



## resTORbio Announces Initiation of Study to Evaluate if Antiviral Prophylaxis with RTB101 Reduces the Severity of COVID-19 in Nursing Home Residents

May 28, 2020

BOSTON, May 28, 2020 (GLOBE NEWSWIRE) -- resTORbio (Nasdaq: TORC) today announced the initiation of a randomized, double-blind, placebo-controlled trial of RTB101, an investigational orally-administered potent small molecule inhibitor of target of rapamycin complex 1 (TORC1), as compared to placebo for COVID-19 prophylaxis in nursing home residents. The study is supported by additional data observed in resTORbio Phase 2b and Phase 3 clinical trials which suggest the potential of RTB101 to reduce the severity of laboratory-confirmed coronavirus infections.

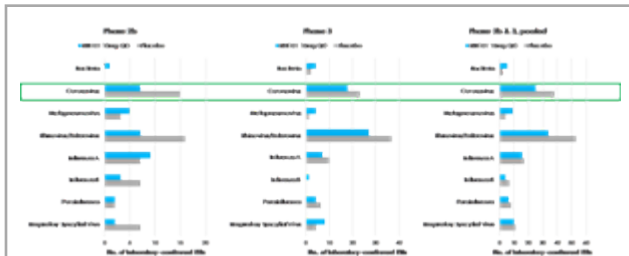


Figure 1. Treatment with RTB101 10mg once daily is associated with a numerical decrease in the incidence and severity of coronavirus infections as compared to placebo.

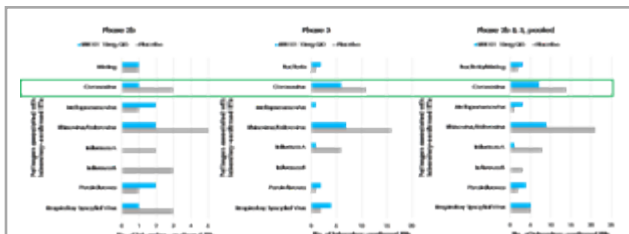


Figure 1. Treatment with RTB101 10mg once daily is associated with a numerical decrease in the incidence and severity of coronavirus infections as compared to placebo.

### Analysis of the incidence of respiratory tract infections caused by specific pathogens including coronavirus in the Phase 2b and Phase 3 Trials of RTB101

As previously disclosed, resTORbio has conducted two double-blind, randomized, placebo-controlled trials of RTB101 for prevention of respiratory tract infections (RTIs) in adults aged  $\geq 65$  years. The first was a Phase 2b study of RTB101 in 652 older adults with comorbidities that elevate risk of RTIs in which RTB101 10 mg once daily was observed to upregulate innate antiviral gene expression and reduced the incidence of laboratory-confirmed RTIs (the primary endpoint of the trial) by 30.6% as compared to placebo ( $p=0.025$ ). The second was a Phase 3 study of RTB101 in 1,024 non-smoking, older adults without chronic obstructive pulmonary disease (COPD) that did not meet its primary endpoint for prevention of “clinically symptomatic respiratory illness” (defined as respiratory symptoms consistent with an RTI, irrespective of whether an infection was laboratory-confirmed). In both trials, RTB101 10 mg once daily was well tolerated.

A prespecified analysis of laboratory-confirmed RTI pathogens in both trials is shown in Figure 1A. Although the Phase 2 and 3 trials predated known SARS-CoV-2-related disease in humans (COVID-19), a trend towards reduced number of other coronavirus infections (OC43, NL63, HKU1, 229E) among older adults treated with RTB101 as compared to placebo was identified in both studies (Figure 1A). Posthoc analyses of causative pathogens associated with laboratory-confirmed RTIs with severe symptoms further identified a trend towards fewer coronavirus RTIs with severe symptoms (Figure 1B), and a reduction in the time to alleviation of moderate to severe coronavirus RTI symptoms among older adults treated with RTB101 as compared to placebo in both studies.

Based on the consistency of the observations across Phase 2b and Phase 3 trials that RTB101 10 mg once daily was well tolerated and associated

with a numerical decrease in the incidence and particularly the severity of other coronavirus infections as compared to placebo, a trial of RTB101 as COVID-19 prophylaxis in nursing home residents is being undertaken.

Figure 1. Treatment with RTB101 10mg once daily is associated with a numerical decrease in the incidence and severity of coronavirus infections as compared to placebo.

#### A. Laboratory-confirmed RTIs

A graphic accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/2efab205-5689-453e-b2c6-5bdb006d89d4>

#### B. Laboratory-confirmed RTIs with severe symptoms

A graphic accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/4e5cdc45-cc2b-4d9a-815f-4907690bb06f>

### **Initiation of a randomized, double-blind, placebo-controlled clinical study of RTB101 prophylaxis to reduce the severity of COVID-19**

The new clinical study is a randomized, double-blind, placebo-controlled study to evaluate whether prophylaxis with RTB101 as compared to placebo reduces the severity of laboratory-confirmed COVID-19 in adults 65 years of age and older who reside in a nursing home in which one or more residents or staff have developed laboratory-confirmed COVID-19. The FDA-approved primary endpoint for the study is the percentage of subjects who develop laboratory-confirmed COVID-19 with protocol-defined progressive symptoms or are hospitalized or die through four weeks of study drug treatment. Approximately 550 subjects are expected to enroll in the study. Subjects will be randomized 1:1 to RTB101 10 mg once daily or matching placebo once daily.

The study will be conducted in collaboration with Investigators at Brown University's Schools of Medicine and Public Health and Insight Therapeutics, LLC, and in certain nursing homes within the Genesis Healthcare system, where patients will be provided the opportunity to volunteer and participate in the study.

"In previous Phase 2 studies, RTB101 was observed to upregulate innate antiviral gene expression, and therefore RTB101 has the potential to be a pan-antiviral immunotherapy. Data concerning coronavirus infections in the Phase 2b and Phase 3 clinical trials should be interpreted with caution as the number of coronavirus infections in both trials was small, and thus no statistically significant conclusions can be drawn. However, given the critical situation faced by residents of nursing homes, we believe a clinical trial evaluating RTB101 as COVID-19 prophylaxis in nursing home residents is warranted," said Dr. Joan Mannick, Co-Founder and Chief Medical Officer of resTORbio.

#### **About RTB101**

RTB101 is an oral, selective, and potent TORC1 inhibitor product candidate that inhibits the phosphorylation of multiple targets downstream of TORC1. Inhibition of TORC1 has been observed to extend lifespan and healthspan in aging preclinical species and to improve the function of aging organ systems, including the immune system and central nervous system, suggesting potential benefits in several aging-related diseases.

#### **About resTORbio**

resTORbio, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to treat aging-related diseases. resTORbio's lead program selectively inhibits TORC1, an evolutionarily conserved pathway that contributes to the decline in function of aging organ systems. Learn more about resTORbio, Inc. at [www.resTORbio.com](http://www.resTORbio.com).

#### **Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, our expectations of the potential impact of COVID-19 on strategy, future operations, and the timing of our clinical trials, including potential impacts on enrollment and initiation; our proposed timing and anticipated results of our clinical trial of RTB101 in patients at risk of laboratory-confirmed COVID-19; our future plans to develop RTB101 alone or in combination with rapalogs, such as everolimus or sirolimus, including the therapeutic potential and clinical benefits thereof; our expectations on the potential patient populations that may be addressed by our product candidates; and our ability to replicate results achieved in our clinical trials in any future trials, constitute forward-looking statements identified by words such as, but not limited to, "believe," "expect," "estimate," "project," "intend," "future," "potential," "continue," "may," "might," "plan," "will," "should," "seek," "anticipate," or "could" and similar words or expressions.

Any forward-looking statements in this statement 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 from those anticipated, including, without limitation, risks associated with: the impact of public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, the timing and anticipated results of our clinical trials; the risk that the results of our clinical trials may not be predictive of future results in connection with future clinical trials; our ability to explore and evaluate strategic alternatives and external opportunities, the timing and outcome of our planned interactions with regulatory authorities; and obtaining, maintaining and protecting our intellectual property as well as those risks more fully discussed in the section entitled "Risk Factors" in the Annual Report on Form 10-K filed by resTORbio, Inc. with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements are neither historical facts nor assurances of future performance. Instead, they represent our beliefs, expectations, assumptions and views only as of today and should not be relied upon as representing our beliefs, expectations, assumptions and views as of any subsequent date. resTORbio explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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