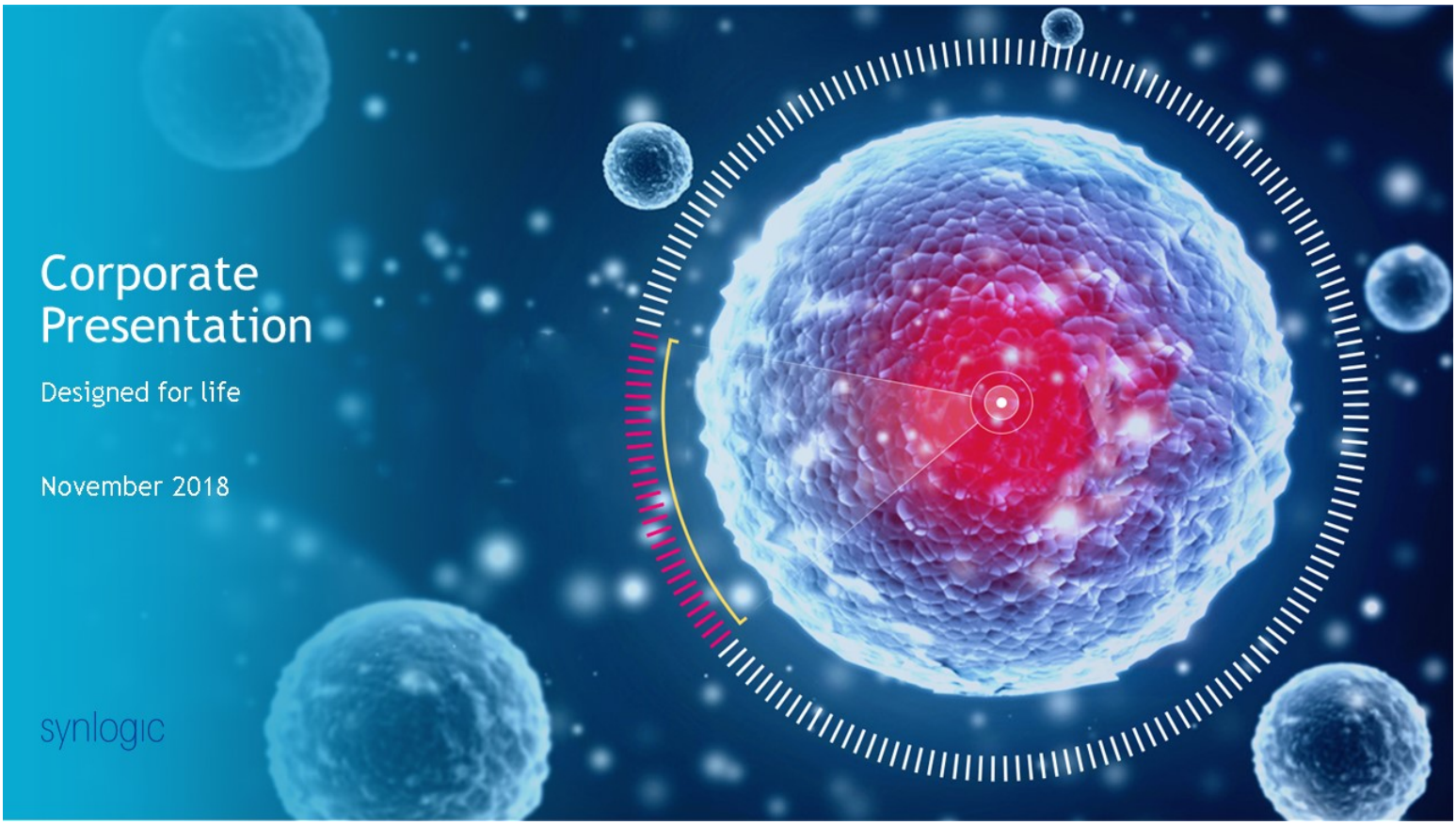
SIGNATURES

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.

SYNLOGIC, INC.

Date: November 19, 2018

By: /s/ Todd Shegog
Name: Todd Shegog
Title: Chief Financial Officer


Corporate
Presentation
Designed for life
November 2018
synlogic

Forward Looking Statements

This presentation contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this presentation regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, the approach we are taking to discover and develop novel therapeutics using synthetic biology; statements regarding the potential of our platform to develop therapeutics to address a wide range of diseases including: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the potential of our technology to treat hyperammonemia and phenylketonuria; the expected timing of our anticipated clinical trial initiations; the benefit of orphan drug and fast track status; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials; the results of our collaborations; and the difficulty in predicting the time and cost of development of our product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the uncertainties inherent in the preclinical development process; our ability to protect our intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in our filings with the SEC. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in our quarterly Report on Form 10-Q filed with the SEC on November 13, 2018. The forward-looking statements contained in this presentation reflect our current views with respect to future events. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date hereof.

Synthetic Biotic™ Medicines: A Novel Class of Living Medicines

Synthetic

Designed genetic circuits

Degradation of disease-causing metabolites

Production of therapeutic molecules

Biotic

Bacterial chassis

Non-pathogenic

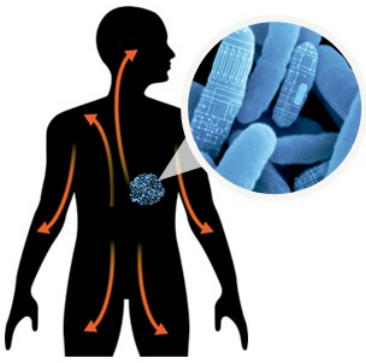
Amenable to genetic manipulation

PROGRAMMABLE POTENCY

Pathways, Combinations, Biomarkers

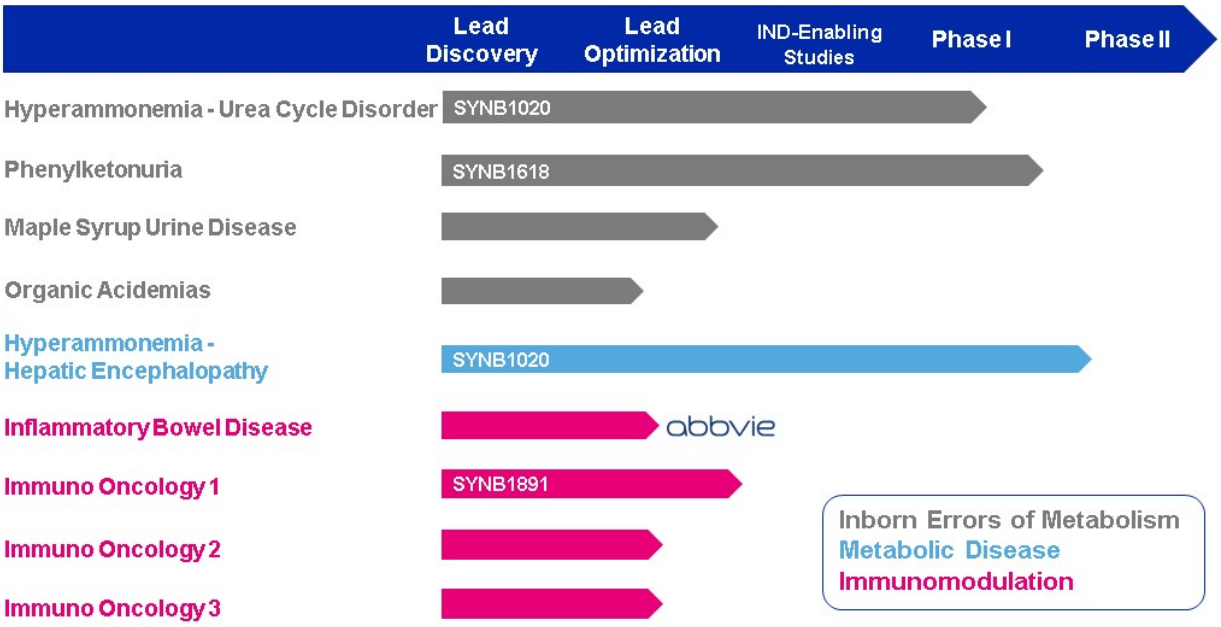
SWITCHES FOR CONTROL, TUNING

LOCAL, REDUCED SYSTEMIC TOXICITY



synlogic

Synthetic Biotic Platform Breath and Potential: Pipeline Focused on Three Therapeutic Areas



synlogic

Initial Synthetic Biotic Programs:

Designed to Evaluate Different Sites of Action

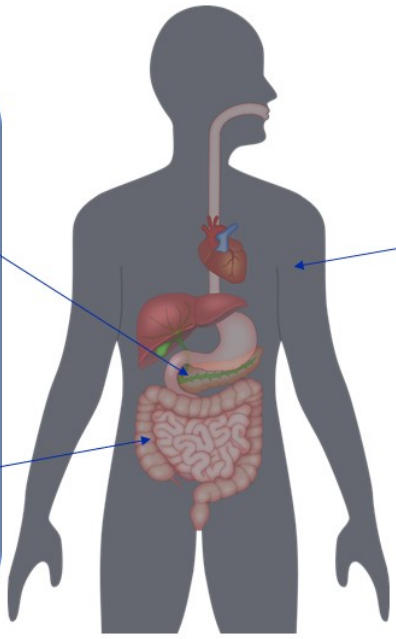
Oral Administration

SYNB1618 for PKU:

- Site of action = small intestine
- Other indications:
  - MSUD
  - IVA

SYNB1020 for hyperammonemia:

- Site of action = Colon
- Other indications:
  - PA
  - MMA



Intra-tumoral Administration

IO program: Site of action = "Cold" solid tumors

synlogic

SYNB1020 for Hyperammonemia Indications

Both diseases are characterized by systemic ammonia accumulation

Hepatic Encephalopathy

- **Neuropsychiatric complication in patients with end-stage liver disease (cirrhosis or hepatitis)**
  - Liver dysfunction leads to ammonia accumulation
  - Toxic to brain, leading to HE crisis & hospitalization
- **Patients:**
  - 165,000 diagnosed overt patients in US
  - Up to 70% of cirrhotic patients characterized as covert
- **Treatment:**
  - Lactulose: laxative - significant side effects
  - Rifaximin reduction in overt HE recurrence

Target Profile to Address Unmet Need:
- Reduce episodes of hospitalization
- Improve cognitive outcomes, QoL

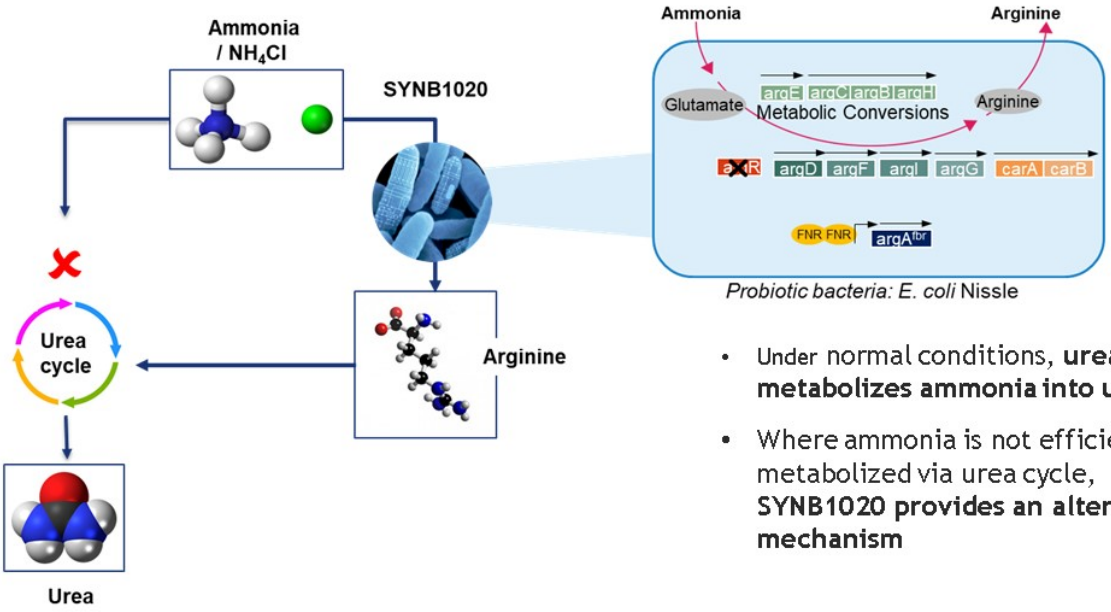
Urea Cycle Disorders

- **Genetic defects in Urea Cycle**
  - Deficiency in one of the six enzymes
  - Nitrogen accumulates as toxic ammonia → HE crisis
- **Patients:**
  - ~2,000 diagnosed in US; similar in EU
- **Treatment:**
  - Ammonia scavengers: buphenyl, Ravicti®
  - Low protein diet with amino acid supplements

Target Profile to Address Unmet Need:
- Maintain blood ammonia in normal range, avoid crisis
- Protein liberalization: 50-100% more per day
- Oral administration

SYNB1020 Mechanism of Action:

Conversion of Toxic Ammonia into Beneficial Arginine for the Treatment of UCD and HE



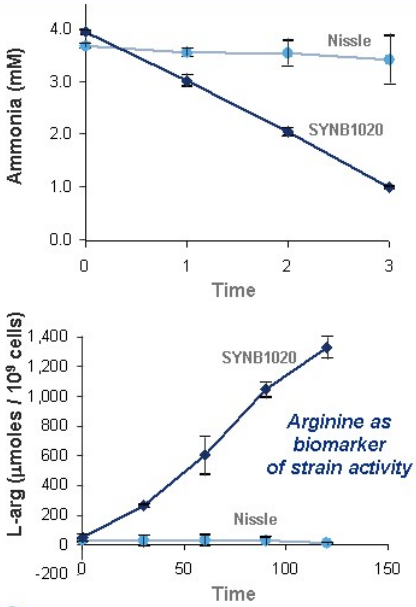
- Under normal conditions, **urea cycle metabolizes ammonia into urea**
- Where ammonia is not efficiently metabolized via urea cycle, **SYNB1020 provides an alternative mechanism**

synlogic

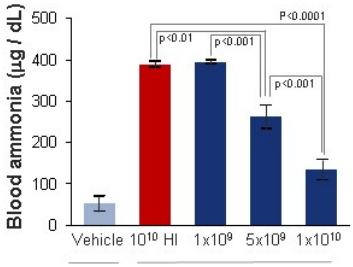
SYNB1020 Preclinical Characterization

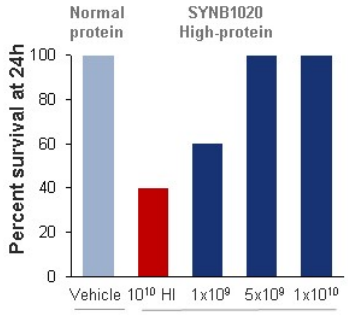
Potent and Efficacious Ammonia Reduction and Improved Survival

In vitro



UCD Model

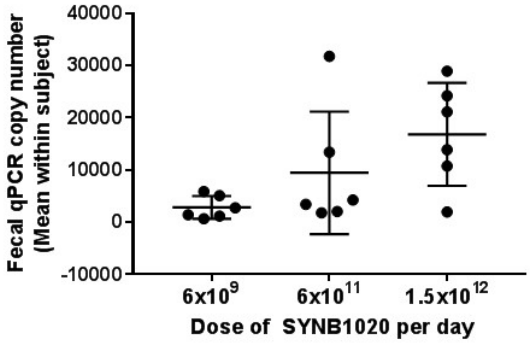


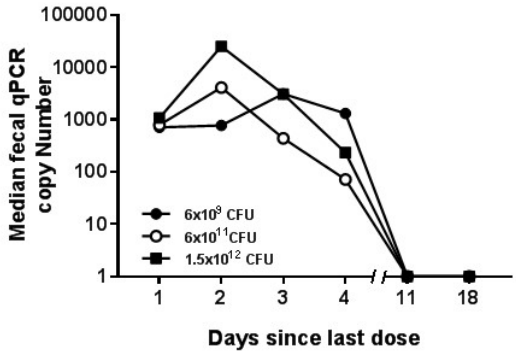


synlogic

Clinical Data SYNB1020 in Healthy Volunteers

Dose-Dependent Increase in SYNB1020 in Feces, Clearance on Cessation of Dosing

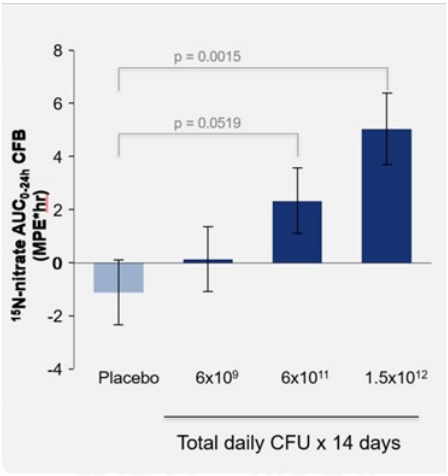




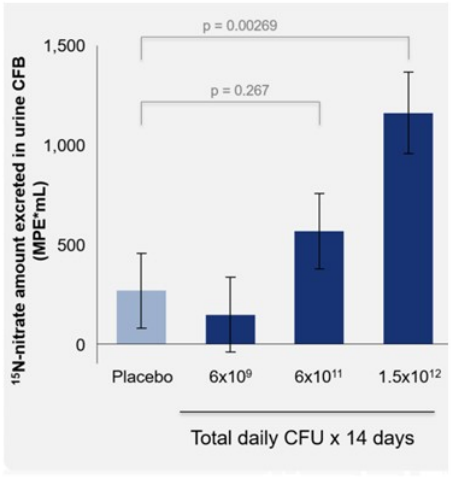
Nitrate as a Biomarker for SYNB1020 Activity

Dose-dependent Production of Plasma and Urinary Nitrate

Plasma Nitrate

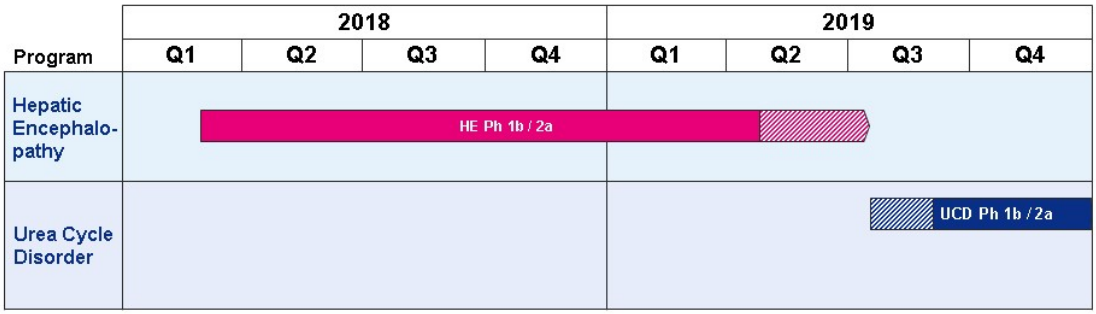


Urinary Nitrate



SYNB1020 Clinical Development

Hepatic Encephalopathy Study Phase 1b/2a in patients with cirrhosis and elevated ammonia



- Randomized, double-blind placebo-controlled study ongoing at multiple sites in the US
- Primary outcome: establish safety/tolerability in hepatic insufficiency - patients with cirrhosis and HE
- Secondary outcome: reduction of ammonia

synlogic

SYNB1618 for Phenylketonuria (PKU):

Goal: Managing Plasma Phe Levels to Enable Increased Intake of Natural Protein

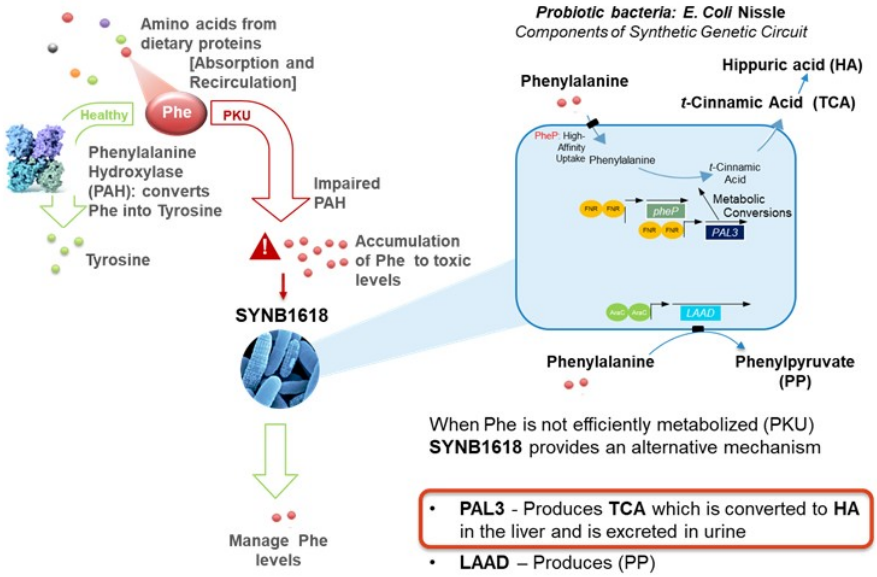
- **PKU is a rare inherited amino acid metabolism disorder**
  - Causes build up of amino acid phenylalanine (Phe) in the body
  - Phenylalanine is found in all proteins
- **Diagnosed:** 16,500 in US, similar in EU5
  - If left untreated, symptoms include cognitive impairment, convulsions, behavior problems, skin rash
- **Treatment:**
  - Low protein diet (no meat, dairy, nuts, eggs)
  - Kuvan: PAH cofactor. 20-40% of patients
  - Palynziq: injectable, pegylated, bacterial enzyme (PAL) (Adults)

- **Target Profile to Address Unmet Need:**
  - Manage Phe: Currently < half adults at target (120 - 360 µmol / L, source: NPKUA)
  - Increase natural protein intake (less than 10g typically)
  - Oral dosing without systemic toxicity

synlogic

SYNB1618 Mechanism of Action

Designed to Convert Toxic Phenylalanine to *trans*-cinnamic Acid



When Phe is not efficiently metabolized (PKU) **SYNB1618** provides an alternative mechanism

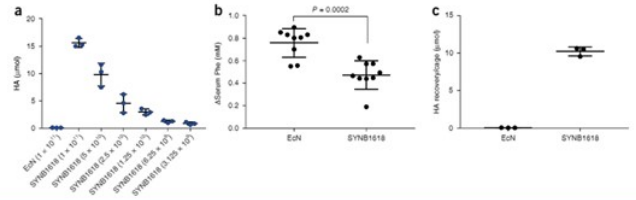
- **PAL3** - Produces **TCA** which is converted to **HA** in the liver and is excreted in urine
- **LAAD** – Produces (PP)

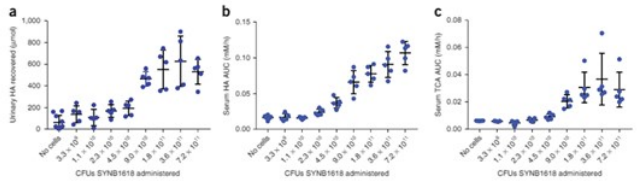
synlogic

Preclinical Characterization of SYNB1618

Biomarkers demonstrate activity of SYNB1618 in mouse model of PKU and healthy NHPs

In vivo activity and efficacy of SYNB1618 in mouse model of (PKU) Pah$^{enu2/enu2}$





Dose response and PD of SYNB1618 in healthy NHPs

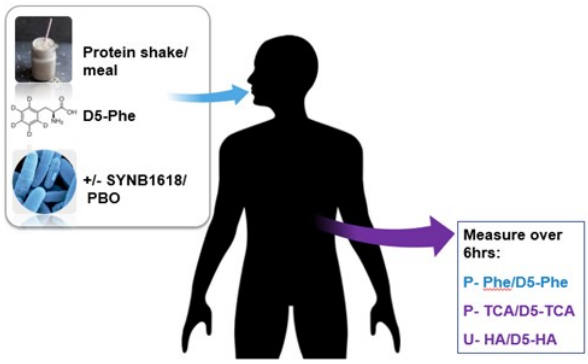
SYNB1618 in the Clinic: Safety

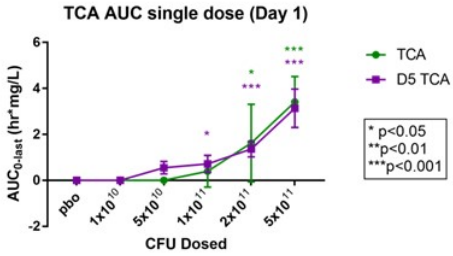
Interim Analysis of Phase 1/2a SAD/MAD Study Demonstrates Safety and Clearance in Healthy Volunteer Cohorts

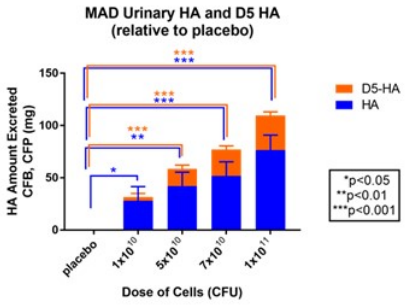
- The study enrolled 56 healthy volunteers, all of whom received at least one dose of SYNB1618 or placebo. The subjects were predominantly male Caucasians and the age range of enrolled subjects was 18-62 years
- There were no treatment-related serious adverse events, no systemic toxicity or infections
- Treatment-emergent adverse events were either mild or moderate in severity, and reversible. Most AEs were GI-related
- All subjects cleared the bacteria. There was no evidence of colonization, and no subject required antibiotics
- Single dose MTD was defined as 2×10^{11} CFU. Doses above this level were associated with dose-limiting GI adverse events
- Based on pharmacodynamic data and tolerability profile a dose was identified for the second part of the study in PKU patients

SYNB1618 in the Clinic: Activity

Statistically significant dose-dependent activity of SYNB1618 in healthy volunteers





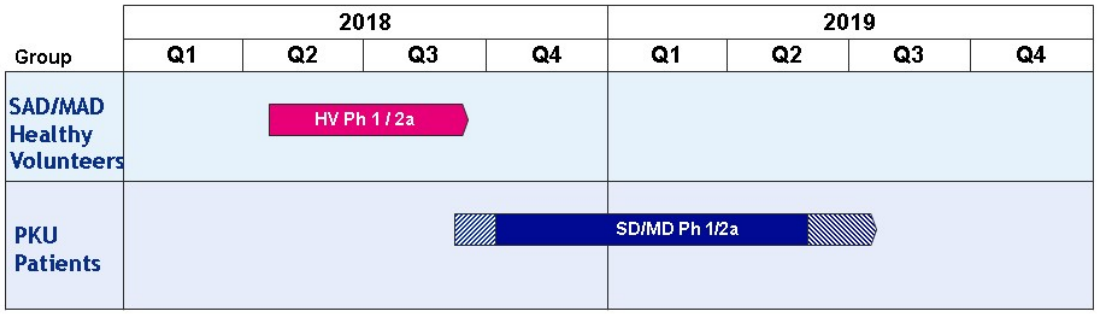


HA=hippurate, D5-HA= labeled HA,
CFB=change from baseline, CFP=change from placebo

synlogic

SYNB1618 Clinical Development

Phase 1/2a SAD/MAD in Healthy Volunteers with Patient Cohort



- **Goal:** assess safety, tolerability and kinetics in healthy volunteers across a range of doses
  - Expansion cohort: PKU patients both SD/MD
- Secondary Endpoint: *trans*-Cinnamic acid and Hippuric acid production

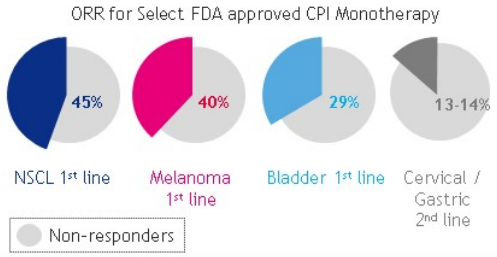
synlogic

Synlogic Vision for Immuno-Oncology

Expand the benefits of immunotherapy broadly across tumor types

TREATMENT FAILURES

For indications where immune checkpoint inhibitors are indicated, 55-87% of patients fail to respond



UNRESPONSIVE TUMORS

Other tumor types show little-to-no response to checkpoint inhibitors, for example:

Colorectal - MSS

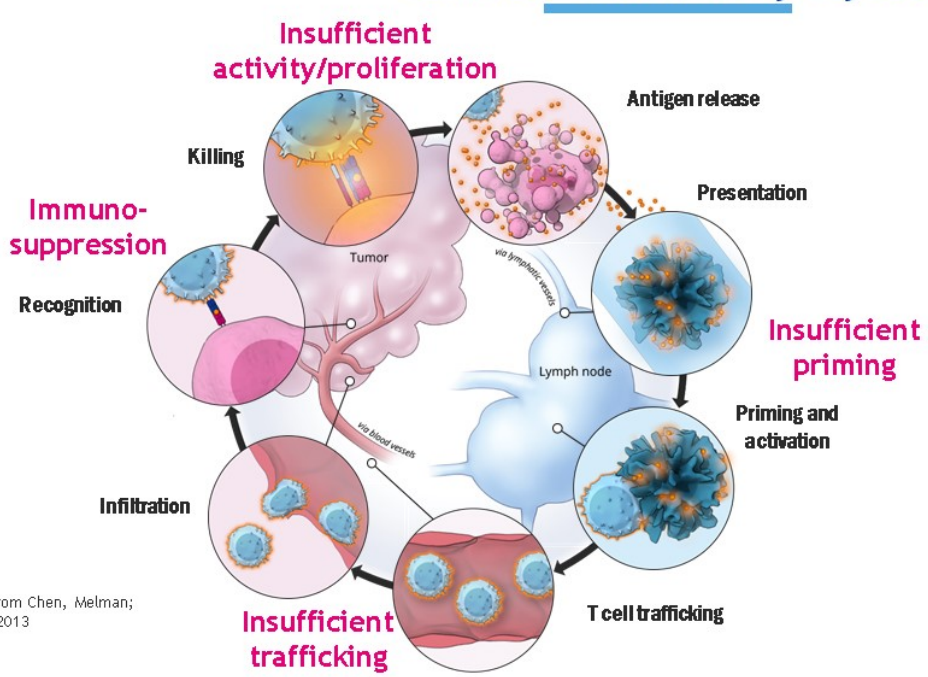
Pancreatic

Prostate - castrate resistant

Breast - ER+, hormone therapy refractory

Enable broad response and remission through engagement of multiple immunomodulatory pathways to enhance tumor inflammation and promote robust T cell responses

A Tumor Can Evade Multiple Critical Aspects of the Cancer-Immunity Cycle



Adapted from Chen, Melman; Immunity 2013

Monotherapies Often Fail to Overcome Tumor Evasion Mechanisms

Recognized Need to Combine Mechanisms to Broaden the Benefit of Immunotherapy

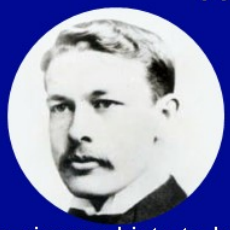
synlogic

© 2018 Synlogic, Inc. All rights reserved.

Synlogic Vision for Immuno-Oncology

Reimagining Early Immunotherapy for Combinatorial Effect

Bacteria Recognized as Earliest Immunotherapy



"Nature often gives us hints to her profoundest secrets, and it is possible that she has given us a hint in which, if we will but follow, may lead us on to the solution of this difficult problem."

Dr. William B. Coley
Immuno-Oncology Pioneer

Engineer a Living Solution: Synthetic Biotic Medicines

Rationally Designed for Combinatorial Effect

Locally Inflame the TME

Systemically Drive Tumor-Antigen Specific Immunity

Neo-antigen Priming and Sustained Immune Response

synlogic

Intra-tumoral Injection of Synthetic Biotic Chassis: Tumor Colonization Without Leakage; Local Innate Immunity

Chassis Distribution

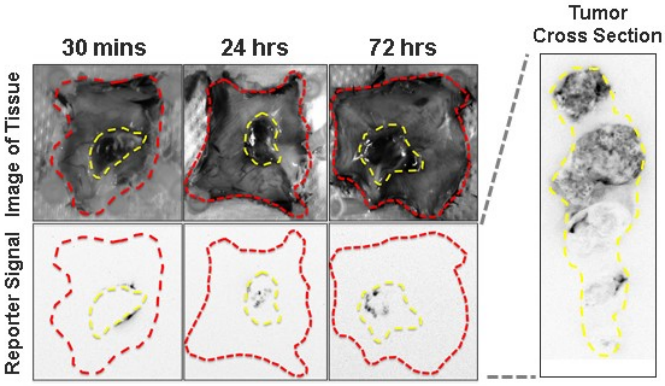
Robust proliferation in tumor.
No significant leakage

Survival/proliferation in tumors
10-15 days post-single dose.
Potential for limited injections

Elicits **innate responses** (IL-6 and TNFα)
in the tumor, Not circulation

Behavior within TME

in B16.F10 Mice



Synthetic Biotic Medicines Engineered for Efficacy

VISION: Rational Design to Locally Inflame the TME
AND Systemically Drive Tumor-Antigen Specific Immunity

Relieve Immunosuppression

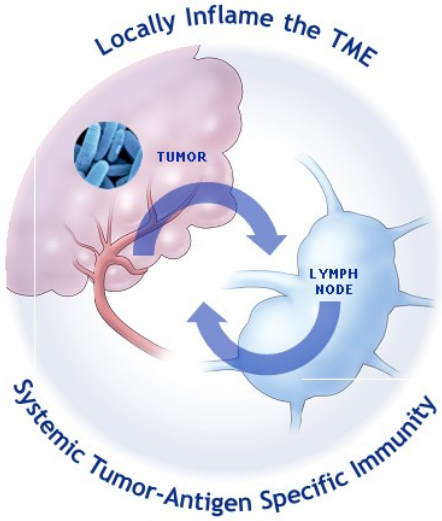
Consume immunosuppressive metabolites

Produce checkpoint inhibitors (e.g., αPD-1)

Promote Trafficking

Chassis effect

Produce cytokines/chemokines



Promote Immune Activation/Proliferation

Produce Immunostimulatory Molecules

Promote Immune Cell Survival and Activity

Prime for Tumor-Antigen-Specific Vaccination

Chassis effect

Produce lytic factors

Produce agonists for immune cell activation

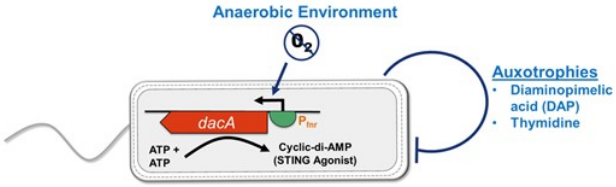
synlogic

Synthetic Biotic Medicines Attributes

Platform Flexibility to Maximize Efficacy, Control, and Safety

	KEY ATTRIBUTES OF NEXT GEN APPROACHES	SYNTHETIC BIOTIC PLATFORM
Efficacy Drivers	Sustained payload delivery	Persistence in TME
	Multiple/combinatorial pro-inflammatory mechanisms	Large gene insert capacity
	Enzymatic activity	Cellular bioreactors
Control	Large Engineering Toolkit	Can design to sense / respond to an inducer
	Manufacturability	No mammalian cell culture
Safety	Systemic Risk	Initial programs intratumoral
	Pathogenic Risk	Non-pathogenic, probiotic chassis Antibiotic deactivation

Dual Innate Immune Activator: Synthetic Biotic Medicine Producing STING Agonist (SYN-STING)

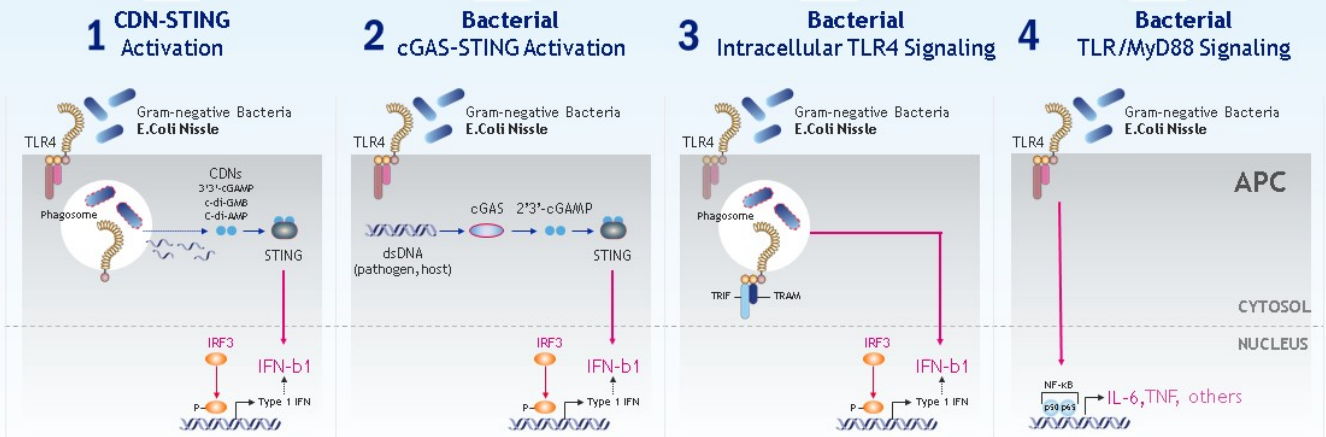


- Synthetic biology applied to IO programs to confer activities for efficacy and control for safety
- SYN-STING designed as a dual innate immune activator: combined benefit of bacterial chassis and STING agonist
- The *dacA* gene is integrated into genome under the control of inducible promoter to produce c-di-AMP
- Dual biosafety feature
- Learnings inform future combinations

synlogic

Dual Innate Immune Activator

TUMOR



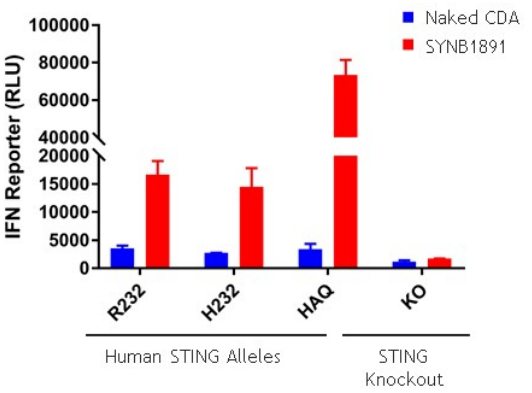
	Promotes Trafficking, Immune Activation/Proliferation, Priming			
SYN-STING	✓	✓	✓	✓
Naked STING Agonist	✓	✓ ⊗	⊗	⊗

synlogic

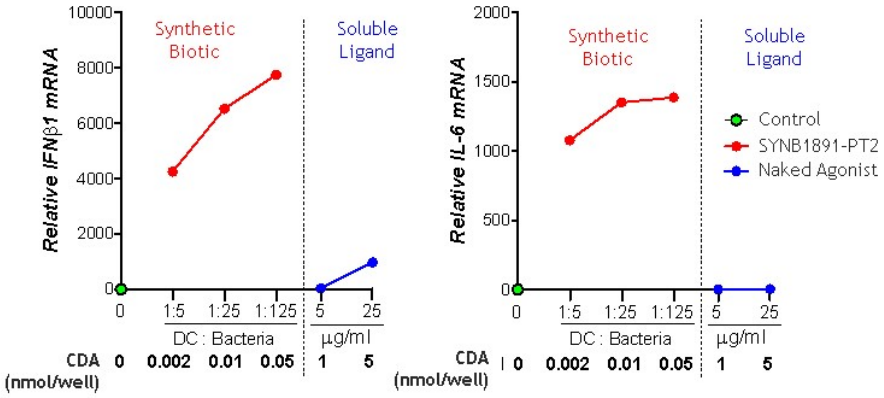
In Vitro Characterization of SYNB1891

Interferon Production Across Multiple Human STING Alleles Greater than Naked STING Agonist
Additional Proinflammatory Pathways Engaged

Reporter THP-1

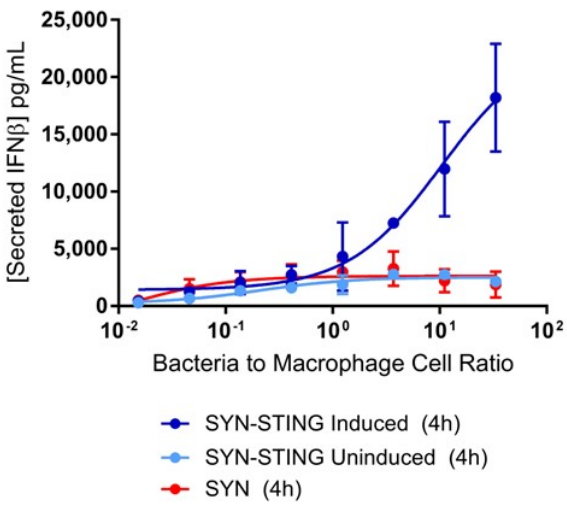


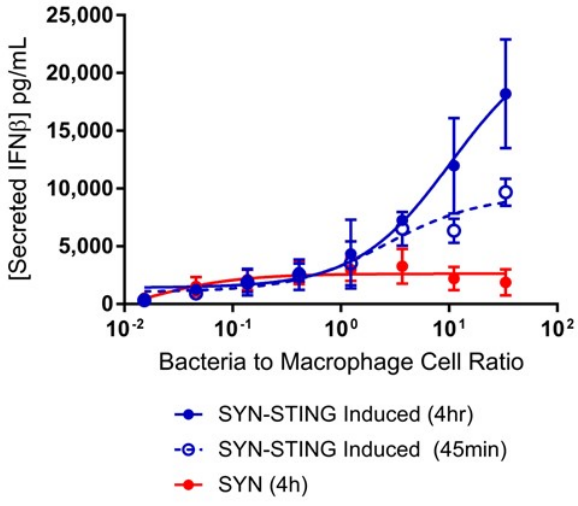
Primary DCs



synlogic

In vitro: STING Agonist Induction by SYN-STING Results in Dose-Dependent Production of IFN-β





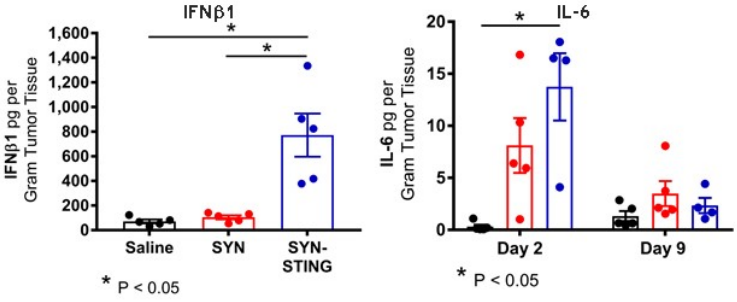
Note: RAW cells

synlogic

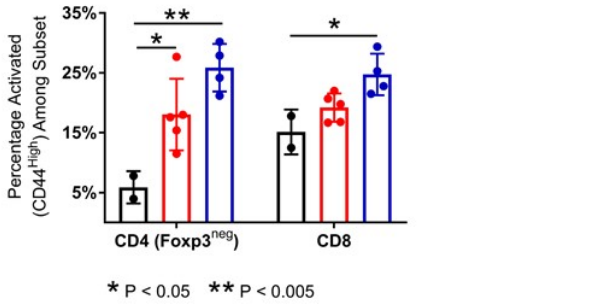
In vivo: SYN-STING Strain Delivers Robust Anti-tumor Activity as Single Agent in B16.F10 Model

Sequence of activation following intratumoral injection of SYN-STING

Key: *Saline* *SYN* *SYN-STING*



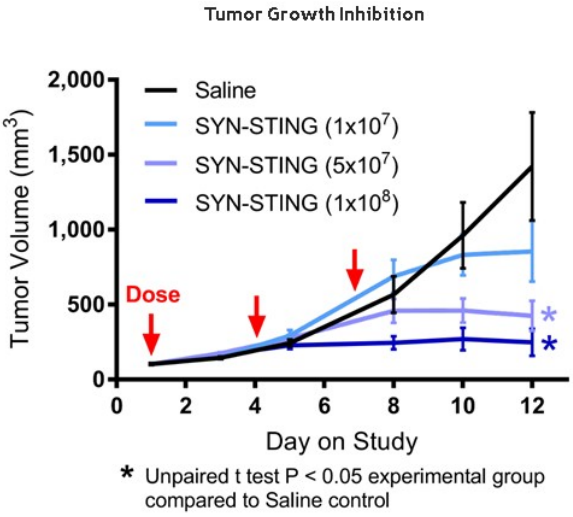
Initial robust Type I IFN production leads to early innate activation at 2 days

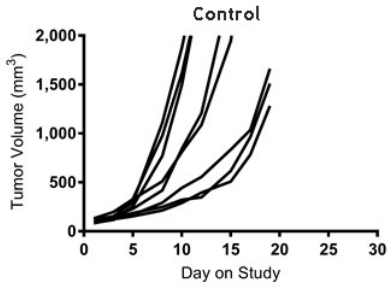


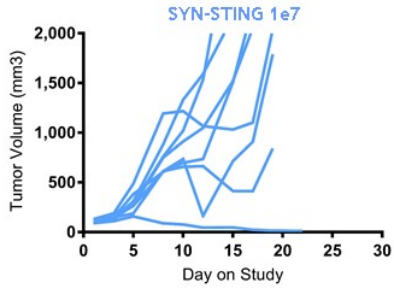
Followed by an adaptive T cell response at 9 days, including production of granzyme B and IL-15

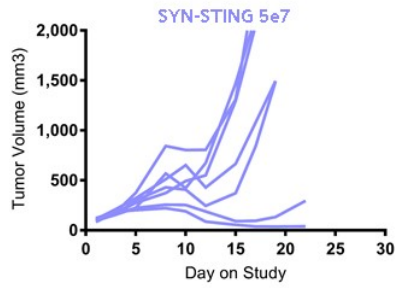
synlogic

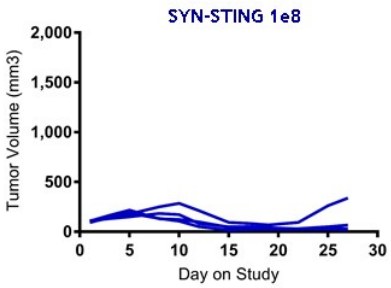
SYN-STING Drives Dose-Dependent Tumor Control in A20 Lymphoma Model







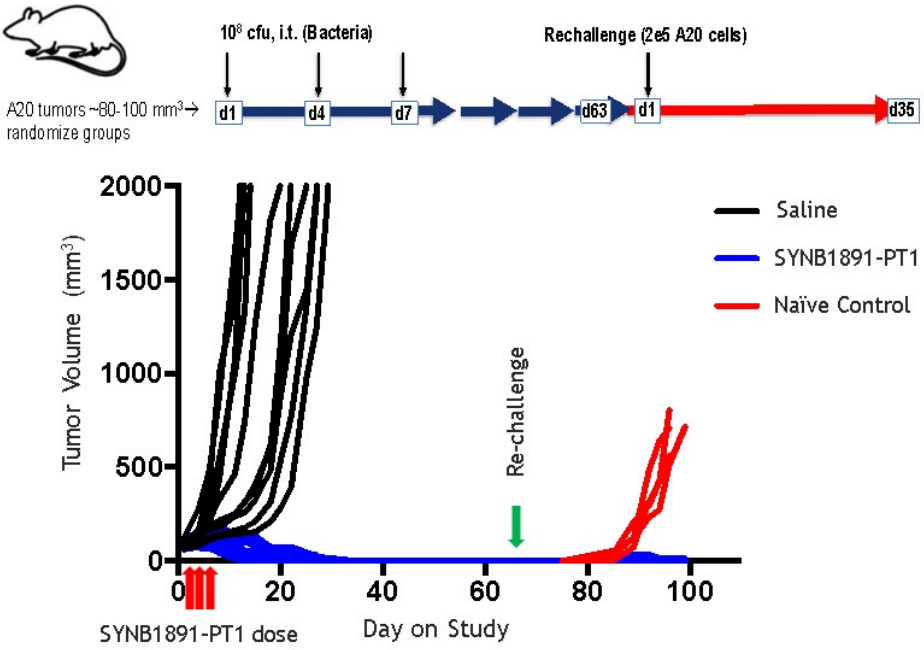




synlogic

In Vivo Characterization of SYNB1891

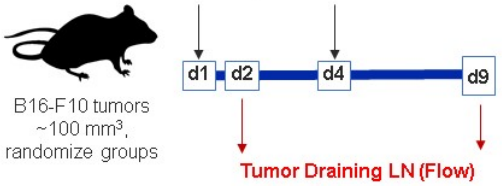
SYNB1891 Prototype Strain Leads to Systemic Anti-tumor Immunity

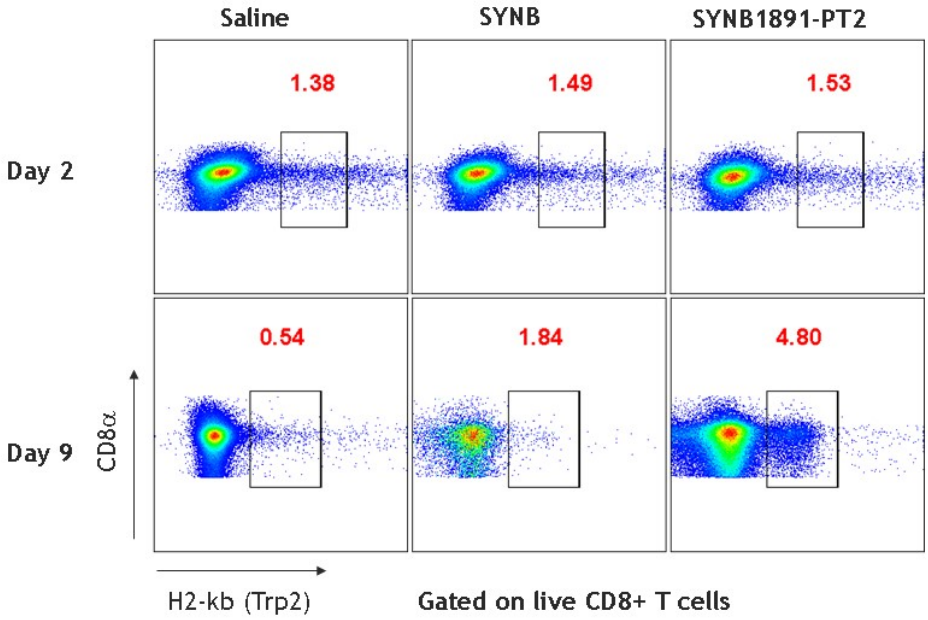


synlogic

In Vivo Characterization of SYNB1891

SYNB1891 Prototype Strain Leads to Generation of Tumor Antigen-specific T Cell





synlogic

Dual Innate Immune Activator SYNB1891

A STING Agonist-producing Synthetic Biotic Designed to Locally Inflame the TME and Systemically Drive Tumor Antigen-Specific Immunity

Progress Towards the Clinic

Tumor Colonization without Leakage

Enhanced Activity vs. Naked STING Agonist

Intracellular Activation of STING and Bacterial-Induced Immune Pathways Within APCs

Dose-dependent Anti-tumor Activity

Immunological Memory

IND Submission 2H19

Promise Over Other Approaches

STING Agonism in Natural Context

Activation of Multiple Innate Immune Pathways

Low Systemic Risk

synlogic

Additional Synthetic Biotic Effectors

VISION: Rational Design to Locally Inflame the TME
AND Systemically Drive Tumor-Antigen Specific Immunity

Relieve Immunosuppression

Kyn Consumption

Ade Consumption

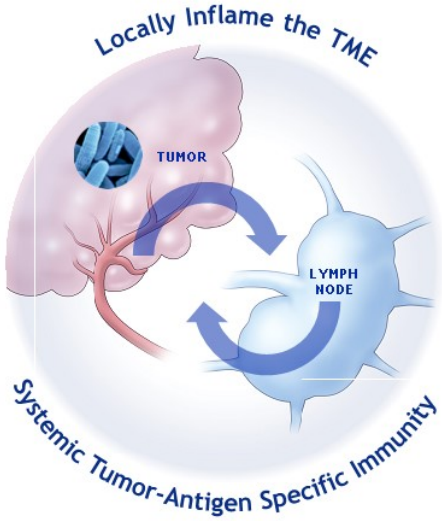
αPD-1 scFv

Promote Trafficking

Chassis effect

CXCL10

Hyaluronidase



Promote and Sustain Immune Activation

IL-15; IL-12

Arg Production

4-1BBL

OX40L

Prime for Tumor-Antigen-Specific Vaccination

Chassis effect	TNFα
5FC→5FU	IFNγ
STING	αCD47 ScFv / Sirpα
αCD40 scFv/CD40L	GM-CSF

synlogic

Broad Ambitions in Immuno-Oncology

Vision: Expand and Exceed the Effect of Cancer Immunotherapies

synlogic