AstraZeneca

December 19, 2013

The Honorable Phil Gingrey, M.D.
442 Cannon House Office Building
House of Representatives
Washington, DC 20515

The Honorable Gene Green
2470 Rayburn House Office Building
House of Representatives
Washington, DC 20515

Dear Representatives Gingrey and Green,

On behalf of AstraZeneca, I am writing in support of the *Antibiotic Development to Address Patient Treatment Act of 2013* (the ADAPT Act). AstraZeneca is a leading global healthcare company dedicated to the research and development of new medicines in several therapeutic areas including infectious disease. AstraZeneca has a robust antibiotic clinical development program, with products in various stages of development.

As you know, antimicrobial resistance is a growing public health crisis on a global scale, and your leadership in tackling this crisis is to be commended. The statistics are staggering. The Centers for Disease Control and Prevention recently estimated that 2,000,000 infections with resistant bacteria occur each year in the United States and that 23,000 patients die as a result. At this critical time, the antibiotic pipeline for new treatments is bleak. A combination of factors has led to this diminishing pipeline, including significant regulatory and economic barriers. A core regulatory challenge is that the traditional FDA framework for approving antibacterial agents rests on the assumption that relatively large studies can be conducted for the pathogen(s) of interest at the body site(s) of interest. While this approach may have worked well in the past, it is problematic for narrow-spectrum agents or those focused on specific types of emerging resistance. In these scenarios, the population of patients in whom these infections occur is limited and thus enrolling large numbers of patients into trials may be impossible or impractical.

The ADAPT Act proposes an innovative approach to antibacterial and antifungal drug development for serious or life-threatening infections where there exists an unmet medical need. This approach should provide substantial flexibility in drug development and approval paradigms in that it would allow the design of programs that might otherwise not have been attempted, for example, greater use of alternative trial endpoints and reliance on preclinical and clinical data as well as datasets of limited size. This approach will encourage the development of greatly needed drugs for present problems and in anticipation of future medical crises.

In addition, we applaud the helpful clarity produced by the alignment of the definition of eligible compounds under the ADAPT Act with the statutory definition of Qualified Infectious Diseases Product – both include antibacterial and antifungal products. Finally, AstraZeneca supports the provisions in your legislation designed to improve how susceptibility test interpretive criteria are established and maintained.

AstraZeneca greatly appreciates your continued focus on this important public health issue. Building on your successful effort in 2012 to champion the *Generating Antibiotic Incentives Now* (GAIN) Act, the ADAPT Act is an important step forward to spur antibiotic research and development. We thank you for the opportunity to convey our support for the ADAPT Act.

Sincerely,

J. Rex, M.D.

John Rex, MD, FACP
Vice President and Head of Infection, Global Medicines Development
AstraZeneca Pharmaceuticals LP

AstraZeneca Pharmaceuticals LP
35 Gatehouse Drive Waltham MA 02451

Tel 781 839 4000
www.astrazeneca-us.com