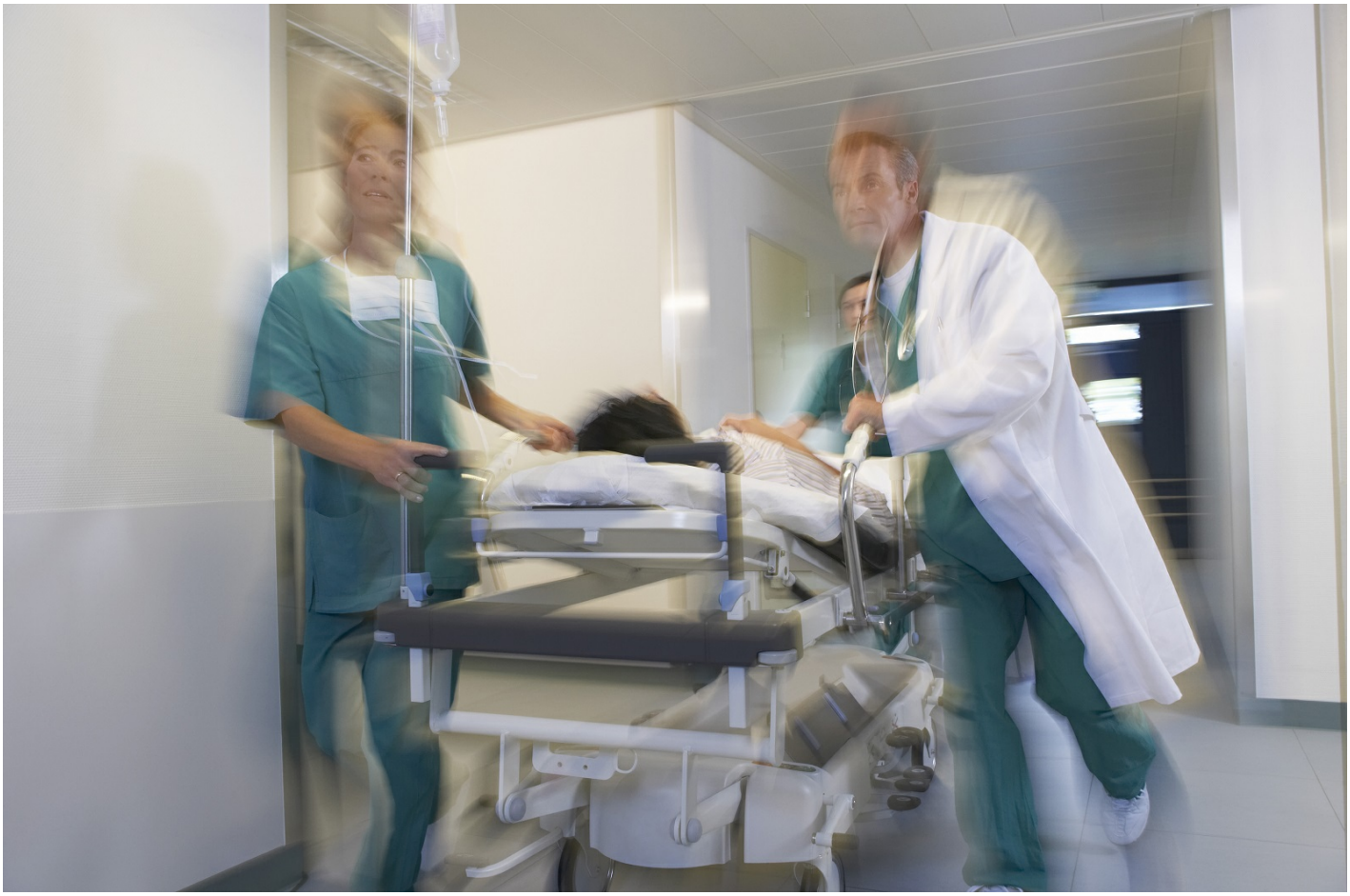
From Pilot Study To Market In Less Than 4 Years, Angiotensin II Stabilizes Critically Ill Patients

George Washington University



GIAPREZA helps patients hospitalized with septic shock that are urgently in need of critical care.

By targeting a new route to raise blood pressure, the first and only FDA-approved drug of its kind, angiotensin II (trade name GIAPREZA™), may save patients' lives.

An infection (sepsis), allergic reaction, or severe accident can decrease blood flow to the brain, heart, and other vital organs. Hormones that target different blood pressure regulation pathways have been in use for years but are not effective for many patients.

The George Washington University (GW) School of Medicine and Health Sciences' Professor Lakhmir Chawla, M.D., tested peptide hormone angiotensin II on 20 patients in a 2014 pilot study. Dr. Chawla found that angiotensin II effectively narrowed blood vessels to increase dangerously low blood pressure in patients with septic shock.

Because Dr. Chawla's promising results could significantly improve the safety or effectiveness of treating, diagnosing, or preventing a serious condition, the FDA allowed angiotensin II to proceed directly from the pilot study to a phase III

clinical trial. It also provided Priority Review, meaning the FDA intends to act on a New Drug Application within just six months, so a treatment can reach patients sooner than usual.

> *It is extremely rare to have a pharmaceutical come out of a university and go straight into a phase III clinical trial," said Steve Kubisen, Managing Director of GW's Technology Commercialization Office (TCO).*

GW's TCO managed patent filings using outside patent prosecution counsel, and managed licensing of the exclusive rights to the patents to the La Jolla Pharmaceutical Co. (LJPC) in 2015. They started with an option agreement and negotiated the exclusive license that followed. GW TCO also managed the royalty monetization process, utilizing a well-known royalty monetization structuring agent.

The FDA approved GIAPREZA™ in 2017, and LJPC began selling the drug in 2018.

GW's TCO also obtained broad international patent protection for GIAPREZA™ which will help provide incentive for LJPC to distribute the drug to patients in need globally.

"In 2019, the European Commission approved GIAPREZA™ and GW's European patent was granted. This provides an opportunity to help patients outside the US," Kubisen said.

Also in 2019, GW struck a deal with financial services firm Barings LLC to sell a portion of its US royalty rights, a common practice for high-value drugs. GW plans to reinvest this game-changing cash infusion into strategic priorities.

"The money could accelerate commercialization in orthopedics, cancer drugs, cardiac devices, diagnostics, and other products GW is developing or licensing out," Kubisen said.

"This is an extraordinary example of GW research and innovation at its best," said GW President Thomas LeBlanc. "A treatment developed here will improve clinical care and save lives, while at the same time provide resources for our university to reinvest in research for the next big discovery. Our impact on society will only continue to grow."

Patent Number(s): 9,572,856; 9,867,863; 10,500,247; 10,322,160; 10,335,451; 10,548,943; 9,220,745; 10,028,995; 10,493,124

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