



FOR IMMEDIATE RELEASE

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## **Curium Announces Drug Master File and Active Substance Master File for Germanium-68 in the U.S. and Europe.**

**(St. Louis, MO – June 9, 2020)** - Curium announced today that it has filed the first stand-alone Drug Master File (DMF) with the U.S. Food and Drug Administration (FDA) and has also filed an Active Substance Master File (ASMF) with the European Medicines Agency (EMA) for Germanium-68. Curium's Germanium-68 Ultra is purity characterized, validated, manufactured and controlled under 21 CFR 211 Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals at its registered drug manufacturing facility located in St. Louis, MO.

There are two primary uses of Germanium-68 – for the production of calibration sources for Positron Emission Tomography (PET) scanners and the manufacture of Germanium-68/Gallium-68 generators, which provide a Gallium-68 positron source for radiopharmaceuticals used in PET imaging. Curium has been producing and selling Germanium-68 to customers domestically and internationally for more than 6 years. In addition, Curium has made significant investments in production capacity and is positioned to meet the growing global demand for Germanium-68, including several new products in development for prostate cancer.

“Gallium-68 generator and finished dosage form manufacturers referencing our Germanium-68 Ultra DMF and ASMF will advance industry compliance standards for PET drugs by meeting FDA and EMA expectations of increased cGMP control for Germanium-68 manufacturing,” said Curium VP of Compliance, North America, Ed Porter.

“The investment to secure the DMF and AMSF was significant, and positions Curium as the only manufacturer offering Germanium-68 that meets these increased control standards sought by regulators,” said Curium CEO, North America, Dan Brague. “We look forward to partnering with current and new customers to provide high quality products for patients in need”.

### **About Curium**

Curium is a world-class nuclear medicine solutions provider and the largest vertically integrated radiopharmaceutical product manufacturer in the industry.

With manufacturing facilities across Europe and the United States, Curium supports over 14 million patients around the world with SPECT, PET, and therapeutic radiopharmaceuticals. The Curium brand name is inspired by the work of radiation researchers Marie and Pierre Curie and emphasizes a focus on nuclear medicine. To learn more, visit [curiumpharma.com](http://curiumpharma.com). For more information about this press release, please contact Janet Ryan media contact for Curium: [janet@ryan-pr.com](mailto:janet@ryan-pr.com).