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Reports on Investigational Agents to Counter Antimicrobial Resistance

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report*. I'm Dr. Linda Bernstein.

The World Health Organization just reported on concerns that the lack of new antibiotics threatens global efforts to contain drug-resistant infections. They state that a reduction in private investment and lack of new and innovative approaches to antibiotic development hinder efforts to fight against drug-resistance. The pipeline for antibiotics that target the most dangerous, resistant bacteria, (Gram-negative bacteria) is weak. Two new reports, (Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline and its companion publication, Antibacterial agents in preclinical development), find that of the 60 products in development (50 antibiotics and 10 biologics) few offer little advantage over existing treatments.

Drug candidates in pre-clinical stages of development are more innovative, but it will take years for these agents to actually benefit patients. Large pharmaceutical companies are leaving the field and the work of research and development for antibiotics is left to small- or medium-sized enterprises.

According to Dr. Tedros Adhanom Ghebreyesus, Director-General of World Health Organization, "Never has the threat of antimicrobial resistance been more immediate and the need for solutions more urgent. Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines."

The World Health Organization in 2017 published the priority pathogens list, including 12 classes of bacteria plus tuberculosis that are posing increasing risk to human health. The list was developed by a World Health Organization (WHO) led group of independent experts to promote research and development (R&D) of new antibiotics, as part of WHO's efforts to address growing global resistance to antimicrobial medicines. The list highlights in particular the threat of gram-negative bacteria that are resistant to multiple antibiotics. The WHO list is divided into three categories according to the urgency of need for new antibiotics: critical, high and medium priority.

32 of the 50 antibiotics in the pipeline target WHO priority pathogens, but most have only limited benefits when compared to existing antibiotics. Two of these are active against the multi-drug resistant Gram-negative bacteria, which are spreading rapidly and need immediate action. Gram-negative bacteria, such as Klebsiella pneumoniae and Escherichia coli, are most dangerous to patients with weak or underdeveloped immune systems, including newborns, the elderly, surgical patients and those undergoing cancer treatment.

Only three antibiotics under development target the highly resistant NDM-1 (New Delhi metallo-beta-lactamase 1) that induces bacterial resistance to a broad range of antibiotics, including those from the carbapenem family, which today are the last line of defense against antibiotic-resistant bacterial infections.

As stated by Hanan Balkhy, WHO Assistant Director-General for Antimicrobial Resistance, "It's important to focus public and private investment on the development of treatments that are effective against the highly resistant bacteria because we are running out of options. And we need to ensure that once we have these new treatments, they will be available to all who need them."

The pipeline for antibacterial agents to treat tuberculosis and Clostridium difficile (which causes diarrhea), on the other hand is more encouraging, with greater than half of the treatments meeting all the development objectives set forth by the WHO.

The pre-clinical pipeline shows more innovation and diversity, with 252 agents under development to treat WHO priority pathogens. The best case scenario for these agents, which are in the very early stages of development and still need to be deemed safe and effective, is that for the first two to five products it will take approximately ten years to be ready for patient use.

The World Health Organization is working on a variety of fronts to counter the threat of antimicrobial resistance. It works with countries and partners to improve infection prevention and control and to promote the appropriate use of existing and future antibiotics.

In the area of research and development, WHO and the Drugs for Neglected Diseases Initiative (DNDi) have established the Global Antibiotic Research and Development Partnership (GARDP), a non-profit research and development organization accelerating the development of new and improved antibiotics to tackle drug-resistant infections. GARDP's strategy is to deliver five new treatments by the year 2025. It is working with more than 50 public and private sector partners in 20 countries to develop and ensure sustainable access to treatments, promoting responsible use and affordability to all in need.

For *The Drug Report,* I'm Pharmacist, Dr. Linda Bernstein.

Announcer:
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