1 July 2013

TO: Anne Whitaker, President, North America, Pharmaceuticals
Damian Braga, Senior Vice President of Commercial Operations
E. Jay Wilusz, Product Life Cycle Management and Business Development
Sanofi
1 Discovery Drive
Swiftwater, PA 18370

Open letter: Reduce rifapentine cost and increase research funding

Dear Ms. Whitaker and Colleagues,

We congratulate and appreciate Sanofi's continued development of rifapentine (Priftin) for tuberculosis (TB) treatment. As you know, critical milestones are within reach for making rifapentine part of latent and active TB treatment regimens. We call upon you to increase your commitment to developing rifapentine for TB treatment shortening. Furthermore, we urge you to do the right thing by lowering the drug's price immediately, in keeping with Sanofi's commitment to improving access to treatments for diseases of the poor. Sanofi has benefitted substantially from public investment in rifapentine's development over the past 20 years through trials supported by the U.S. Centers for Disease Control and Prevention (CDC)'s Tuberculosis Trials Consortium (TBTC) and the National Institutes of Health/National Institute of Allergy and Infectious Diseases and its AIDS Clinical Trials Group. Yet the same taxpayers who funded research advances have not been able to access the drug due to its price.

We appeal to Sanofi to uphold its pledge to make rifapentine affordable. After promising conversations between Sanofi representatives and signatories to this letter at the Critical Path to TB Drug Regimens meeting in Arlington, Virginia, U.S. in October 2012 and during the Union World Conference on Lung Health in Kuala Lumpur, Malaysia in November 2012, collaboration ground to a halt. Sanofi rejected our formal request in January 2013 to 1) modestly lower the price of rifapentine to $35/box, and 2) extend this discount to all public TB care providers. Given the broader market for rifapentine if its price were lowered, we expect this reduction would in fact benefit Sanofi, as well as those with TB, their loved ones, and their caregivers.

The need for shorter, simpler regimens to cure and prevent TB are particularly urgent in these times of limited resources for TB programs, frequent drug shortages, and increasing calls for zero TB deaths and suffering. Rifapentine's ability to shorten and simplify TB treatment from the burdensome standard six to nine months of daily dosing is an important public health advance.

Sanofi's laudable research collaborations with the public sector and with academia have demonstrated that replacing rifampicin with rifapentine (in combination with moxifloxacin) in the last four months of active TB treatment could allow for once-weekly, rather than daily, dosing. They also showed that administering rifapentine with

isoniazid could shorten latent TB treatment to just 12 once-weekly doses, and resulted in a policy recommendation by the CDC in late 2011.

These contributions to advance TB research are wasted if rifapentine is ultimately unaffordable and inaccessible to programs. Rifapentine is rarely used in the U.S. and globally, in large part due to its exorbitant pricing. Rifapentine's "discounted" price for select U.S. programs of $51.20 per box of 32 tablets of 150mg (or $221.01 for a course for active TB and $115.20 for a 12 week course for latent TB for the rifapentine alone) is out of reach for a majority of TB programs in the U.S. In Holland et al.'s study published in 2011, models using rifapentine as part of a latent TB treatment regimen showed that "…the primary driver of the cost difference among regimens is rifapentine; if it becomes cheaper, our results [on rifapentine's cost-effectiveness] would only become more robust."

Additional trials to determine the potential of rifapentine to shorten active TB treatment are necessary. TBTC 29X, a publically funded phase II study, recently demonstrated that rifapentine has tremendous potential to shorten treatment for active TB disease. However, a subsequent phase III trial is in jeopardy due to sequestration and other budget cuts to the TBTC. We therefore call upon you to commit meaningfully to the continued development of rifapentine by pledging an additional $2 million to the TBTC. Sanofi stands to benefit greatly from rifapentine's incorporation into a treatment-shortening regimen for active TB; your company should expand its support of TBTC to match the public sector's historic and future contributions to the development of a private sector drug.

The millions of people worldwide with TB (including nearly 10,000 people in the U.S. alone, and their hundreds of thousands of infected contacts) need better treatment options urgently. And care providers, TB programs and taxpayers urgently need these to be affordable, now. Sanofi, we ask you to take a stand and demonstrate your commitment to rifapentine development and access by:

1. **Lowering the price of rifapentine to $35 per box of 32 tablets of 150 mg; and**
2. **Pledging $2 million to the TBTC for the continued development of rifapentine.**

We appreciate your cooperation and ask you to please contact erica.lessem@treatmentactiongroup.org at your earliest convenience to set up a time to discuss this issue further.

Thank you,

Organizational Signatories
American Medical Association (USA)
American Thoracic Society (USA)
Arkansas Department of Health TB Program (Arkansas, USA)
California TB Controllers Association (California, USA)

Community Research Advisors Group to the Tuberculosis Trials Consortium (USA, Global)
Global TB Community Advisory Board (Global)
Hawaii State Department of Health TB Control Program (Hawaii, USA)
Houston Department of Health and Human Services Bureau of TB Control (Texas, USA)
National Association of County and City Health Officials (USA)
National Society of TB Clinicians (USA)
National TB Controllers Association (USA)
RESULTS (USA)
Treatment Action Group (New York, USA)

Individual Signatories
Note: institutions listed as affiliations only
Ms. Heidi Behm, RN, BSN, MPH, TB Controller, HIV/STD/TB Section, Oregon Health Authority (Oregon, USA)

Dr. Robert Benjamin, Public Health Consultant (California, USA)

Ms. Barbarah Brissette, RN, President Elect of the National TB Nurses Coalition; Chief Nurse of the Houston Department of Health and Human Services Bureau of TB Control (Texas, USA)

Dr. Joseph Burzynski, Acting Assistant Commissioner, Bureau of Tuberculosis Control, New York City Department of Health and Mental Hygiene (New York, USA)

Dr. Richard E. Chaisson, Professor of Medicine, Epidemiology, and Health, and Director, Center for TB Research and Center for AIDS Research, Johns Hopkins University (Maryland, USA)

Dr. Wendy Cronin, US state TB control employee and periodic international consultant (USA)

Dr. Jennifer Flood, President, National TB Controllers Association (USA)

Mr. Phil Griffin, TB Controller, Kansas Department of Health and Environment (Kansas, USA)

Dr. Carol Dukes Hamilton, Director of Scientific Affairs, Global Health, Population & Nutrition of FHI 360 (North Carolina, USA)

Dr. Ilse R. Levin, American Medical Association (USA)

Dr. Michelle Macaraig, Director of Planning and Policy, Bureau of Tuberculosis Control, New York City Department of Health and Mental Hygiene (New York, USA)

Dr. Elizabeth MacNeill, MD, TB Control Physician, State of Hawaii (Hawaii, USA)

Ms. Maureen Murphy-Weiss, RN, Department of Health TB Program (Ohio, USA)

Dr. Edward A. Nardell, Associate Professor, Harvard Medical School and Harvard School of Public Health; Brigham and Women's Hospital, Division of Global Health Equity, Partners In Health (Massachusetts, USA)

Dr. Naveen Patil, Section Chief and State TB Control Officer, Department of Health TB Program (Arkansas, USA)

Dr. Lee Reichman, Executive Director of the New Jersey Medical School Global TB Institute (New Jersey, USA)

Dr. Barbara Seaworth, President Elect, National Society of TB Clinicians (USA)

Mr. Richard Stancil, Bureau Chief of the Houston Department of Health and Human Services Bureau of TB Control and NTCA member (Texas, USA)

Dr. Jeffrey Starke, Professor of Pediatrics, Baylor College of Medicine (Texas, USA)

Dr. Jason Stout, TB Controller/Medical Director, North Carolina TB Control Program and Duke University Medical Center, Division of Infectious Diseases and International Health (North Carolina, USA)

Dr. Dean Tsukayama, President, National Society of TB Clinicians (USA)

CC: Elias Zerhouni, President, Global R&D
David Meeker, Chief Executive Officer, Genzyme
Robert Sebbag, Vice President, Access to Medicines
Benedict Blayney, Associate Vice President, Neglected Disease and Tuberculosis
Isabelle Cieren-Puiseux, Senior Manager, Tuberculosis Program
Marilyn Maroni, Medical Manager, Tuberculosis
Neila Fourcroy, Regulatory Affairs