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For: US Specialty Formulations, LLC

**FOR IMMEDIATE RELEASE**

**THE INDEPENDENT BIOTECH FACILITY IS ON A MISSION TO BRING A MUCOSAL  
COVID VACCINE TO MARKET AND  
MITIGATE THE SPREAD OF THE VIRUS WORLDWIDE**

ALLENTOWN, Pennsylvania – From a small bio-tech firm in Allentown, Pennsylvania two scientists are leading their team to bring an oral COVID-19 vaccine to market – one that will be easier to use, longer lasting and with less side effects. Dr. Kyle Flanigan and Dr. Garry Morefield co-founded US Specialty Formulations LLC (USSF) through a series of discussions while watching their daughters compete in gymnastics. With just \$100,000 and the ambition to grow their site into a successful biotech and pharmaceutical facility. Today, the 41,000 sq. ft. manufacturing facility spans over two acres and has become a hub of experts creating diverse solutions, applications and approaches to help clients overcome hurdles in drug discovery and development.

USSF is a minority-controlled business that is a certified Current Good Manufacturing Practice (cGMP) manufacturer of sterile injectable, topical and specialty pharmaceuticals. It manufactures its own branded prescription products, in addition to providing clinical materials for investigational new drug applications. specialty formulations, adjuvants and fermentation and purification services requested by a variety of biotech companies.

The USSF team applies Agile High-Performance Teams system to facilitate collaboration and problem solving – ensuring each of their and their clients’ products go to market efficiently and seamlessly. From initial stages of development to commercial manufacture, they leverage their proven methods, analytics, scale-up technologies and technology transfer to guide both small compound and vaccine development.

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 COVID-19 vaccine to market. Their formula was 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.

**About the founders**

**Co-Founder and CEO Dr. Kyle Flanigan, Ph.D.**

With more than 25 years of experience, [Dr. Kyle Flanigan](#), Co-founder and CEO of [US Specialty Formulations](#) LLC (USSF), is an expert in all pharmaceutical and medical performance materials

development stages. He consults with several companies, providing robust and stable solutions and services for formulation, scale-up technology, contingency planning, supply-chain issues, quality systems implementation and new facility design. He brings this knowledge and guidance to USSF's manufacturing and development teams enabling their clients' and their pharmaceutical and medical developments on the best path to market.

Dr. Flanigan shared his expertise in top-tier and niche publications, such examples are:

- Startup USSF bringing oral COVID vaccine to market, [Labiotech](#)
- The Future of Travel in the Post-COVID World, [Medium.com](#)
- White Paper: Vaccine Trend Report: The Latest Challenges and Opportunities, [BioPharma Dive](#)

Before becoming one of the few Black Ph.D.'s to co-found and own a biotech firm, Dr. Flanigan's former positions include serving as the Director of Electronic Materials with Avantor (formerly Mallinckrodt/Baker, Inc.) and Sr. Staff Scientist within Technology and Manufacturing, Fab Materials (Intel Corporation).

When he is not at the USSF facility or spending time with his wife, two daughters and two dogs, Dr. Flanigan loves travel, exploration, aerospace and is a semi-active private pilot. He was a member of the Bison and Husky Ski/Snowboard Teams and enjoys drone photography.

### **Co-founder and COO Dr. Garry Morefield, Ph.D.**

In addition to co-founding USSF, Dr. Garry Morefield founded VaxForm LLC. He brings more than two decades of experience in all stages of development and production in the biologics and pharmaceutical industries. Before joining Dr. Flanigan in creating their own facility for consulting and product development in their local city, he served as deputy director of formulation and stability at Sanofi-Pasteur. Inc.

Dr. Morefield has been closely involved in various industrial collaborations that have led to breakthrough innovations with Sanofi Pasteur; Pfizer; Astellas; Janssen; Serum Institute of India; Lundbeck; Affinivax; and Advanced Bioscience Laboratories (ABL). Throughout his career, he has also worked on the treatment and prevention of numerous diseases, including: Group A Strep; Covid-19; Pertussis; Group B Strep; Meningococcus; Influenza, C. Difficile; Hepatitis B; Rabies; Diphtheria; Tetanus; S. Aureus; HIV; Anthrax, Plague, Botulinum toxin and combination products.

To learn more about US Specialty Formulations LLC (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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**EDITOR'S NOTE:** 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 [pam@trentandcompany.com](mailto:pam@trentandcompany.com).