29. Sitzung des Unterausschusses Globale Gesundheit

Deutscher Bundestag

Ausschuss für Gesundheit
UA Globale Gesundheit

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12.11.2024

Die stille Pandemie – Antibiotikaresistenzen

11 November 2024

Peter Beyer

Deputy Executive Director

GARDP

Dem Ausschuss ist das vorliegende Dokument in nicht barrierefreier Form zugeleitet worden.

Who we are:

- Innovative **antibiotic R&D and access partnership** driven to protect people from the spread of drug-resistant infections
- **By forging public & private partnerships,** we develop and make accessible antibiotic treatments for people who need them

GARDP created by WHO and the Drugs for Neglected Disease initiative (DNDi)

2016

GARDP established as a Swiss foundation (GARDP Foundation)

2018

GARDP is a not-for-profit global health organization with c. 100 staff in Geneva and strategic locations worldwide

TODAY

The Telegraph

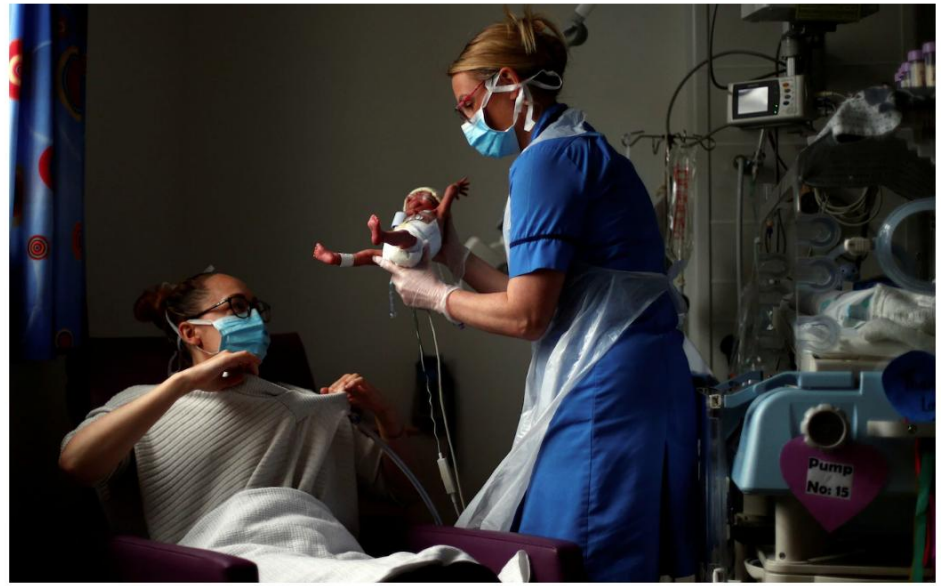
Antibiotic treatments ‘outdated’ as study shows thousands of babies dying from preventable infection

Western policy guidelines around the use of antibiotics may be causing more harm than good in Africa and other developing areas

Verity Bowman

Related Topics
Global Health Security, Sepsis, Antibiotics, Superbugs - Antibiotic resistance, World Health Organisation, Child health

09 June 2023 12:01am BST



WHO guidelines generated from high income country settings, inappropriately applied in an African context, have resuted in a mismatch Credit: Hannah McKay/PA Wire

The World Health Organization has been urged to update its guidelines on the use of antibiotics in developing countries after a study found that thousands of infants were dying from infections that could be prevented.

The study, which stretched over 11 countries and involved over 3,200 babies, is one of the largest of its kind ever conducted and suggests that western policy

Developing new treatments for children and newborns

New combination treatments for neonatal sepsis

Launched global trial (“NeoSep1”) in Kenya and South Africa to rank the safety and efficacy of three new antibiotic combinations against common antibiotic regimens used to treat neonatal sepsis

Essential research to improve treatments

In preparation for Neosep1, GARDP completed one of the largest observational studies on babies with sepsis—3,200 newborns in 11 countries—and identified 3 promising antibiotics for use in combination

GARDP welcomes positive results in Venatorx phase 3 clinical trial of new treatment for serious bacterial infections

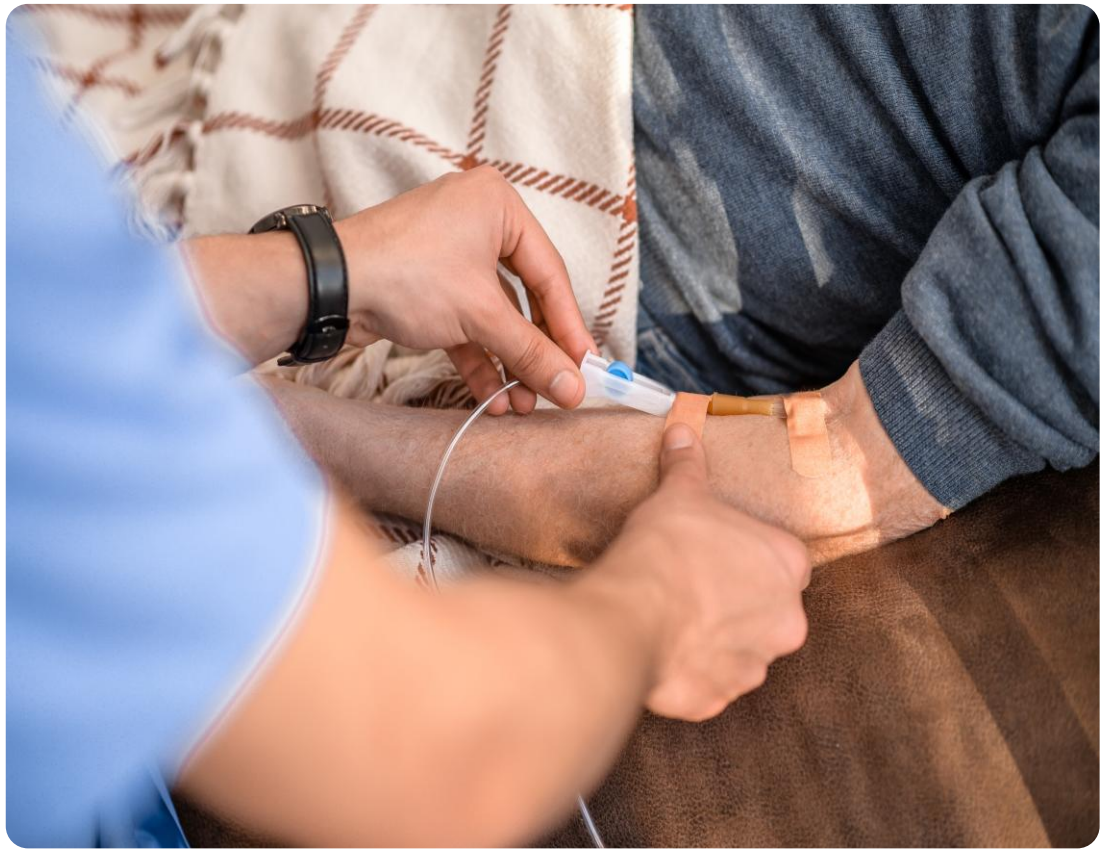
10 March 2022

Venatorx Pharmaceuticals, Inc., a GARDP collaborator, today announced positive results from its pivotal phase 3 study evaluating cefepime-taniborbactam as a treatment for hospitalized adult patients with complicated urinary tract infections, including acute pyelonephritis (i.e. kidney infections). Cefepime-taniborbactam offers a potential treatment option for patients with serious infections caused by highly resistant bacteria, even those resistant to last-resort carbapenem antibiotics. Since April 2020, GARDP and Venatorx have been working together to accelerate the development of cefepime-taniborbactam, and the New Drug Application is on track to be filed with the US Food and Drug Administration in the fourth quarter of 2022. If approved, cefepime-taniborbactam will be the first new antibiotic treatment to be launched in collaboration with GARDP since its foundation.

Since it was introduced in the 1990s, the antibiotic cefepime (known as a "beta-lactam" because of its chemical structure) has faced growing resistance from bacteria that produce special enzymes (beta-lactamases), which break down antibiotics like cefepime that had the potential to destroy them. Taniborbactam (a potent beta-lactamase inhibitor) shields cefepime against these destructive enzymes for renewed activity. This new investigational beta-lactam/beta-lactamase inhibitor combination (cefepime-taniborbactam) has activity against carbapenem-resistant Enterobacterales and carbapenem-resistant *Pseudomonas aeruginosa*, which have been identified as priority pathogens in urgent need of new treatments by the World Health Organization.

"We are very pleased to collaborate with Venatorx to advance the development of a new treatment for serious bacterial infections," said Subasree Srinivasan, Medical Director of GARDP. "The positive phase 3 clinical trial results bring cefepime-taniborbactam closer to becoming a potential treatment option for patients with infections caused by some of the most difficult-to-treat bacteria. Public-private partnerships, with crucial support from donors, enable GARDP to deliver solutions as soon as possible for people who are

Cefepime-taniborbactam drug development project



- Since March 2020, GARDP and Venatorx Pharmaceuticals Inc. have been collaborating to accelerate the development of cefepime-taniborbactam
- Cefepime-taniborbactam has activity against resistant bacteria, including CR Enterobacterales and CR *Pseudomonas aeruginosa*
- Following a successful pivotal phase 3 clinical trial, Venatorx submitted a New Drug Application for cefepime-taniborbactam to the US Food and Drug Administration (FDA)
- The FDA has requested that critical manufacturing issues be addressed, delaying the NDA.

THE HINDU

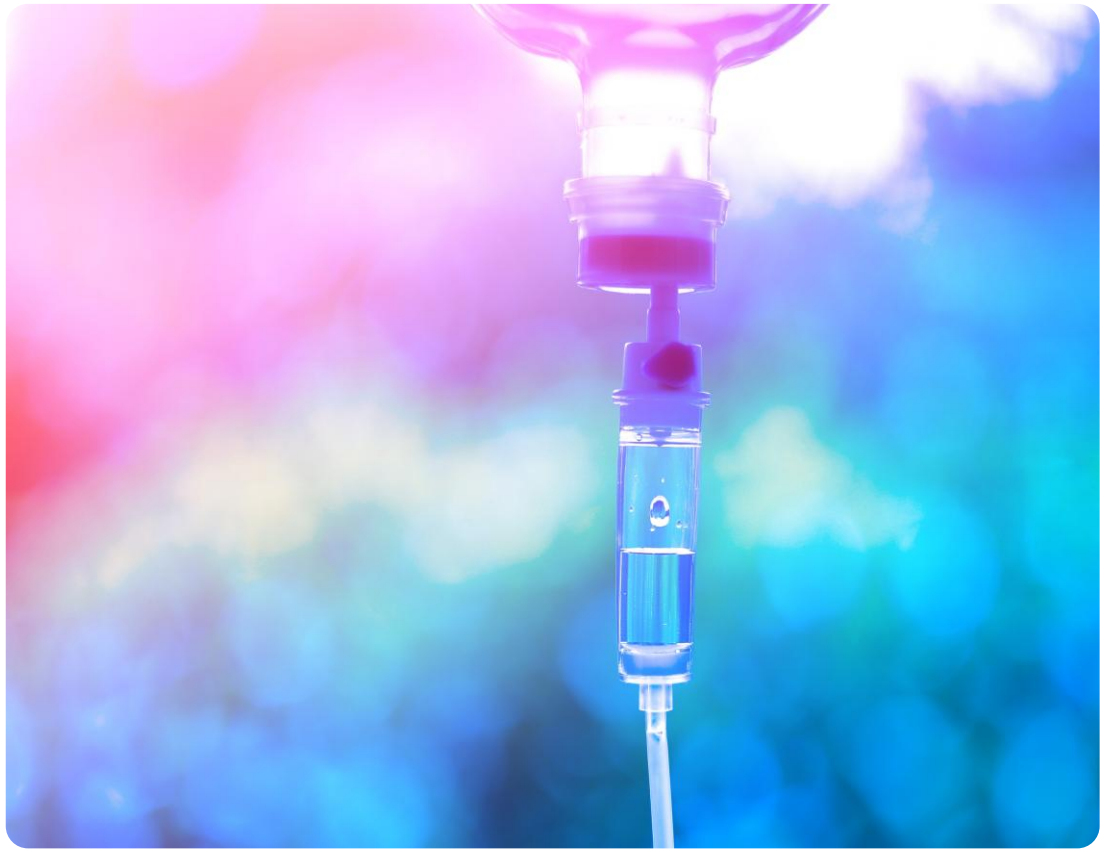
Bugworks and GARDP collaborate to accelerate development of novel antibiotic to treat serious infections

Bugworks is currently developing a compound that aims to address problems arising from serious hospital and community infections

Updated – August 08, 2023 12:27 pm IST – Bengaluru

THE HINDU BUREAU

Co-development of novel broad-spectrum treatment for serious bacterial infections



- In 2024, GARDP signed a collaboration agreement with Indian-based Bugworks to provide technical and financial support for the pharmaceutical and clinical co-development of compound BWC0977
- This innovative compound that benefitted from CARBx funding for phase 1 has broad-spectrum antibiotic activity against multidrug-resistant bacteria that cause life-threatening infections
- Bugworks has granted GARDP manufacturing and commercialization rights in 146 countries

The New York Times

Gonorrhea Is Becoming Drug Resistant. Scientists Just Found a Solution.

A new antibiotic, zoliflodacin, is as effective as the current standard of care. Its creation may hasten the arrival of other needed antibiotics.

By Apoorva Mandavilli

Nov. 10, 2023

Frankfurter Allgemeine

Neue Tripper-Therapie

Antibiotikum hilft gegen multiresistente Keime

Die im Volksmund Tripper genannte Gonorrhö lässt sich zunehmend schwer behandeln. Denn der Erreger dieser Geschlechtskrankheit, das Bakterium Neisseria gonorrhoeae, hat gegen die meisten Antibiotika Resistenzen entwickelt. Dies ist insofern bedenklich, als die Zahl der infizierten Menschen weltweit merklich zugenommen hat.

Auch in Deutschland befindet sich der Tripper seit einigen Jahren auf dem Vormarsch. Genaue Statistiken fehlen zwar. Eine Vorstellung von der Größenordnung vermittelt gleichwohl die Situation in Sachsen, dem einzigen Bundesland mit einer Meldepflicht für die Gonorrhö. Hier hat die Ansteckungsrate zwischen 2001 und 2019 um das Zehnfache zugenommen – von knapp zwei auf rund zwanzig Fälle pro hunderttausend Einwohner. Das Heimtückische am Tripper ist, dass er häufig symptomlos verläuft und daher unbemerkt weitergegeben werden kann. Seine gesundheitlichen Folgen können zudem erheblich sein. So geht er mit einem um das Fünffache erhöhten Risiko für eine HIV-Infektion einher, kann zu Unfruchtbarkeit führen und schwere Infektionen bis hin zu einer Sepsis hervorrufen.

Eine gute Nachricht ist es daher, nanz erhalten“, sagt Pierre Daram, der bei der GARDP die Entwicklung neuer Arzneimittel gegen Geschlechtskrankheiten leitet. „Denn es gab schon seit mehr als dreißig Jahren keine neue Therapie mehr gegen die Gonorrhö.“ Wie der Mikrobiologe hinzufügt, attackiert Zoliflodacin die Bakterien an einer anderen Stelle als andere Antibiotika. Als besonders wichtig bezeichnet Daram es dabei, dass der neue Wirkstoff auch multiresistente Keime eliminieren könne. Darunter versteht man Bakterien, die gegen zahlreiche herkömmliche Antibiotika unempfindlich geworden sind.

Neben Zoliflodacin entwickelt die GARDP noch eine ganze Reihe weiterer Wirkstoffe gegen antibiotikaresistente Mikroben. Dass eine gemeinnützige Organisation solchen Tätigkeiten nachgeht, ist ein der Not geschuldetes Novum. So werden viele, einst besiegt geglaubte Infektionskrankheiten – dazu zählen unter anderem auch Lebensmittelvergiftungen und Lungenentzündungen – erneut zu einer Lebensbedrohung, weil die vorhandenen therapeutischen Waffen inzwischen stumpf geworden sind. Die pharmazeutische Industrie hat sich aus der Antibiotika-Forschung zudem weitgehend verabschiedet, da die Gewinnaussich-

Sexually transmitted infections

Developing a new innovative treatment for gonorrhoea

GARDP sponsored a clinical phase 3 trial to evaluate zoliflodacin with nearly a 1000 patients in five countries

In November 2023, GARDP in collaboration with Innoviva Specialty Therapeutics announced positive phase 3 trial results

The submission to the US Federal Drug Administration for approval is expected in Q1 2025

Shionogi, GARDP und CHAI kündigen richtungsweisende Lizenz- und Kooperationsvereinbarungen an, um den Zugang zu Cefiderocol für Patienten mit bakteriellen Infektionen in 135 Ländern zu erweitern

Published 9:51 PM GMT+1, June 15, 2022

Share

OSAKA, Japan & GENF & BOSTON--(BUSINESS WIRE)--Jun 15, 2022--

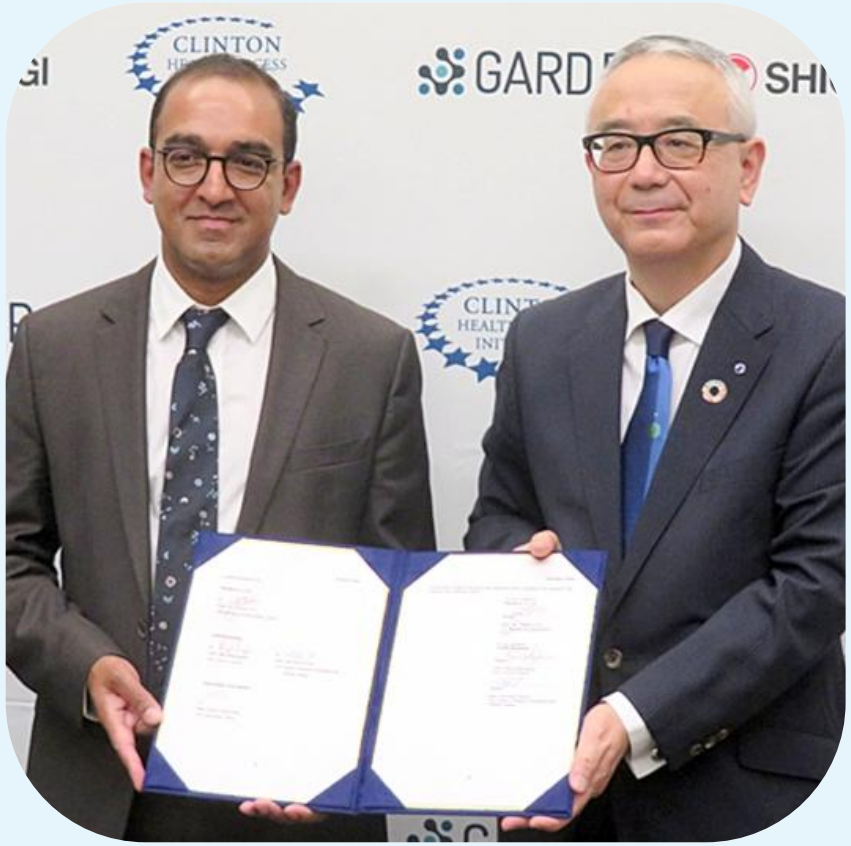
Shionogi & Co. Ltd. (Shionogi) und die Global Antibiotic Research and Development Partnership (GARDP) haben heute den Abschluss einer Lizenz- und Technologietransfervereinbarung sowie einer Kooperationsvereinbarung mit der Clinton Health Access Initiative (CHAI) bekannt gegeben. Diese Vereinbarungen zielen darauf ab, den Zugang zu Antibiotika für Länder auf der ganzen Welt erheblich zu verbessern.

Diese Pressemitteilung enthält multimediale Inhalte. Die vollständige Mitteilung hier ansehen: https://www.businesswire.com/news/home/20220614006071/de/

SHIONOGI

The cefiderocol access project

A groundbreaking project to expand antibiotic access



- The cefiderocol license and technology transfer agreement is the first such agreement between a pharmaceutical company and a non-profit organization driven by public health priorities
- Expands access to cefiderocol in up to 135 countries, covering ~1/2 of the world's population
- The technology transfer from Shionogi to Orchid Pharma (India) is in progress. Initial patient access planned for 2027-2028

Our funding partners

€116.8M

€26.9M

€35.7M

€7.9M

€5.3M

€1.1M

€1.1M

€0.2M

€0.2M

€0.1M

€4.6M

An additional EUR 15M from private funders

EUR 215M in total funding 2017-2024

Your support is vital to ensure the continued development and access to lifesaving antibiotics.