

# Allentown biopharmaceutical firm calls oral COVID-19 vaccine a game changer

By: *Stacy Wescoe*

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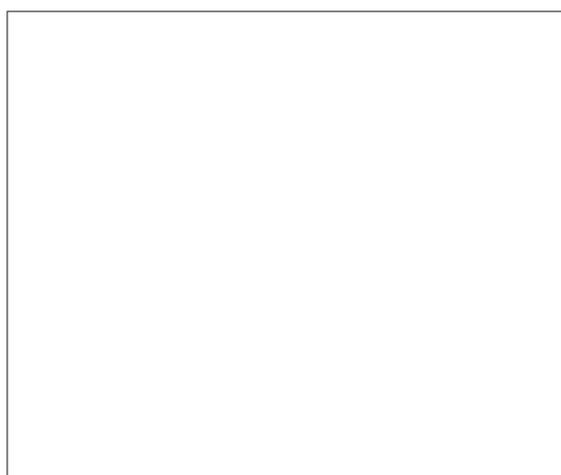
Kyle Flannigan and Garry Morefield of U.S. Specialty Formulations. PHOTO/COURTESY OF U.S. SPECIALTY FORMULATIONS –

An Allentown biopharmaceutical firm is making progress on an oral vaccine for the COVID-19 virus that could be a game changer in the fight against the disease.

Kyle Flannigan and Garry Morefield of U.S. Specialty formulations said the ease and safety of the vaccine is what's needed in the next stage in the fight against COVID-19 in the U.S. and around the globe.

"It's of strategic importance and an advantage to the U.S.," said Morefield.

The week of March 13 is Patient Safety Week, and the safety of vaccine is one of its key advantages, said Flannigan.



“What we’ve done is created and shown that an oral platform works. It’s stable at normal and even higher temperatures,” he said. “It doesn’t require a healthcare professional to administer it and it doesn’t require any special kind of shipping,” he said.

It’s the partners’ hope that the ease of the oral vaccine will help get the vaccine to more impoverished countries with less health care infrastructure or even more rural regions of the country where people don’t have easy access to health care.

“There’s some places even in the U.S. where people may have to drive 70, even 80 miles just to get to a pharmacy let alone a health care provider,” Flannigan said. “With this they don’t need to visit a health care provider it can be mailed to them.

There is also an advantage to the safety of the patient receiving the vaccine.

“It has a very good patient experience. You’re not stabbing someone with a needle,” Flannigan said.

The hope is that the lack of a needle stick might make the oral vaccine more attractive to people who have been holdouts on getting the vaccine.

Morefield said that in early clinical trials patients reported very few side effects. With no injection there was no arm pain, and most of those who received the vaccine reported milder reactions and didn’t need the two or three days of recovery that some people have needed with the vaccines that are currently in use.

The partners don’t have an estimate, yet, on when the vaccine could be available to the public. They are currently getting ready to start the second phase of clinical trials, which will involve a greater number of people and will provide a broader picture of the efficacy and impact of the vaccine.

It would then move onto a phase three trial, which could take up to 12 months.

However, because of the global health crisis caused by the COVID-19 pandemic, Morefield said the Federal Drug Administration in the U.S. and the health governing bodies of other countries have been granting Emergency Use Authorization (EUA) for many of the vaccines that have been developed and most have been given EUAs while still in phase three clinical trials.

Manufacturing should also be easier than for a traditional injectable vaccine.

“Because it is oral it doesn’t require the same type of sterile manufacturing facility that an injectable does,” said Flannigan.

That could have production up and running much faster than traditional vaccines would.

Morefield said getting the vaccine to market will be a major step towards stopping the spread of COVID-19 around the globe.

“It can have a huge impact in other parts of the world,” he said. “Until the entire global community is protected, there’s going to be variants that will make it back to the United States.”

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Writer Stacy Wescoe has her finger on the pulse of the business community in the Greater Lehigh Valley and keeps you up-to-date with technology and trends, plus what coworkers and competitors are talking about around the water cooler – and on social media. She can be reached at [swescoe@bridgetowermedia.com](mailto:swescoe@bridgetowermedia.com) or 610-807-9619, ext. 4104. Follow her on Twitter and on Facebook.

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