Voyageur Pharmaceuticals Ltd. Completes Medical Imaging CT Contrast Agent Production Testing and Begins Production Scale-up of SmoothX (TM)

written by Raj Shah | November 28, 2022

November 28, 2022 (Source) – Voyageur Pharmaceuticals Ltd. **(TSXV:VM)** (OTC:VYYRF) (the "Company" or "Voyageur") announces completion of the production test batch of its SmoothX™ barium sulfate CT contrast media oral suspension for the CT imaging market in Canada. This development represents a significant transition for Voyageur from the development phase to the production phase, where the focus will change to scaling up to commercially viable volumes of SmoothX to supply the Canadian imaging market. Management estimates that these two milestones will likely speed up first commercial sales in Canada and the FDA filing for approval in the US.

Voyageur continues to advance the development and testing of four additional Health Canada approved imaging products for sales in the Canadian radiology market. Voyageur currently holds Health Canada approval licenses for five barium contrast media products.

Brent Willis, Voyageur's CEO stated: "The completion of production testing for SmoothX and the scaleup to commercial quantities to launch sales in Canada is an important milestone for the Company. It also marks a key point in our journey to create a fully integrated Canadian supply chain for barium contrast media. It also supports Canada's national strategy of

de-coupling from China for the supply of critical minerals and critical pharmaceutical production. Basing our production testing on FDA protocols will advance our preparation for a generic drug submission to the FDA for the approval of SmoothX for gastrointestinal imaging. We have been engaged with the FDA on the path to approval for SmoothX since earlier this year and are now formally in contact with the FDA's Office of Generic Drugs regarding the specific requirements of approval for SmoothX."

In preparation for a generic drug submission to the US FDA, Voyageur has produced the recent batch in a manner that adheres to the Company's FDA and Health Canada compliant quality management system. This system has been implemented to ensure that a consistent and high-quality product is delivered to Voyageur's customer base. The product batch that has been produced will be scaled up and, after completion of 180 days stability tests, will be submitted to the FDA as part of the application process for approval of SmoothX for sale in the United States market. This submission is expected to occur in the second quarter of 2023.

The Company contract manufacturer (CMO) of its's barium contrast media product line recently received their FDA site registration, an important step for the Company's plan to penetrate the US market. Subject to financing, the Company continues to advance towards the construction of its own certified pharmaceutical manufacturing facility. The Company has completed the feasibility study and facility design phase and is currently finalizing the capital plan. In the interim, the Company will continue its relationship with its CMO for production and testing of its imaging products for sale into the Canadian and US markets.

About Voyageur

Voyageur is a Canadian public company listed on the TSXV under the trading symbol VM. Voyageur is focused on the development of barium and iodine Active Pharmaceutical Ingredients ("API") and high-performance cost-effective imaging contrast agents for the medical imaging marketplace. Voyageur's goal is to fully integrate the barium and iodine contrast market by producing its own minerals of barium and iodine. The business plan is to initially generate cash flow from operations using third party GMP pharmaceutical manufacturers in Canada and validate the products for regulatory agencies globally. Then transitioning into a high margin domestic manufacturer of radiology drugs. Voyageur has plans to build carbon neutral infrastructure to become 100% self-sufficient across all manufacturing activities. Voyageur owns a 100% interest in three Canadian barium sulphate (barite) projects including the Frances Creek property, suitable in grade for the pharmaceutical marketplace, with additional interests in a high-grade iodine, lithium & bromine brine project located in Utah, USA. Voyageur is moving forward with its business plan of becoming the only fully integrated carbon neutral company in the radiology contrast media drug market, by controlling all primary input costs under the motto of:

"From the Earth to the Bottle".

For Further Media Information or to set up an interview, please contact:	
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This news release may contain certain forward-looking information and statements, including without limitation, statements pertaining to: successfully transitioning to the production phase; successful completion of the FDA approval process; submission of the batch to the FDA in the second quarter of 2023; and financing. All statements included herein, other than statements of historical fact, are forward-looking information and such information involves various risks and uncertainties. There can be no assurance that such information will prove to be accurate, and actual results and future events could differ materially from those anticipated in such information. A description of assumptions used to develop such forward-looking information and a description of risk factors that may cause actual results to differ materially from forward-looking information can be found in the Company’s disclosure documents on the SEDAR website at www.sedar.com. Voyageur does not undertake to update any forward-looking information except in accordance with applicable securities laws.