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For: Ben Franklin Technology Partners

FOR IMMEDIATE RELEASE

US SPECIALTY FORMULATIONS WINS BEN FRANKLIN TECHNOLOGY PARTNERS OF NORTHEASTERN PENNSYLVANIA'S R. CHADWICK PAUL, JR. INCUBATOR GRADUATE AWARD

Bio-tech leader honored for its quality pharmaceutical manufacturing, state-of-theart processes, and development of game changing oral COVID vaccine

ALLENTOWN, Pennsylvania – US Specialty Formulations of Allentown, Pennsylvania, co-founded by Dr. Kyle Flanigan and Dr. Garry Morefield, will be recognized by the Ben Franklin Technology Partners of Northeastern Pennsylvania (BFTP_NEPA) during its annual iXchange event, to be held virtually this year at 3:30-5:00 PM on Wednesday, May 18. The event honors early-stage technology companies, established manufacturers, and individuals who have helped advance the technology economy in northeastern Pennsylvania. US Specialty Formulations will receive the R. Chadwick Paul, Jr. Incubator Graduate Award for its success in providing state-of-the-art quality processes to pharmaceutical manufacturing and development, and effectively overcoming challenges in the development of its game-changing oral COVID vaccine.

This new oral vaccine platform and oral COVID-19 vaccine candidate help better reduce the transmission of the COVID virus. In addition, it provides a better safety profile with a more pleasant user experience post vaccination, and is additionally more easily distributed due to its high temperature stability (up to 145°F) when compared to existing injectable vaccines. Ben Franklin has been an ongoing supporter of this bio-tech company since its establishment in 2013.

"We are grateful to the Ben Franklin Technology Partners for its faith in the vision I articulated from the very beginning, as well as the support it has continuously provided to us through its financial investments in US Specialty Formulations," said Dr. Flanigan. "Ben Franklin's support has helped us fulfill our mission in revolutionizing the pharmaceutical manufacturing industry. Ben Franklin also supported our pivoting this technology from other oral vaccine development efforts into the new oral COVID vaccine, developed in conjunction with VaxForm. Bringing this oral vaccine to the market is essential as we continue to see additional variants emerge.

US Specialty Formulations Co-Founder Dr. Morefield added, "Through the development of our oral platform and validation using the oral COVID vaccine, we have achieved a huge leap in vaccine technology. US Specialty Formulations now has a pipeline beyond COVID for creating oral vaccines, to address other respiratory diseases and enteric diseases that continue to afflict populations worldwide."

Dr. Flanigan and Dr. Morefield co-founded US Specialty Formulations in 2013 with just \$100,000, building the company's first clean room in Ben Franklin TechVentures, BFTP_NEPA's business technology incubator in Bethlehem, Pennsylvania, from a kit. Since then, they have grown it into one of today's up-and-coming boutique bio-tech pharmaceutical development and manufacturing companies, known by its customers for high quality and flexibility.

With a credentialed portfolio that includes a range of vaccine candidates and small molecule formulations, along with botanical pharmaceutical grade extracts, Dr. Flanigan and Dr. Morefield have the expertise and equipment to bring their safe, accessible mucosal oral vaccine to market. Their formula was developed after the company pivoted from its efforts in developing an oral DTaP (Diphtheria, Tetanus, and acellular-Pertusis), a childhood vaccine most of the population has received that was originally targeted for human clinical trials in early 2020.

US Specialty Formulations has completed the first-stage human clinical trials of its oral COVID vaccine and plans to roll out its second-stage human trials in the U.S. and abroad. Despite there being several injectable vaccines already approved, there is still a great need for more vaccines in areas of the world with poor distribution infrastructure and/or faltering vaccination programs.

USSF is seeking \$60 million in funding for this trial. Succeeding in these trials will further prove that US Specialty Formulations' oral vaccine provides better protection than that of injectable vaccines through use of two lines of defense, (IgA Mucosal and IgG blood stream delivery), with the benefit of fewer side effects. In leading this oral vaccine to market, this brings us another step closer to a safer population for our nation and the world.

"Ben Franklin competitively selected USSF for our Incubator Graduate Award in recognition of the incredible skill and tenacity Dr. Flanigan and Dr. Morefield exhibited in developing and executing their product concept," said Laura Eppler, Chief Marketing Officer of the Ben Franklin Technology Partners of Northeastern Pennsylvania. "Their products address real market needs. We have high hopes for USSF's continued success in improving the human condition while creating highly paid, sustainable jobs."

The iXchange is a premier business/technology event in northeastern Pennsylvania, during which the Ben Franklin Technology Partners of Northeastern Pennsylvania presents six innovation awards to early-stage technology companies, established manufacturers, and individuals who have helped Ben Franklin to advance the technology economy of northeastern Pennsylvania. Other awards presented at this event will include The Entrepreneurial Achievement Award, The Product Innovation Award, The Innovative Application of Technology Award, The Manufacturing Achievement Award, and The Frederick J. Beste III Partnership Award. The iXchange is presented virtually and free-of-charge to guests; register at https://ixchange.ticketmambo.com/index.cfm?e=home.

About the Ben Franklin Technology Partners of Northeastern Pennsylvania

The <u>Ben Franklin Technology Partners of Northeastern Pennsylvania</u> (BFTP_NEPA) creates and retains highly paid, sustainable jobs by investing in and linking companies with experts, universities, follow-on funding, and other resources to help them prosper through innovation. It is part of a four-center economic development initiative of the <u>Pennsylvania Department of</u> <u>Community and Economic Development</u> and is funded by the Ben Franklin Technology Development Authority.

BFTP_NEPA owns, manages, and is headquartered in <u>Ben Franklin TechVentures</u>®, an awardwinning business incubator/post-incubator facility on Lehigh University's campus in Bethlehem. BFTP_NEPA also owns and manages the <u>Bloomsburg Regional Technology Center</u>. Applying more than 38 years of experience and two international awards for excellence in business incubation, BFTP_NEPA leads a 14-member business incubator network that is among the largest in the nation.

About US Specialty Formulations, LLC

US Specialty Formulations, LLC (USSF) is both a bio-pharmaceutical contract manufacturing (CMO) and bio-pharmaceutical contract development organization (CDMO). USSF was founded in 2013 with friends and family funding as well as start-up loans from the Ben Franklin Technology Partners of Northeastern Pennsylvania. Initially the company consisted of only its two co-founders Drs. Flanigan and Morefield. The original facilities were built by the two of them from cleanroom kits and installed in the rented space within Ben Franklin TechVentures, a technology business incubator. The companies first contract fill was completed in November of 2014 and its first commercial product released for sale in January of 2015. In 2019, the firm relocated into its new 41,800 ft² (3,888m²) facility. The company now employs 16 full-time staff with several consultants to support a variety of projects. USSF services customers in the USA as well as in EU, Canada, and UK. USSF supplies a variety of different finished injectable drugs to the market, including botanical distillates, small-molecule, and perfusion chemistries, as well as vaccines. USSF is providing formulation guidance and clinical materials into more than 11 clinical trials being conducted in the USA. Procedures, protocols, and infrastructure have been built up over the years, as these are critical to ensuring a new therapy successfully emerges from regulatory review processes. To learn more about USSF, please visit its website.

This press release contains forward-looking statements within the meaning of the amended Private Securities Litigation Reform Act of 1995. In some cases, forward-looking statements can be identified by terminology such as "will," may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors, many of which are beyond US Specialty Formulations LLC's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. Except as required by law, US Specialty Formulations LLC disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on US Specialty Formulations LLC's current expectations and speak only as of the date of this press release.

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<u>EDITOR'S NOTE</u>: For more information about USSF and to arrange to speak with a company spokesperson, please contact Nancy Trent or Pamela Wadler at 212-966-0024 or <u>pam@trentandcompany.com</u>.

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For: US Specialty Formulations, LLC

FOR IMMEDIATE RELEASE

IN A RACE TO DEVELOP AN ORAL COVID-19 VACCINE, THIS SMALL, BLACK-OWNED BIO-TECH COMPANY HAS A SOLUTION How one small bio-tech company started from the ground-up to develop a safer, easier oral COVID-19 Vaccine

ALLENTOWN, Pennsylvania – Injectable vaccines were administered as an initial solution to help protect people from COVID-19. But the race to bring an oral vaccine to the market continues. In that hurdle to the finish line, is Dr. Kyle Flanigan, Ph.D. and his small bio-tech company, US Specialty Formulations LLC (USSF). Since the onset of the pandemic, he, along with Co-Founder Dr. Garry Morefield, Ph.D. and their team have worked tirelessly to develop an easy to administer oral vaccine that will offer not only protection against COVID-19, but with less side effects with more accessible storage and transport options than existing injectable vaccines.

Dr. Flanigan is one of the very few Black owners of a biotech company. Since co-founding USSF with just \$100,000, he has grown the site into a successful biotech and pharmaceutical facility. With a credentialed portfolio that includes a range of vaccine candidates and small molecule formulations along with botanical pharmaceutical grade extracts, Dr. Flanigan and Dr. Morefield have the expertise and equipment to bring their safe, accessible mucosal vaccine to market. Their formula is pivoted from an oral DTaP (Diphtheria), a childhood vaccine most of the population has received that was originally targeted for human clinical trials in early 2020.

How will USSF's oral vaccine help the fight against COVID-19?

- 1. **Protect against mutations:** Every COVID-19 infection provides an opportunity for the virus to mutate. Mutations will have a high chance to breakthrough previous rounds of vaccines so it's imperative we be ready with new and improved vaccines. USSF's oral vaccine is uniquely positioned to update thoroughly as new variants are identified.
- 2. **Reduce Risk of Transmission:** Recent data shows that even immunized people 'shed' live virus after exposure into their surroundings. This mucosal type vaccine also acts to significantly reduce the quantity of virus in the mucosal cavities, thus reducing the 'shedding' effect and risk of transmission.
- 3. Less side effects and longer-lasting protection: Conventional mRNA (Messenger RNA) injectable vaccines can be developed and made to work quickly, but they can be full of side effects. While there are high levels of protection early on, the levels drop off. Initially it was important to get a vaccine on the market; speed was important. This oral vaccine has shown that the acceptable levels of antibodies persist for a significant time