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The API Innovation Center Partners with the Glioblastoma Foundation and Continuity Pharma to Solve the Lomustine API Supply Crisis

U.S. Produced Source of Lomustine Will Make Treatment More Accessible and Affordable for Glioblastoma Patients

St. Louis, Mo. (July 25, 2022)— The API Innovation Center (APIIC) @ Cortex today announced its partnership with the Glioblastoma Foundation and Continuity Pharma to reshore the active pharmaceutical ingredient (API) for lomustine. Lomustine is a chemotherapy drug used to treat glioblastoma, the most common and aggressive form of brain cancer. There is currently no U.S. source of lomustine.

“Our nation’s over-reliance on foreign-sourced API has made our drug supply chain vulnerable and created a public health and national security risk. The APIIC is driving coordination with stakeholders and innovators of new technology to de-risk the return of API manufacturing to the U.S. providing resilience and health security. The U.S. production of lomustine is also a perfect example demonstrating how this model can strengthen manufacturing, create new R&D startups and foster job growth,” said Tony Sardella, CEO and Chair of the APIIC.

According to the Society for Neuro-Oncology, “the field of neuro-oncology is in the midst of a crisis with lomustine.” Recently, this sole-sourced, foreign-manufactured drug has experienced a significant price increase, making clinical trials cost-prohibitive. In 2021, the supplier also pulled out of the federal discount program for Medicare patients, leaving many patients struggling to afford treatment. The lomustine crisis is being solved by the APIIC @ Cortex in collaboration with the Glioblastoma Foundation, a nonprofit that will develop lomustine and make it more affordable and accessible for glioblastoma patients. Continuity Pharma is the innovator of the new manufacturing technology.

“The Glioblastoma Foundation is actively working to resolve the lomustine crisis and make it more affordable and accessible to patients who need it most,” said Gita Kwatra, PharmD and Chief Executive Officer of the Glioblastoma Foundation. “We have partnered with Continuity Pharma in collaboration with API Innovation Center (APIIC) to bring manufacturing to the U.S.



so this drug can be more readily and affordably accessible. No one should ever have to give up their chance at life due to money.”

Lomustine will be manufactured by Continuity Pharma, a pharmaceutical manufacturing company that develops novel continuous flow methods to domestically produce API. The API will be manufactured utilizing innovative advanced drug manufacturing processes that utilize continuous flow methods. These continuous flow manufacturing processes are more efficient than decades-old batch manufacturing and can significantly improve drug quality, accelerate time to market, and strengthen the overall manufacturing competitiveness of the U.S.

“Continuity Pharma is proud to be at the forefront of this initiative to lead the reshoring of the API for lomustine. This is only the beginning of our efforts to ensure the availability of critical medicines for patients and resolve drug shortages throughout the U.S.,” said David Thompson, PhD, Co-Founder and CSO of Continuity Pharma.

According to the [National Brain Tumor Society](#), more than 13,400 Americans will be diagnosed with glioblastoma in 2022 and the five-year survival rate for patients is only 6.8%. Glioblastoma is the deadliest type of brain cancer. In 2015, U.S. President Joe Biden’s son, Beau Biden, died of glioblastoma at the age of 42. In 2018, U.S. Senator John McCain passed away from glioblastoma. To learn more about glioblastoma or to find out how you can support the Glioblastoma Foundation, visit www.glioblastomafoundation.org.

For more information on the APIIC @ Cortex and its commitment to de-risk and safeguard the nation’s API supply chain, visit: www.apicenter.org. To learn more about Continuity Pharma and its work to ensure the availability of essential medicines for patients, visit: www.continuitypharma.com.

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About APIIC @ Cortex:

The API Innovation Center @ Cortex is a non-profit organization, headquartered in St. Louis, Missouri, dedicated to delivering market-competitive commercial supply of US-made Active Pharmaceutical Ingredients (APIs) to address national health security. By fostering collaboration amongst a network of companies, academic and research institutions, and startups, the APIIC @ Cortex stewards innovations in advanced manufacturing and enables solutions for drug supply chain fragility. The center also works to create a diverse talent pipeline by partnering with local educational and apprenticeship programs that target underrepresented communities. To learn more about APIIC @ Cortex, visit: www.apicenter.org.

About Glioblastoma Foundation:



Glioblastoma Foundation, Inc. is a national 501(c)(3) nonprofit charitable foundation headquartered in Durham, North Carolina. The mission is to transform the standard of care for glioblastoma by supporting the development of new drugs and other effective therapies. The Glioblastoma Foundation uses funds to support research that will transform glioblastoma into a manageable chronic condition. Contact info@glioblastomafoundation.org for more information or visit the [website](#).

About Continuity Pharma:

Continuity Pharma, headquartered in West Lafayette, Indiana, was formed with the mission to ensure a consistent supply of high-quality critical medicines utilizing advanced manufacturing methods. They accomplish this by applying their innovative process design expertise to develop efficient, robust, and environmentally friendly API continuous manufacturing systems. For more information, visit: www.continuitypharma.com.