# Media release – Coalition for Epidemic Preparedness Innovations

# \*\*\*Under strict embargo until 22:00 GMT on Wednesday 18 January 2017\*\*\*

## Global partnership launched to prevent epidemics with new vaccines

A global coalition to create new vaccines for emerging infectious diseases, designed to help give the world an insurance policy against epidemics, launches today at the World Economic Forum in Davos, Switzerland.

With an initial investment of US\$460m from the governments of Germany, Japan and Norway, plus the Bill & Melinda Gates Foundation and the Wellcome Trust, CEPI - the <u>Coalition for Epidemic Preparedness Innovations</u> will seek to outsmart epidemics by developing safe and effective vaccines against known infectious disease threats that could be deployed rapidly to contain outbreaks, before they become global health emergencies.

CEPI also hopes to shorten the time it takes to develop new vaccines to protect against viruses that emerge suddenly as public health threats, as Zika did recently, by capitalising on exciting developments in adaptable vaccine technology and investing in facilities that could respond quickly to previously unknown pathogens.

Today's financial commitments mean that CEPI has raised almost half of the \$1bn it needs for its first five years, and it is now calling for proposals from researchers and companies around the world to support the development of vaccines against its first target diseases.

CEPI will initially target the MERS-CoV, Lassa and Nipah viruses, which have known potential to cause serious epidemics. It aims to develop two promising vaccine candidates against each of these diseases before any epidemic, so these are available without delay if and when an outbreak begins. CEPI will also scope out potential support for vaccines against multiple strains of the Ebola and Marburg viruses, and Zika.

To achieve all these goals, CEPI will need significant additional investment, and the initial CEPI funders are calling today for other governments and philanthropic organisations to join them in helping to protect the world against future epidemics. CEPI is looking to complete its fundraising by the end of 2017.

Erna Solberg, Prime Minister of Norway, said: "Just over a year ago 193 states adopted the Sustainable Development Goals – the roadmap for the future we want. Epidemics threaten that future. They can ruin societies on a scale only matched by wars and natural disasters. They respect no borders and don't care if we are rich or poor. Protecting the vulnerable is protecting ourselves. This is why we all must work together to be better prepared – and why my Government is fully committed to ensure that CEPI achieves its mission."

Bill Gates, Co-chair of the Bill and Melinda Gates Foundation, said: "Ebola and Zika showed that the world is tragically unprepared to detect local outbreaks and respond quickly

enough to prevent them from becoming global pandemics. Without investments in research and development, we will remain unequipped when we face the next threat.

"The ability to rapidly develop and deliver vaccines when new 'unknown' diseases emerge offers our best hope to outpace outbreaks, save lives and avert disastrous economic consequences. CEPI is a great example of how supporting innovation and R&D can help the world to address some of its most pressing health challenges."

Dr Jeremy Farrar, Director of the Wellcome Trust, said: "We know from Ebola, Zika and SARS that epidemics are among the significant threats we face to life, health and prosperity. Vaccines can protect us, but we've done too little to develop them as an insurance policy. CEPI is our chance to learn the lessons of recent tragedies, and outsmart epidemics with new vaccine defences. If others join us in supporting CEPI, we can realise our goal of creating a safer world."

CEPI is a direct response to calls from four independent expert reports into the Ebola epidemic for a new system for stimulating the development of vaccines against epidemic threats. It was founded by the governments of India and Norway, the Bill & Melinda Gates Foundation, Wellcome and the World Economic Forum, which has played a key convening role, bringing together stakeholders at the 2016 Davos meeting and other events.

CEPI is also backed by major pharmaceutical corporations, the World Health Organization and Médecins Sans Frontières / Doctors Without Borders, as well as philanthropies and leading academic vaccine research groups.

The Government of India is currently finalising the level of a significant funding commitment to CEPI. In addition to financing for vaccine development that will be available through CEPI's pooled fund, the European Commission will contribute to CEPI's objectives and plans to co-fund actions with CEPI, such as through the Innovative Medicines Initiative (IMI).

#### **Additional information**

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- Nipah virus background information

#### Additional CEPI partner quotes

**John-Arne Røttingen, CEPI interim CEO:** "Today we are launching the first call for proposals from CEPI. We know there is a lot of interest from both public research organizations and large and small companies in responding to the threats of MERS, Lassa and Nipah, and we're excited to finally be developing effective vaccines for these and other epidemic threats."

Yasuhisa Shiozaki, Minister of Health, Labour, and Welfare, Government of Japan: "Japan has highlighted the importance of pandemic preparedness and Universal Health Coverage. I

believe the CEPI will contribute to achieving them through encouraging development of vaccines."

**Professor Dr Johanna Wanka, German Federal Minister of Education and Research:** "The Ebola crisis made us painfully aware of the gaps in the international health system. Prevention is the best means to ensuring healthy lives for all as set out in Agenda 2030. At the same time, a well-prepared system of crisis management must – if the situation arises – quickly contain the spread of contagious diseases. We are convinced that the Coalition for Epidemic Preparedness Innovations will play a key role in the prevention of health crises and enable a quick response in case of crisis. Germany is therefore lending both financial and scientific support to CEPI."

**Carlos Moedas, EU Commissioner for Research, Science and Innovation:** "Recent epidemics taught the world the hard way that infectious diseases know no borders. The EU shares the CEPI objective to develop new vaccines that will help prevent and contain future epidemics, and is committed to collaborating with CEPI in joint efforts towards this goal."

K Vijay Raghavan, Secretary of the Indian Department of Biotechnology and Chair of CEPI's interim board: "India's partnership in CEPI signals our commitment to work with the WHO and other partners to develop and use vaccines to prevent the spread of epidemic disease. India's vaccine companies have changed vaccine accessibility and availability for routine immunisation and for campaigns globally. We are committed to continuing to support global health and ensuring access to vaccines when and where needed."

Marie-Paule Kieny, Assistant Director-General, World Health Organization: "WHO and CEPI share the goal to research and develop safe, effective, and affordable interventions to address infections of epidemic potential. WHO, through the R&D Blueprint for Action against Epidemics, will support the Coalition in several ways, including by providing normative guidance on priorities, by working with governments to streamline regulations, and by ensuring that policies will support public health and equitable access to affordable vaccines."

# Dr Joanne Liu, International President of Médecins Sans Frontières / Doctors Without Borders:

"There is an urgent need for new vaccines, diagnostics and treatments to prevent and treat emerging infections with epidemic potential. For new vaccines to be game changers, they must be developed and tested before outbreaks hit and made accessible and affordable for all communities in times of health crisis. These are the conditions that will determine CEPI's success and ensure this new initiative saves lives."

**Sir Andrew Witty, CEO of GSK said:** "Finding better ways to anticipate and prepare for future health threats is one of the greatest challenges of our time. We strongly support the creation of CEPI and its focus on vaccines development as a solution to protecting against infectious disease outbreaks. GSK has developed a proposal for a Biopreparedness Organisation, a dedicated and permanent facility that would use our scientific expertise and technologies to develop vaccines that could be deployed to protect citizens in the world's poorest countries against future epidemics and pandemics. This facility would operate on a

cost coverage basis to help maximise sustainable access. We stand ready to partner with CEPI to advance epidemic preparedness."

**Paul Stoffels, MD, Chief Scientific Officer, Johnson & Johnson:** "We are delighted to be part of this exciting new public health initiative. The most recent Ebola outbreak – the worst in history – was a wakeup call that brought pandemic preparedness to the forefront and showed us how critically important an effort like this is to protecting society. As part of our commitment, we will work together with CEPI partners, regulators, and all stakeholders in forging a path forward to bring our Ebola vaccines to those in need. We are tremendously grateful for the support of the European Commission, Innovative Medicines Initiative, BARDA and NIH."

Julie Gerberding, Executive VP, Strategic Communications, Global Public Policy, and Population Health at Merck: "Private sector vaccine companies have capability, capacity, and commitment to protecting health and wellbeing worldwide. CEPI is potentially an evolutionary leap forward in how we collectively conduct R&D into infectious diseases that come and go, posing challenges for clinical trials, for manufacturing, and for just-in-time delivery."

**Rajeev Venkayya, MD, President, Global Vaccine Business Unit, Takeda Pharmaceuticals:** "During the next outbreak of an emerging infectious disease, the world will demand a vaccine to protect vulnerable populations everywhere. CEPI will help to prepare for that day, by tapping into the substantial R&D capabilities across industry to create a pipeline of vaccines to address some of the most pressing threats to human health. This is an important global initiative that is applying the many lessons learned from recent outbreaks, and Takeda is proud to be a partner."

Nima Farzan, PaxVax President and CEO, who represents the Biotechnology Innovation Organisation on CEPI's interim board: "Only by working together can we address barriers to vaccine development and prevent and contain infectious global health epidemics. Working alone, industry players face barriers to vaccine development. CEPI's collaborative approach is vital in helping biotechs and other industry leaders pursue innovative efforts to help prepare against future pandemics and fight against global public health threats."

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#### Media contacts

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#### CEPI background

#### Why CEPI is needed

Epidemics cost the world at least \$60bn every year<sup>1</sup>. The most recent Ebola outbreak in West Africa killed over 11,000 people and caused an estimated economic loss of \$2.2bn in the worst-affected countries in 2015 alone<sup>2</sup>. In a world of greater mobility, denser cities and ecological change, their ability to disrupt society is increasing.

Vaccines are one of the world's most important health achievements. Yet their life-saving potential hasn't yet been realised for many known and unknown epidemic threats, particularly in low-income countries, where the risks and needs are often greatest.

The risks and costs of vaccine development, which are always significant, are especially high for epidemic diseases because outbreaks are sporadic, hit poor countries the hardest and the potential market for any such product is unpredictable.

During the Ebola outbreak the global scientific community, including pharmaceutical companies, academics, funders, emergency responders and the WHO, came together to accelerate clinical trials of several promising vaccines. But this success relied on ad-hoc collaboration and the commitment of a handful of vaccine companies – a model that is unsustainable for future outbreaks.

#### **How CEPI works**

CEPI will create a new model to advance promising vaccines through the development process, working with industry, regulators and civil society organisations to ensure that the vaccines developed are affordable and reach the people who need them most.

CEPI will take an end-to-end approach to vaccine development. It will not take on discovery research or vaccine deployment, but it will work through all the steps in between, filling a gap in the current global health ecosystem.

For diseases we know could cause a serious epidemic – as outlined on the <u>WHO priority list</u> – CEPI will develop vaccine candidates "just in case". It will move promising vaccines through preclinical development to phase 2 trials in advance of an outbreak, in contrast to the world's experience with Ebola. If an outbreak does occur, these candidate vaccines could then be deployed rapidly in large-scale clinical trials.

It will also pursue a "just in time" approach, to help defend against unknown or new viruses, which are just as likely to be the source of the next serious epidemic.

Current approaches to vaccine development can take years which means that our current capacity to contain the global spread of a newly discovered and highly infectious pathogen remains limited. CEPI will help to address this by exploring recent breakthroughs in genetic science to explore the possibility of using the genetic sequences of newly discovered pathogens to instruct human cells on how to produce their own antibodies against infection.

The virtue of these DNA- and RNA-based constructs is that could identify quickly effective antibodies and allow for the rapid development of "plug-and-play" vaccines that could be produced and delivered on a mass scale.

## How CEPI was formed

Repeated outbreaks, most recently Ebola and Zika, have forged a global consensus that current models for developing sporadic epidemic vaccines are not working, and that a new system is urgently needed. Four expert reports on the Ebola outbreak reached the same conclusion: a new system is needed to drive product innovation to prevent and contain future infectious disease epidemics.

The idea of a global vaccine development fund was proposed in July 2015 by Stanley Plotkin, Adel Mahmoud and Wellcome Director Jeremy Farrar, writing in the <u>New England Journal of</u> <u>Medicine</u>.

### Who is involved

CEPI is an innovative partnership between public, private, philanthropic and civil organisations. It was founded by the governments of India and Norway, the Bill & Melinda Gates Foundation, Wellcome and the World Economic Forum. Other partners include multinational pharmaceutical corporations, the World Health Organization and NGOs.

CEPI is supported by several leading pharmaceutical companies with strength in vaccines – GSK, Merck, Johnson & Johnson, Pfizer, Sanofi and Takeda, plus the Biotechnology Innovation Organisation. CEPI will draw on this deep expertise in vaccine research and development to its efforts. Companies have been developing different models to respond to CEPI's forthcoming request for proposal, for example providing scientific expertise and vaccine development and manufacturing capabilities.

## **Financial contributions**

- The Norwegian Government are preparing for an investment of NOK 1Billion (currently around \$120m) for the initial 5 year period.
- The Government of Japan will invest around \$25m a year, equivalent to \$125M in 5 years.
- The Federal Government of Germany has announced an initial commitment of €10m (around \$10.6m) in 2017, and is planning to allocate additional funds over 5 years.
- Wellcome and the Bill & Melinda Gates Foundation will each invest \$100m over 5 years.
- The Government of India is one of the founders of CEPI and is currently finalizing the level of a significant funding commitment.
- The European Commission will also contribute to CEPI's objectives and plans to cofund actions with CEPI, such as through the Innovative Medicines Initiative (IMI).

## ENDS

### NOTES TO EDITORS

- 1. <u>http://www.nap.edu/read/21891/chapter/1</u>
- 2. <u>http://www.worldbank.org/en/topic/health/brief/world-bank-group-ebola-fact-sheet</u>

## Further detail on CEPI partners:

Funders and founders: Governments of Norway, India, Japan, Germany, plus Wellcome, Bill & Melinda Gates Foundation, World Economic Forum.

Industry partners: GSK, Takada, Pfizer, Johnson & Johnson, Merck, Sanofi, Biotechnology Innovation Organisation (represented by PaxVax), developing country manufacturers represented by Serum Institute of India

Other governments: South Africa, Australia, Brazil, UK, Ethiopia, Liberia, France, China, USA,

A full list of CEPi Board members, SAC members and Joint Coordinating Group representatives can be found on the <u>CEPI website</u>.

### **Disease information**

## **MERS-CoV**

#### What is it?

MERS-CoV is the virus that causes Middle East respiratory syndrome (MERS). It is a coronavirus, part of the same family of viruses that causes the common cold and SARS (severe acute respiratory syndrome).MERS is a zoonotic disease, meaning it passes from animals to humans. It's thought that camels are a major source of infection for people. Raising camels, eating undercooked camel meat and drinking raw camel milk or urine are risk factors for the disease in humans. MERS-CoV can spread from person to person, usually through close contact.

#### Where does it occur?

The disease was first reported in Saudi Arabia in 2012, and the majority of reported cases have been linked to countries in and around the Arabian Peninsula. According to WHO, 1,864 cases were confirmed between September 2012 and 19 December 2016, in 27 countries.

In 2015, a large outbreak occurred in South Korea, following a single <u>"super-spreader"[1]</u> transmitting the virus to 82 people in three days. In early 2016, Saudi Arabia's ministry of health <u>reported three new MERS-CoV cases[2]</u>.

#### What does it do?

MERS-CoV can infect people of any age. It causes a severe acute respiratory illness with fever, cough and shortness of breath. Gastrointestinal symptoms can also occur. Around 36

per cent of people reported as having MERS have died, many of whom already had an underlying medical condition. There is no specific antiviral treatment for MERS-CoV infection.

## How do we currently prevent infections?

People are advised to try and prevent getting infected by avoiding undercooked or raw camel products, and by being hygienic, especially around animals. There is currently no vaccine against MERS-CoV . In December 2015, MERS was included in <u>WHO's list of disease priorities needing urgent research and development attention[3]</u>, and MERS-CoV was one of the first targets announced by CEPI, the <u>Coalition for Epidemic Preparedness Innovations[4]</u>, in January 2017.

## Sources of information:

- WHO coronavirus infection outbreak news
  <u>http://www.who.int/csr/don/archive/disease/coronavirus\_infections/en/</u>
- University of Minnesota's Center for Infectious Disease Research and Policy
  <u>http://www.cidrap.umn.edu/infectious-disease-topics/mers-cov</u>
- CDC pages on MERS-CoV https://www.cdc.gov/coronavirus/mers/index.html
- WHO pages on MERS-CoV <a href="http://www.who.int/emergencies/mers-cov/en/">http://www.who.int/emergencies/mers-cov/en/</a>

### References

- 1. <u>http://uk.reuters.com/article/uk-health-southkorea-mers-idUKKCN0ZO2K5</u>
- 2. <u>http://www.cidrap.umn.edu/infectious-disease-topics/mers-cov</u>
- 3. <u>http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en/</u>
- 4. <u>http://cepi.net/</u>

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## Lassa virus

## What is it?

Lassa virus belongs to the *Arenaviridae* family and causes Lassa fever, also known as Lassa haemorrhagic fever (LHF). It is a haemorrhagic illness that occurs between one and three weeks after infection. Lassa fever is a zoonotic disease, meaning it passes from animals to humans. The natural host of Lassa virus is the rodent *Mastomys natalensis*, otherwise known as the Natal multimammate mouse or rat. The virus is spread when a person comes into contact with items contaminated with the rodent's urine or faeces – for example, by handling objects, eating or through open wounds. It can also be inhaled. Lassa virus can pass from person to person via bodily fluids, and can spread in healthcare settings if suitable precautions are not taken.

## Where does it occur?

Lassa virus was identified in 1969 after the death of two missionary nuns in Nigeria. Lassa fever occurs regularly (is endemic) in parts of West Africa, including Benin, Ghana, Guinea, Liberia, Mali, Sierra Leone and Nigeria. <u>Various outbreaks</u>[1] were reported in West Africa in 2016. In March 2016, a healthcare worker evacuated from Togo to Germany died and was subsequently diagnosed with Lassa fever. A funeral home employee who handled the corpse then contracted the disease, but recovered. In Sweden, a <u>72-year-old woman was</u> <u>diagnosed</u>[2] with Lassa fever following a six-week trip to Liberia. She was later discharged.

## What does it do?

Around 80 per cent of patients with Lassa fever have no symptoms. Those that do can experience mild fever or headache. More serious symptoms include:

- vomiting
- swelling of the face
- pain in the chest, back and abdomen
- bleeding from body parts, including the eyes and nose.

Patients can be given rehydration therapy and supportive care. An antiviral drug ribavirin has been used successfully in some cases. One per cent of infections are fatal, usually within two weeks of symptoms beginning. Around 15 to 20 per cent of people hospitalised with Lassa fever die from it. A common complication in survivors of Lassa fever is hearing loss.

## How do we currently prevent infections?

People are advised to avoid contact with *Mastomys* rodents, including by keeping homes clean and storing food away from rodents. Healthcare workers should follow <u>specific</u> <u>infection control methods</u>[3]. There is currently no vaccine against Lassa virus. In December 2015, Lassa fever was included in <u>WHO's list of disease priorities needing urgent research</u> <u>and development attention</u>[4], and Lassa virus was one of the first targets announced by CEPI, the <u>Coalition for Epidemic Preparedness Innovations</u>[5], in January 2017.

## Sources of information

- CDC pages on Lassa fever <u>https://www.cdc.gov/vhf/lassa/</u>
- WHO fact sheet on Lassa fever <u>http://www.who.int/mediacentre/factsheets/fs179/en/</u>
- WHO Lassa fever outbreak news:
  <a href="http://www.who.int/csr/don/archive/disease/lassa">http://www.who.int/csr/don/archive/disease/lassa</a> fever/en/

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- 6. <u>http://ofid.oxfordjournals.org/content/early/2016/10/19/ofid.ofw198.full</u>
- 7. https://www.cdc.gov/vhf/abroad/healthcare-workers.html
- 8. <u>http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en/</u>
- 9. <u>http://cepi.net/</u>

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# Nipah virus

## What is it?

Nipah virus (NiV) belongs to the *Paramyxoviridae* family of viruses, genus *Henipavirus*, alongside Hendra virus. Nipah is a zoonotic disease, meaning it passes from animals to humans. The natural hosts of the virus are fruit bats (also known as flying foxes) of the genus *Pteropus*. Nipah virus can be spread to people from infected bats, infected pigs or infected people.

### Where does it occur?

Nipah virus was first identified in 1999 during an outbreak of illness affecting pig farmers and others living in close contact with pigs. Over 100 human deaths were reported, and over a million pigs were killed to stop the outbreak. No cases of person-to-person spread were reported. In 2001, there was an outbreak of Nipah virus in people in Bangladesh, and a separate outbreak in a hospital in India. In both countries, person-to-person transmission occurred. Outbreaks in Bangladesh happen nearly every year – with <u>over 300 confirmed</u> <u>cases[1]</u> occurring there from 2001 to 2015.

### What does it do?

Nipah virus infection can cause severe, rapidly progressive illness that affects the respiratory system and the central nervous system, including inflammation of the brain (encephalitis). Symptoms begin between 5 and 14 days after infection, and include fever, altered mental state, cough and respiratory problems.

## How do we currently prevent infections?

People are advised to avoid contact with ill pigs and bats in countries where Nipah virus is known to occur. They are also advised to avoid drinking raw date palm sap, which can be infected with bodily fluids from bats. There are currently no vaccines or specific therapeutics against Nipah virus approved for use in humans. In December 2015, Nipah was included in WHO's list of disease priorities needing urgent research and development attention[2], and was one of the first targets announced by CEPI, the <u>Coalition for Epidemic Preparedness</u> Innovations[3], in January 2017.

#### Sources of information

- CDC pages on Nipah virus <a href="https://www.cdc.gov/vhf/nipah/index.html">https://www.cdc.gov/vhf/nipah/index.html</a>
- WHO page on Nipah virus <a href="http://www.who.int/csr/disease/nipah/en/">http://www.who.int/csr/disease/nipah/en/</a>
- WHO Nipah fever outbreak news:
  <u>http://www.who.int/csr/don/archive/disease/nipah\_virus/en/</u>

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- 1. <u>http://www.sciencedirect.com/science/article/pii/S0264410X16002966</u>
- 2. <u>http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en/</u>
- 3. <u>http://cepi.net/</u>

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