# 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): October 3, 2019**

# resTORbio, Inc.
**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-38359** | **81-3305277** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **500 Boylston Street, 12th Floor**<br>**Boston, MA** | **02116** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (857) 315-5521**

**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:

☐ 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, par value $0.0001 per share** | **TORC** | **The Nasdaq Global Select 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.**

resTORbio, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation (the "Presentation") is furnished herewith as Exhibit 99.1 and incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials furnished herewith as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Corporate slide presentation of resTORbio, Inc., dated October 3, 2019. |

**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: October 3, 2019

**resTORbio, Inc.**

By: /s/ Chen Schor
Chen Schor
President and Chief Executive Officer

Exhibit 99.1

# TORC1 inhibition with RTB101 as a potential pan-antiviral immunotherapy to decrease the incidence of respiratory tract infections due to multiple respiratory viruses in older adults

resTORbio™

Joan Mannick MD

Amelia Tomlinson PhD, Grace Teo PhD, Sarb Shergill PhD, Lloyd Klickstein MD PhD

# Forward-looking statements

This presentation has been prepared by resTORbio, Inc. ("we," "us," "our," "resTORbio," or the "Company") and is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities. This presentation may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the safety, efficacy and regulatory and clinical progress of our product candidates, including RTB101 alone and in combination with a rapalog, such as everolimus or sirolimus. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. The use of words such as, but not limited to, "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar words or expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, current and prospective product candidates, ongoing planned clinical trials and preclinical activities, including the initiation, timing, enrollment, progress and results of our preclinical and clinical studies and our research and development programs, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, including our ability to advance RTB101 alone or in combination with a rapalog, such as everolimus or sirolimus into, and successfully complete, clinical studies, the timing and likelihood of success of our Phase 3 clinical trials of RTB101, and the timing or likelihood of regulatory filings and approvals, expectations regarding market acceptance and size, plans for launch and commercialization, plans and objectives of management for future operations, and future results of anticipated product candidates, are forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

These statements are also subject to a number of material risks and uncertainties that are discussed in the section entitled "Risk Factors" in resTORbio's annual report on Form 10-K for the fiscal year ended December 31, 2018, as well as discussions of potential risks, uncertainties, and other important factors in resTORbio's subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and we make no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

RTIs are the **4th most common** cause for hospitalization in people 65+[1] (2nd in 85+[1])…

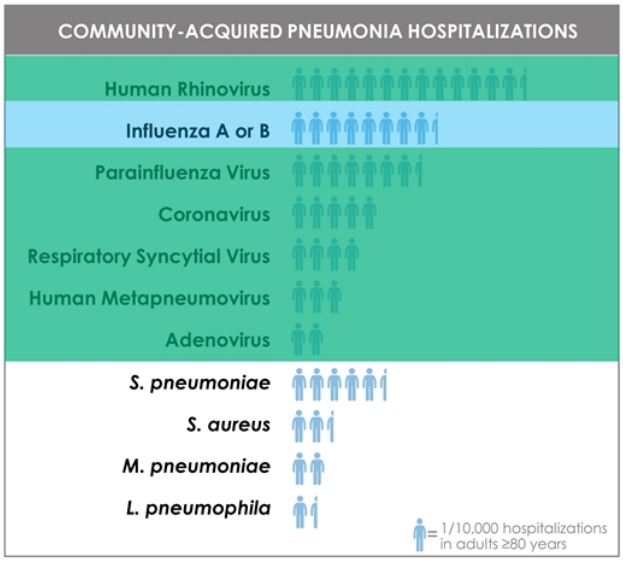
…and the **8th leading cause of death** in people 65+[2] (7th in 85+[2])

The majority of RTIs are **caused by viruses** for which there are no approved therapies[3]

Decreasing the incidence of RTIs in older adults may significantly **decrease health care resource utilization**

[1]Pfunter, HCUP Statistical Brief #162, 2013; [2]National Vital Statistics Report (2019), Deaths, Final Data for 2017; [3]Jain, S., et al., NEJM (2015) 373: 415-427

Most of the viral pathogens causing pneumonia in the elderly currently have neither preventative vaccines nor treatments

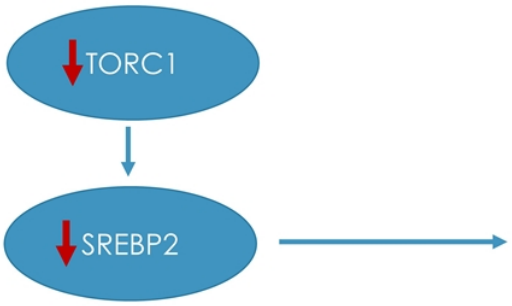



An immunotherapy that upregulates innate pan-antiviral immunity may offer a new approach to preventing RTIs in the elderly

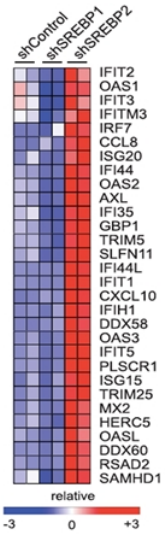
Adapted from Jain S, et al. *NEJM* 2015

# TORC1 inhibition may increase innate antiviral immunity

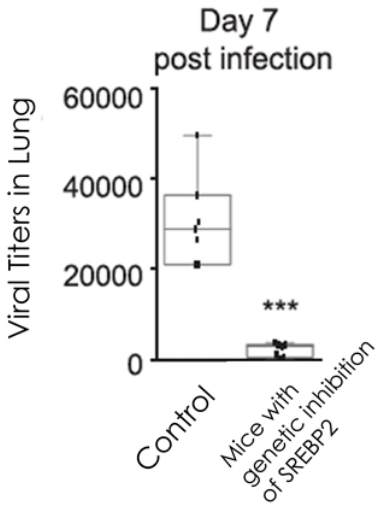
TORC1 inhibition decreases SREBP2 activation




Inhibition of SREBP2 with shRNA upregulates antiviral gene expression




Inhibition of SREBP2 decreases viral titers in lungs of mice infected with murine gammaherpesvirus MHV-68



# Phase 2b study to determine if TORC1 inhibition upregulates innate antiviral immunity and decreases RTI incidence in high-risk elderly patients

**Phase 2b Study Design**

**POPULATION:**

85 and older | 65 and older w/ asthma | 65 and older w/ diabetes | 65 and older w/ COPD | 65 and older, smokers

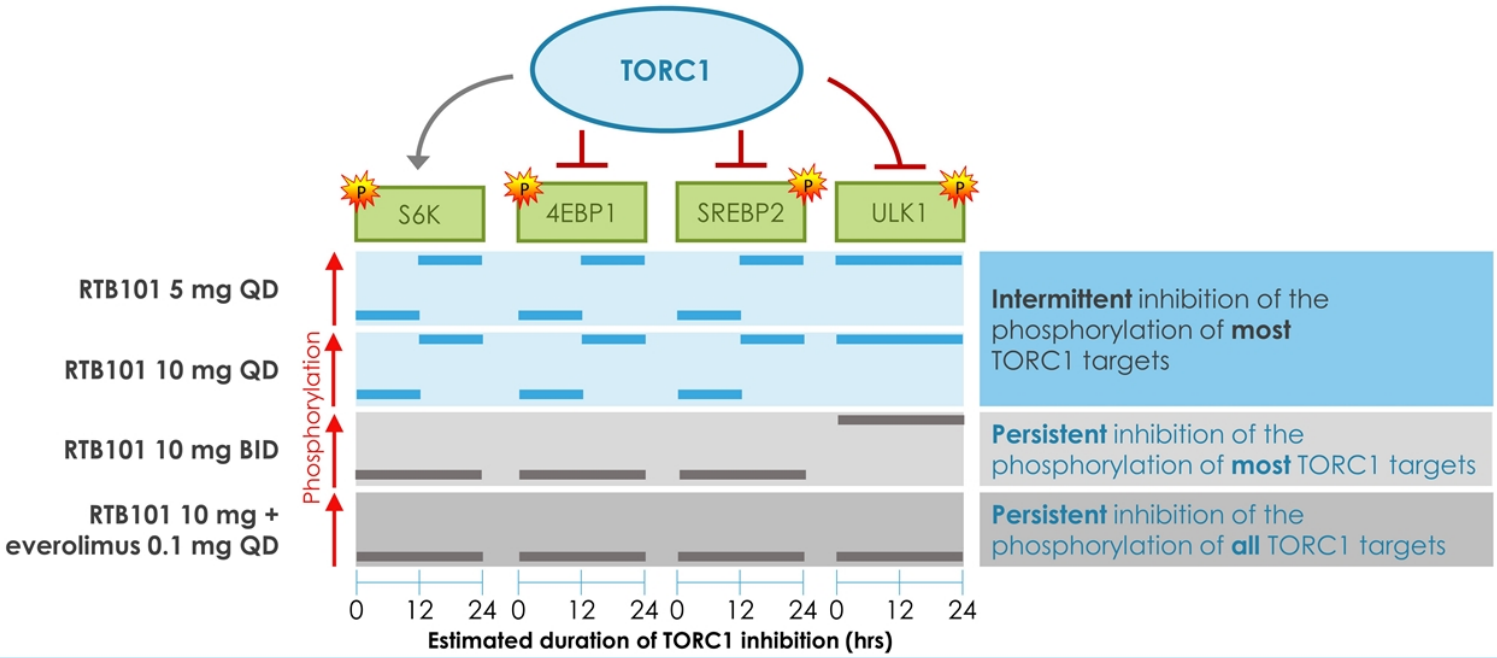
% of subjects with ≥ 1 laboratory-confirmed RTIs

**DOSING DURATION:** 16 weeks during winter cold and flu season

RTB101, an oral TORC1 inhibitor, alone or in combination with everolimus, another TORC1 inhibitor

Matching placebo

# Phase 2b evaluation of a range of TORC1 inhibitory regimens for reduction of RTIs in high-risk patients ≥65 years old

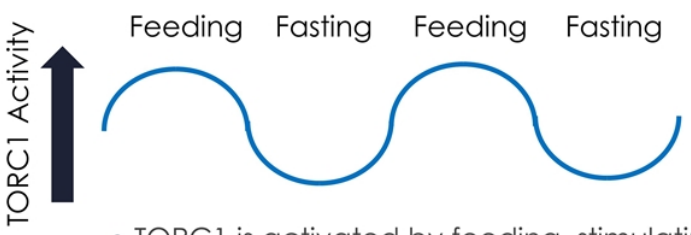



QD = once daily; BID = twice daily

# Why might intermittent TORC1 inhibition lead to improvement in immune function?

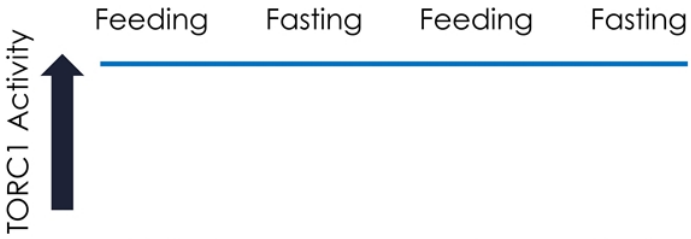
**TORC1 becomes dysregulated and overactive with aging**

## Young Animals




- TORC1 is activated by feeding, stimulating cell growth
- TORC1 is inhibited by fasting, leading to upregulation of protective pathways

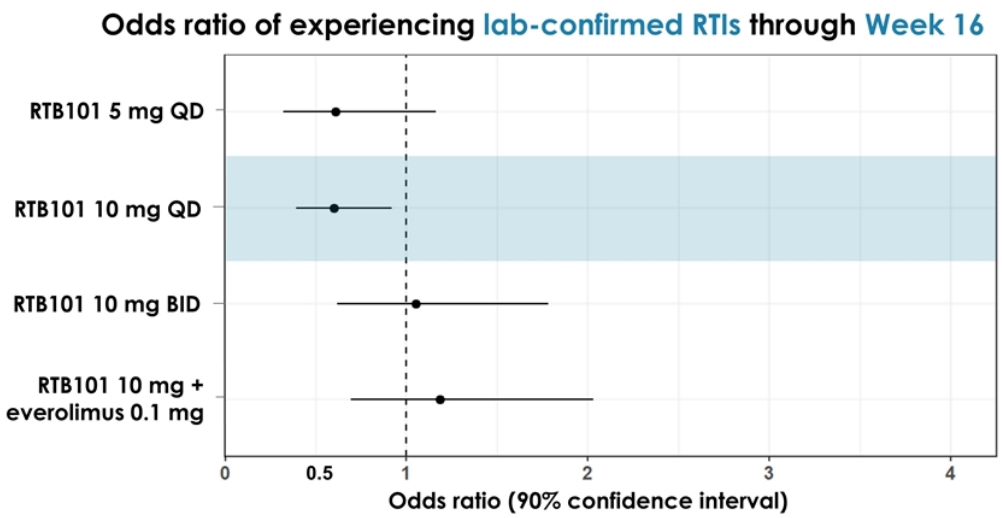
## Old Animals




- TORC1 remains persistently activated, preventing upregulation of protective pathways

**Therefore turning down TORC1 to young levels even intermittently may have health benefits in elderly humans**

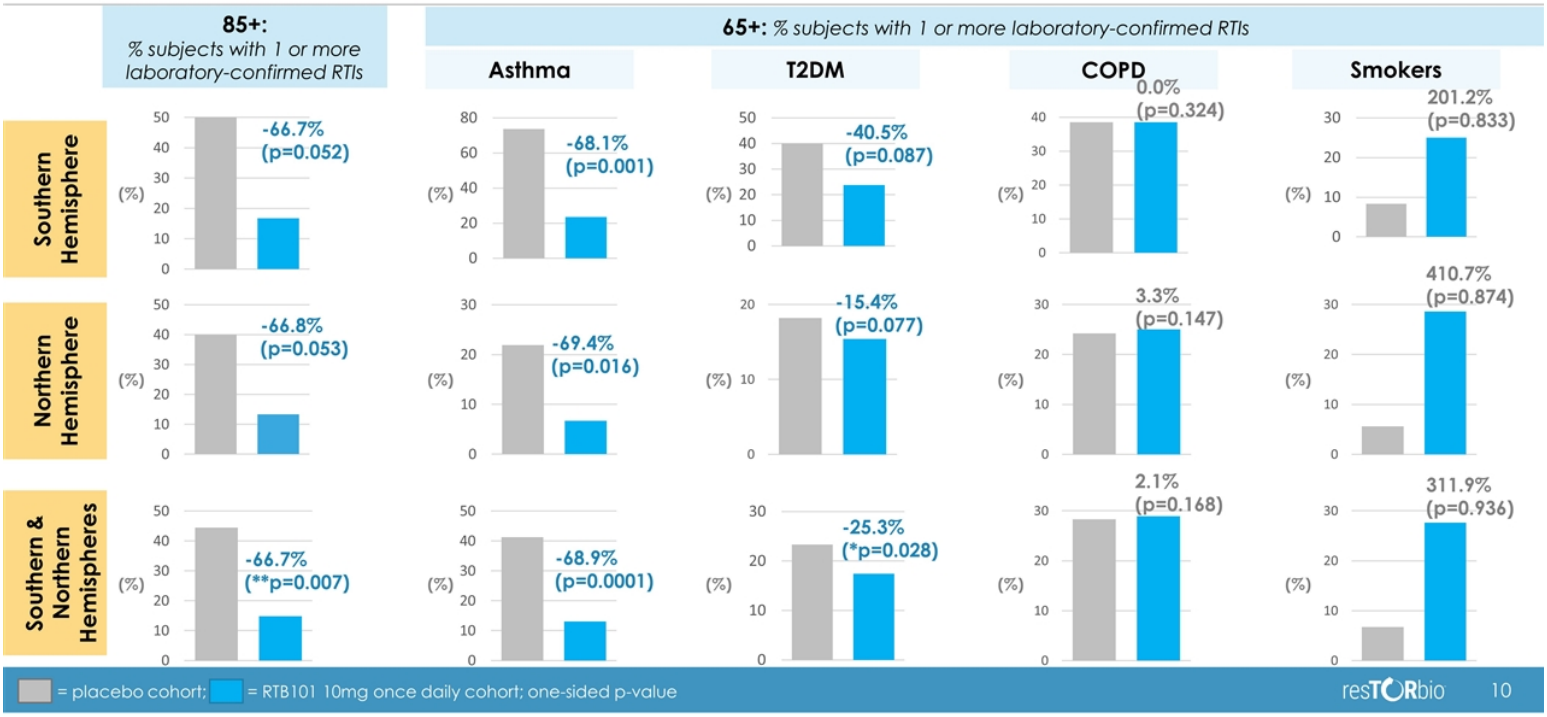
# RTB101 10mg QD was observed to reduce the incidence of laboratory-confirmed RTIs through Week 16




| | Active incidence[1] | Placebo incidence[1] | Odds ratio[2] | p-value[3] |
|---|---|---|---|---|
| RTB101 5 mg QD | 21/61 | 26/60 | 0.618 | 0.109 |
| **RTB101 10 mg QD** | **34/176** | **50/180** | **0.601** | **0.025*** |
| RTB101 10 mg BID | 25/120 | 24/120 | 1.050 | 0.560 |
| RTB101 10 mg + everolimus 0.1 mg | 25/115 | 24/120 | 1.187 | 0.700 |

RTB101 10 mg QD demonstrated a 30.6% reduction in the percentage of subjects with laboratory-confirmed RTIs compared to placebo

[1]No. of subjects in cohort with one or more laboratory-confirmed RTIs/No. of subjects in cohort; [2]Odds ratio represents the odds of experiencing one or more laboratory-confirmed RTIs in the active treatment group versus the placebo group; [3]One-sided p-value; *p<0.05


85+:
% subjects with 1 or more laboratory-confirmed RTIs
65+: % subjects with 1 or more laboratory-confirmed RTIs
Asthma
T2DM
COPD
Smokers
Southern Hemisphere
Northern Hemisphere
Southern & Northern Hemispheres
(%)
-66.7% (p=0.052)
-68.1% (p=0.001)
-40.5% (p=0.087)
0.0% (p=0.324)
201.2% (p=0.833)
-66.8% (p=0.053)
-69.4% (p=0.016)
-15.4% (p=0.077)
3.3% (p=0.147)
410.7% (p=0.874)
-66.7% (**p=0.007)
-68.9% (p=0.0001)
-25.3% (*p=0.028)
2.1% (p=0.168)
311.9% (p=0.936)
= placebo cohort; = RTB101 10mg once daily cohort; one-sided p-value
resTORbio
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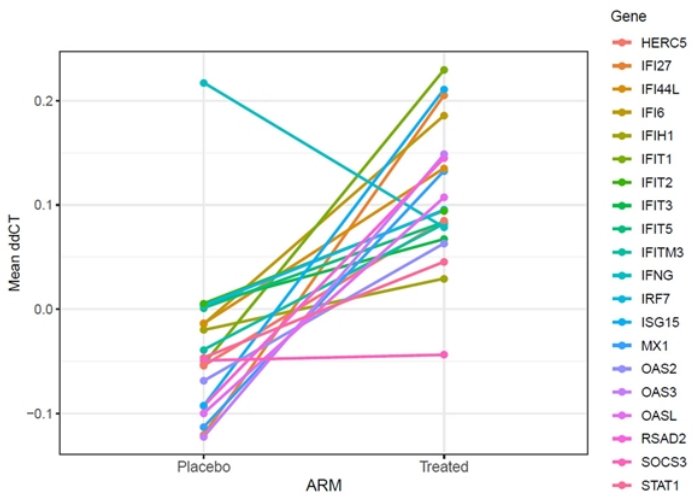
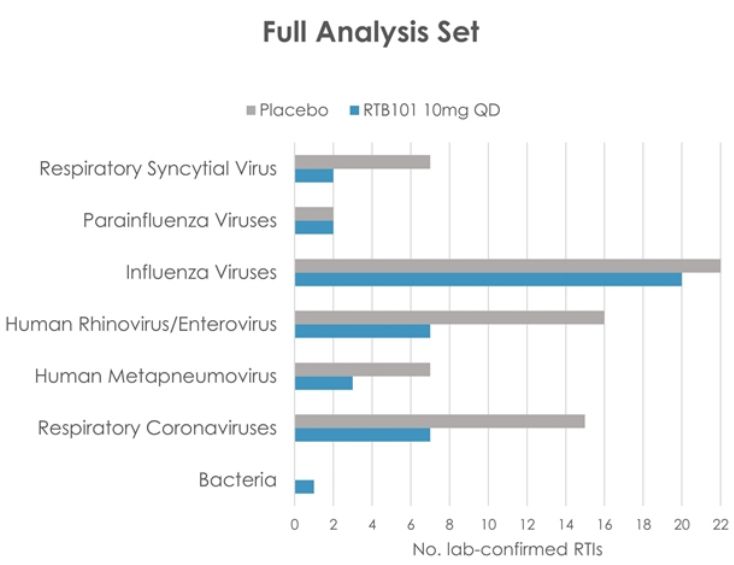
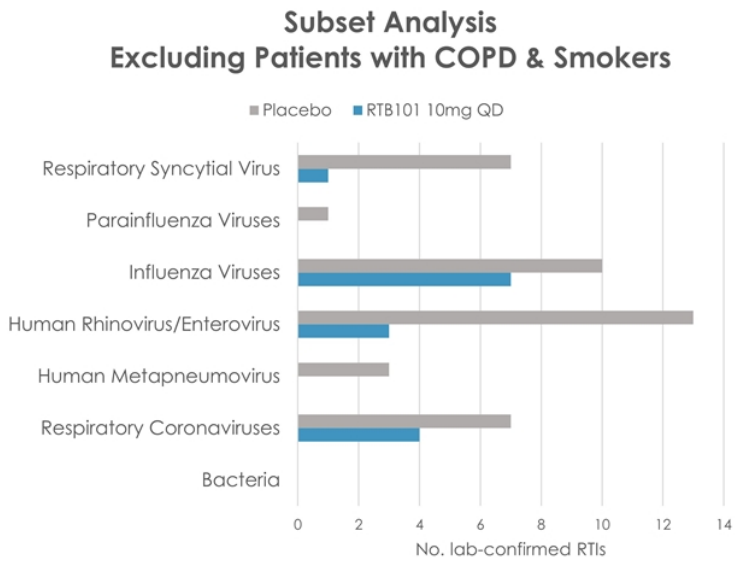
# RTB101 10mg QD was observed to increase expression of interferon-stimulated antiviral genes




| | Placebo n (%) | RTB101 10mg QD n (%) | *p*-value |
|---|---|---|---|
| ISGs upregulated(mean ddCT ≤0) | 5 (25%) | 19 (95%) | 0.00001 |
| ISGs not upregulated (mean ddCT >0) | 15 (75%) | 1 (5%) | - |

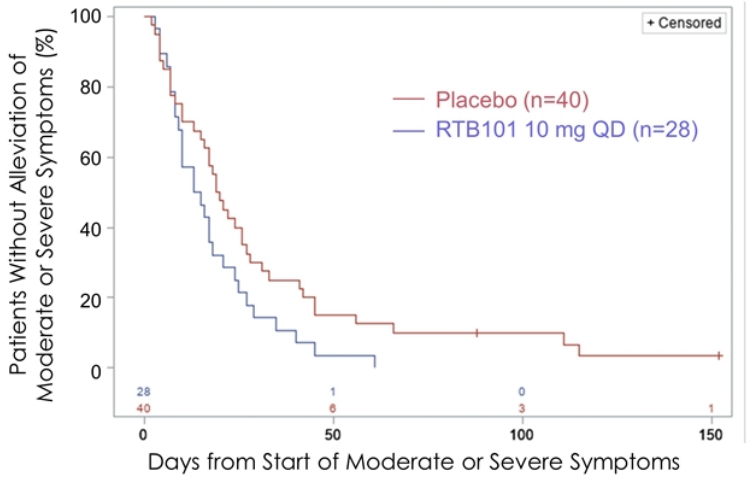
# RTB101 10mg QD was observed to reduce RTIs due to multiple viruses



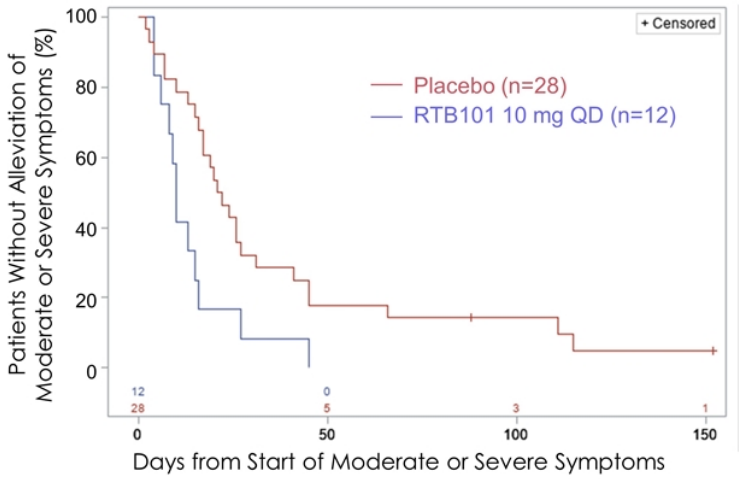



# Post-hoc analysis: RTB101 10 mg QD was observed to reduce time to alleviation of moderate or severe symptoms

Full Analysis Set




Subset Analysis Excluding Smokers & Patients with COPD




| Treatment | Median time to alleviation (days; 90% CI) | p value* |
|---|---|---|
| Placebo | 19.5 (16.0, 26.0) | 0.025 |
| RTB101 10 mg QD | 14.0 (10.0, 18.0) | |

| Treatment | Median time to alleviation (days; 90% CI) | p value* |
|---|---|---|
| Placebo | 21.5 (17.0, 27.0) | 0.0067 |
| RTB101 10 mg QD | 10.0 (6.0, 15.0) | |

*One-sided p-value

# Post-hoc analysis: RTB101 10mg QD was observed to reduce all-cause hospitalization at Week 16

| | Number of events in treatment group | | | |
|---|---|---|---|---|
| | RTB101 10 mg QD | Placebo | Rate Ratio (90% CI) | p-value* |
| **All-cause hospitalization** | 6 | 14 | 0.439 (0.196-0.983) | 0.047 |

*One-sided p-value

# RTB101 was well tolerated when given to older adult subjects for 16 weeks during winter cold and flu season

- 10mg QD is 1/120th of the RTB101 maximum tolerated dose in humans
- Adverse events (AEs) were balanced between the RTB101 10 mg QD and placebo cohorts
- 3 unrelated deaths:
  - 1 patient in RTB101 10 mg QD cohort hit by car while riding a bicycle
  - 1 unrelated death occurred in the RTB101 10 mg BID cohort from unknown cause
  - 1 in placebo cohort from unknown cause

| | % of patients in treatment group | |
|---|---|---|
| | RTB101 10 mg QD | Placebo |
| **Mild AEs** | 74.4% | 71.7% |
| **Moderate AEs** | 38.1% | 40.6% |
| **Severe AEs** | 5.7% | 7.8% |
| **Serious AEs** | 4.5% | 7.8% |
| **Discontinued study drug due to an AE** | 5.1% | 5.6% |

# Summary

- In a Phase 2b study, RTB101 10mg once daily was well tolerated and observed to upregulate innate antiviral gene expression and reduce the incidence of RTIs caused by multiple different viruses
- A Phase 3 program is underway to confirm these findings

# Many thanks to the resTORbio team

resTORbio™

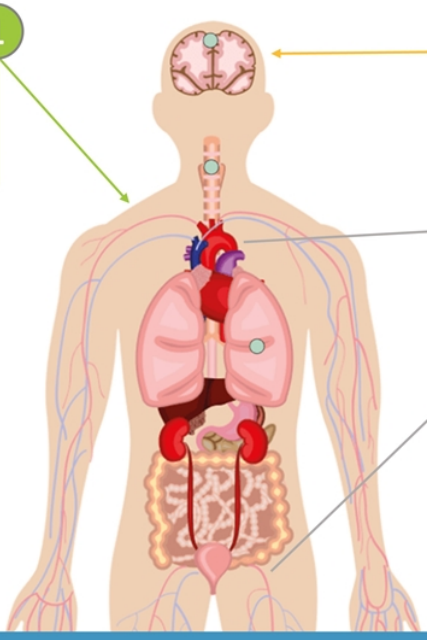
Backup Slides

# Inhibition of TORC1 has potential to improve the function of multiple aging organ systems

**1**

**Reversal of aging-related immune dysregulation**

Chen et al., *Science Sig*, 2009
Selman et al., *Science*, 2011
Neff et al., *JCI*, 2013
Hurez et al., *Aging Cell*, 2015



**2**

**Improved neurologic function**

Tain et al., *Nature Neuroscience*, 2009
Malagelada et al., *J Neurosci*, 2010
Spilman et al., *PLoS ONE*, 2010
Halloran et al., *Neuroscience*, 2012
Majumder et al., *Aging Cell*, 2012
Neff et al., *JCI*, 2013

**Reversal of aging-related cardiac dysfunction**

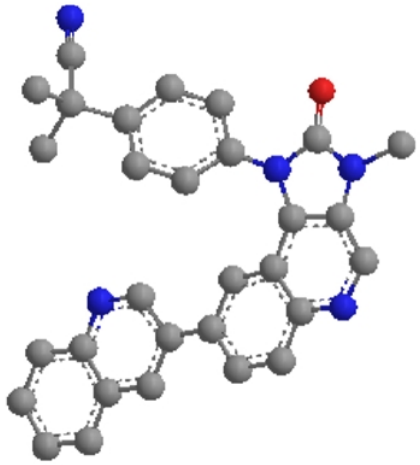
Flynn et al., *Aging Cell*, 2013
Dai et al., *Aging Cell*, 2014
Chiao et al., *Aging*, 2016

**Improvement in physical activity**

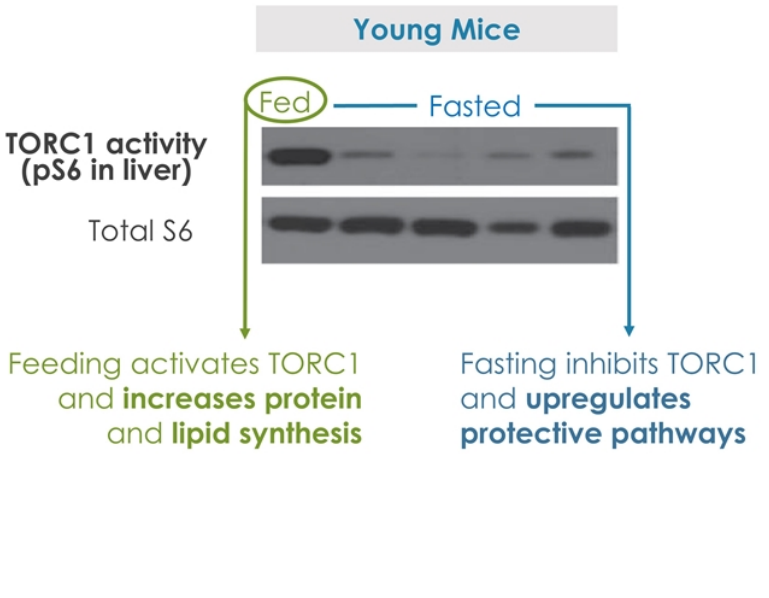
Selman et al., *Science*, 2011
Harrison et al., *Nature*, 2009
Wilkinson et al., *Aging Cell*, 2014
Flynn et al., *Aging Cell*, 2013

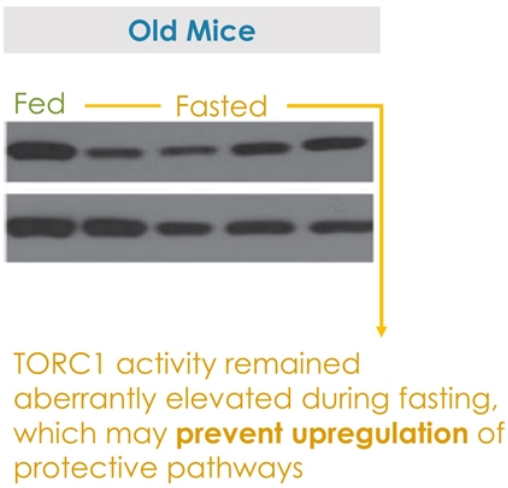
# RTB101 is an oral, potent inhibitor of TORC1

- RTB101 offers a potential new approach: harnessing the innate immune system to defend against illnesses associated with viral RTIs
- Half-life = 4-6 hours
- Therapeutic dose is 1/120$^{th}$ of the maximum tolerated dose in humans
- Dosed in >1,000 subjects
- Potential to address multiple aging related diseases

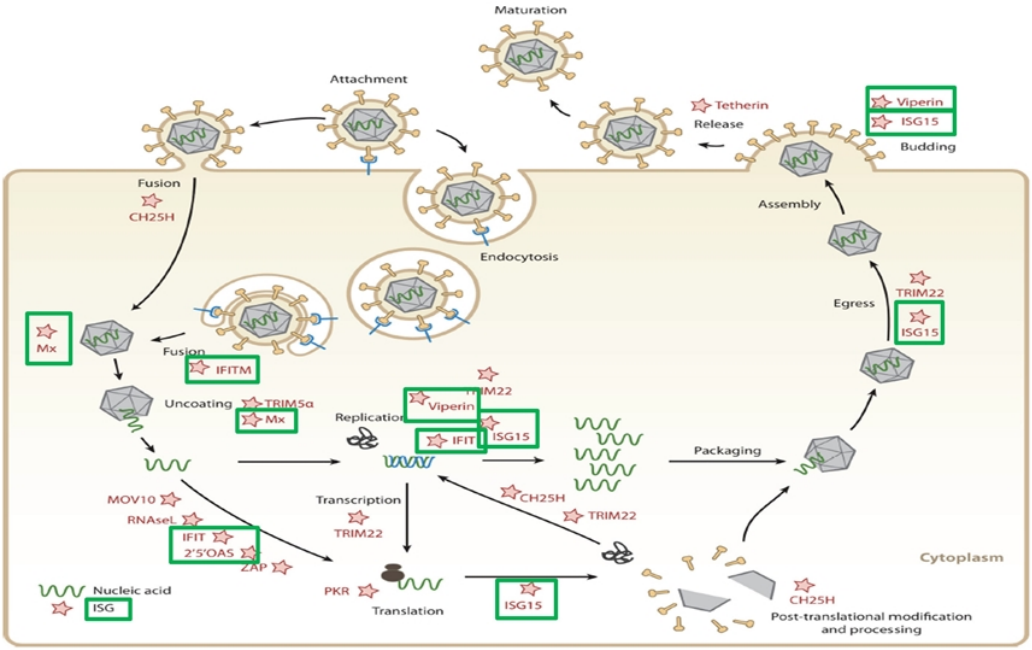


# Intermittent TORC1 inhibition may restore the normal circadian rhythm of TORC1




Adapted from Sengupta et al., *Nature*, 2010.




Adapted from Schneider et al. *Annu Rev Immunol*, 2014

# Treatment-emergent AEs observed in ≥2% of subjects in RTB101 10 mg QD or placebo cohorts through week 16

| | n (%) of patients in treatment group | |
|---|---|---|
| | RTB101 10mg QD | Placebo |
| | (N = 176) | (N = 180) |
| Headache | 10 (5.7) | 13 (7.2) |
| Constipation | 3 (1.7) | 10 (5.6) |
| Diarrhea | 8 (4.5) | 6 (3.3) |
| Fatigue | 6 (3.4) | 6 (3.3) |
| Fall | 6 (3.4) | 6 (3.3) |
| Nausea | 1 (0.6) | 6 (3.3) |
| Anemia | 2 (1.1) | 5 (2.8) |
| Arthralgia | 2 (1.1) | 5 (2.8) |
| Blood creatinine increased | 4 (2.3) | 3 (1.7) |
| Pain | 2 (1.1) | 4 (2.2) |
| Back pain | 4 (2.3) | 2 (1.1) |
| Hyperglycemia | 4 (2.3) | 2 (1.1) |
| Limb injury | 1 (0.6) | 4 (2.2) |
| Tooth abscess | 4 (2.3) | 1 (0.6) |
| Decreased appetite | 1 (0.6) | 4 (2.2) |
| Skin abrasion | 4 (2.3) | 0 (0) |

# Future directions: Phase 3 Program PROTECTOR

**Patient population: ≥65 years, excluding smokers/COPD patients**