Manhattan Isotope Technology Completes Drug Master File With Federal Drug Administration

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LUBBOCK, Texas, Aug. 22, 2012 /PRNewswire/ -- Positron Corporation, (OTCBB:POSC) a leading molecular imaging healthcare company, is pleased to announce the submission of a Drug Master File (DMF), with the Federal Drug Administration (FDA), for the production of Active Pharmaceutical Ingredient (API) grade strontium-82, through its wholly owned subsidiary Manhattan Isotope Technology, LLC.

A Drug Master File (DMF) is a document submitted to the FDA, which contains complete information on an Active Pharmaceutical Ingredient (API) or finished drug dosage form. The DMF contains factual and complete information on a drug product's chemistry, manufacturer, stability, purity, impurity profile, packaging, and the cGMP status of any human drug product. The main objective of the DMF is to support regulatory requirements and to prove the quality, safety and efficacy of the medicinal product.

Manhattan Isotope's DMF submission initiates the protocol, procedures, and compliance required to produce Sr-82 for radiopharmaceutical applications, specifically for commercial use in Sr-82/Rb-82 generators. Sr-82/Rb-82 generator manufacturers may now qualify MIT as a supply source and vendor for API grade Sr-82.

Manhattan Isotope's DMF positions the Company as the only commercial entity in the United States in the Sr-82 processing and production arena. Currently, the U.S. Department of Energy (DOE) is the only domestic supplier for many of the over 300 different isotopes, which are critical in medical, commercial, research, and national security applications. Recent shortages have emphasized the importance of managing the demand for critical isotopes, substantiating Positron's timely entrance into this market.

Jason Kitten, President of Manhattan Isotope Technology stated, "Our submission of the DMF is a very significant milestone, as it signifies Positron's evolution towards a vertically integrated nuclear
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