



resTORbio Announces Early Completion of Enrollment of Phase 3 PROTECTOR 1 Trial with RTB101 in Clinically Symptomatic Respiratory Illness

July 23, 2019

– Company plans to announce topline data from PROTECTOR 1 by early first quarter of 2020 –

– PROTECTOR 2 is planned to start in the fourth quarter of 2019, with topline data expected in mid-2020 –

BOSTON, July 23, 2019 (GLOBE NEWSWIRE) -- resTORbio, Inc. (Nasdaq: TORC) today announced that it has completed patient enrollment of the Phase 3 PROTECTOR 1 trial, ahead of previously announced clinical timelines, with 1,024 patients randomized. PROTECTOR 1 is the first of two global Phase 3 clinical trials evaluating the potential of RTB101 to improve the immune function of patients aged 65 and older and thereby decrease the incidence of illness associated with respiratory tract infections (RTIs).

"We are very pleased with the rapid pace of enrollment of PROTECTOR 1, which now puts us on a timeline to potentially announce topline data from this Phase 3 study by early first quarter of 2020," said Chen Schor, co-founder, president and chief executive officer of resTORbio. "This is a significant milestone for the company, and we believe it underscores the strong interest of clinicians and patients in the potential clinical benefits of RTB101. We believe that RTB101 has the potential to be a paradigm-shifting treatment to reduce the incidence of illness associated with RTIs in older adults. RTIs are the fourth leading cause of hospitalization and seventh leading cause of death in people 65 years of age and older in the U.S. The majority of RTIs are caused by many different types of viruses, most of which lack effective treatment."

The design of the Phase 3 PROTECTOR program is based on results from two Phase 2 trials and incorporates feedback from both the U.S. Food and Drug Administration and the European Medicines Agency. In two Phase 2 clinical trials that enrolled more than 900 older adults, RTB101 was observed to improve immune function by upregulation of pan antiviral gene expression and to reduce the incidence of RTIs.

About the Phase 3 PROTECTOR Program

The Phase 3 PROTECTOR program includes two randomized, double-blind, placebo-controlled clinical trials: PROTECTOR 1 and PROTECTOR 2. The program was designed to evaluate the safety and efficacy of RTB101 10mg given orally once daily for 16 weeks during winter cold and flu season in adults 65 years of age and older, excluding current smokers and chronic obstructive pulmonary disease patients. The primary endpoint of both trials is the reduction in the percentage of patients with clinically symptomatic respiratory illness, defined as illness associated with RTIs, based on prespecified diagnostic criteria.

PROTECTOR 1, currently underway in the southern hemisphere, has completed enrollment of 1,024 patients. PROTECTOR 2 is expected to be initiated in the northern hemisphere in the fourth quarter of 2019 and to enroll approximately 1,600 patients. Based on current enrollment expectations for PROTECTOR 2, resTORbio anticipates announcing topline data from this trial in mid-2020.

About Respiratory Tract Infections in Older Adults

As part of the aging process, the immune system weakens and becomes less effective at detecting and fighting infections such as RTIs. As a result, RTIs are more likely to be of greater severity, prolonged duration, and are more likely to be associated with medical complications in people 65 years of age and older compared to younger adults. In the U.S., RTIs are the fourth leading cause of hospitalization and seventh leading cause of death in people 65 years of age and older. Given that the majority of RTIs are caused by many different types of viruses, most of which lack effective therapies, there remains a significant unmet medical need for an immunotherapy that enhances the ability of the immune system to fight multiple viruses to reduce illness associated with RTIs in older adults.

About RTB101

RTB101 is an oral, selective, and potent TORC1 inhibitor product candidate. TORC1 inhibition has been shown to be of therapeutic benefit in multiple aging-related conditions in preclinical species including immunosenescence (aging-related decline in immune function). In two Phase 2 clinical trials enrolling over 900 elderly people, RTB101 was observed to improve immune function by upregulation of pan-antiviral gene expression and to reduce the incidence of RTIs.

About resTORbio

resTORbio, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases. resTORbio's lead program selectively inhibits TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems, including immune, neurologic and cardiac function. Learn more about resTORbio, Inc. at 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, express or implied statements or guidance regarding our proposed timing, enrollment, trial design and anticipated results for our PROTECTOR Phase 3 clinical program of RTB101, 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 and the potential patient populations that may be addressed by our product candidates, our ongoing and future clinical trials for RTB101, including the timing of the initiation and anticipated results of these trials, and our ability to replicate results achieved in our clinical trials in any future trials, constitute forward-looking statements identified by words like "believe," "expect," "may," "will," "should," "seek," "anticipate," or "could" and similar expressions.

Such forward-looking statements 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: our PROTECTOR Phase 3 program; our planned Phase 3 clinical trials in RTIs and/or

development of RTB101, either alone or in combination with a rapalog, such as everolimus or sirolimus; uncertainties related to the results of our clinical trials predictive of future results in connection with future trials, including our Phase 3 clinical trials; 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 represent our views only as of today and should not be relied upon as representing its views as of any subsequent date. resTORbio explicitly disclaims any obligation to update any forward-looking statements.

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