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Researchers launch Phase 1 clinical trial of potential MRSA treatment

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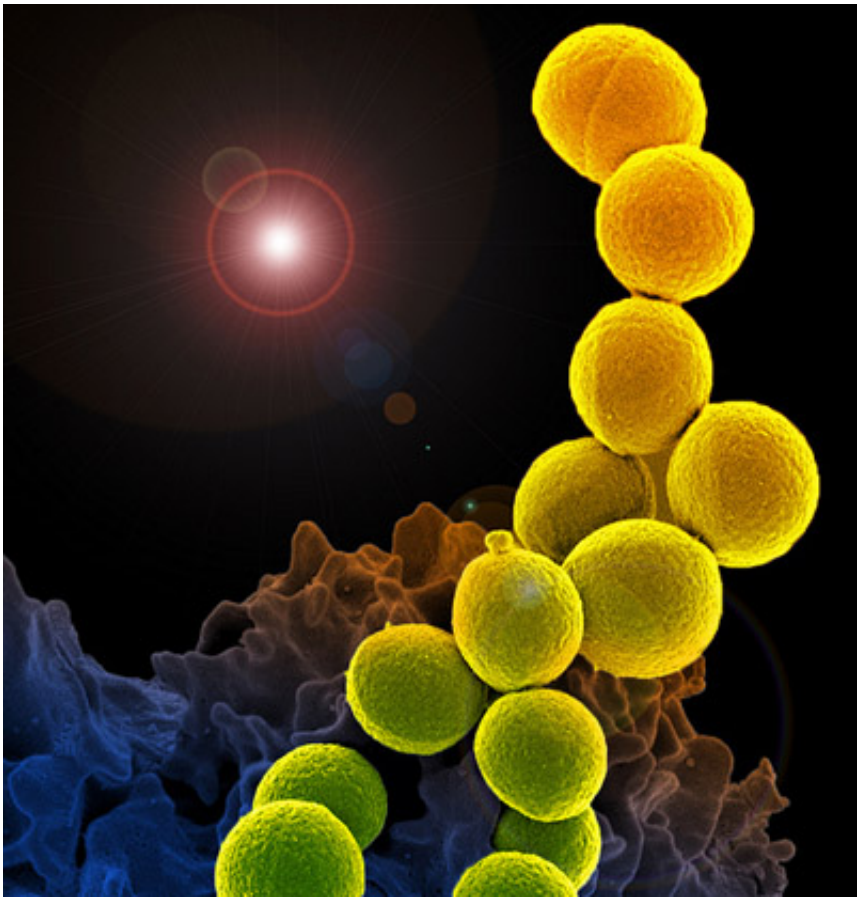

This is a colorized scanning electron micrograph of a white blood cell (blue and brown) interacting with an antibiotic-resistant strain of *Staphylococcus aureus* (yellow). Credit: NIAID

Scientists have begun the first human clinical trial of EDP-788, an

investigational oral antibiotic intended to treat methicillin-resistant *Staphylococcus aureus* (MRSA) infections. The Phase 1 trial, which will enroll as many as 64 healthy men and women ages 18 to 45, will evaluate the investigational drug's safety as well as how it is broken down and processed in the body. The trial is being conducted by the Massachusetts-based biotechnology company Enanta Pharmaceuticals through contract funding from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. NIAID funded Enanta's earlier preclinical testing and development of EDP-788.

Infections with bacteria resistant to antibiotic drugs were first reported in the 1940s, with the earliest cases of MRSA appearing in the 1960s. Since then, MRSA and other antibiotic-resistant infections have become more common in both health care settings and the broader community. EDP-788 belongs to a novel class of antibiotics known as bicyclolides, which were designed to overcome resistance. In laboratory and small animal experiments, EDP-788 and other bicyclolides have demonstrated potent activity against a variety of infectious bacteria, including MRSA.

In the new trial, participants will receive either a single dose of EDP-788 in pill form or a placebo. Two weeks later, a subset of participants will receive a second dose or placebo—either in liquid form, to assess the effect of formulation on absorption into the body; or in pill form along with a meal, to assess the effect of food on absorption. Blood levels of the drug will be measured for three days after receiving each dose, and participants' safety will be monitored for eight to ten days after each dose.

Information about this clinical trial is available at ClinicalTrials.gov using the identifier NCT01999725. For information on the drug development process and NIAID's role, see the NIAID video "How a Drug Becomes a Drug".