Voyageur Commences Testing of Innovative Barium Contrast Product Line in Human Radiology Scans, Paving the Way for Near-Term Market Launch

written by Raj Shah | January 13, 2025 January 13, 2025 (<u>Source</u>) - Voyageur Pharmaceuticals Ltd. (TSX.V:VM) (OTC Pink:VYYRF) ("Voyageur" or the "Company") is pleased to announce that it has begun human testing on its latest barium contrast suite of products (as outlined below). This is a necessary and critical step for the Company, as it marks another milestone in the Company's path forward towards the Company's launch. Five of market innovative products SmoothLD®, SmoothHD®, VisionHD®, VisionLD® and a new gas agent VGas, will be used during the testing. Voyageur has completed all testing of its product SmoothX®. The radiology exam results from the human testing will be analysed by Voyageur's group of radiology consultants and scientific advisory board.

Brent Willis, CEO of Voyageur states: "We have begun a pivotal milestone after over a year and a half of formulation and development work. With successful results, we can begin to roll out our full suite of products to the Canadian market to relieve the supply chain constraints and opening the markets to diversification. This product launch will also allow our company to begin penetrating the international markets that accept Health Canada standards. We believe 2025 is going to be a

transformative year for Voyageur Pharmaceuticals".

The testing is being done in two phases. The first phase will focus on performance of the products over the course of the first quarter, and success will be judged by key performance indicators (KPIs) for barium contrast in radiology imaging, which may be categorized into clinical, operational, and patient-centered metrics. These indicators help measure the effectiveness, safety, and efficiency of using barium contrast agents. The following are some KPIs:

1. Clinical Effectiveness

- Imaging quality, diagnostic yield, contrast administration success rate, detection sensitivity, adverse reaction rate, patient safety, adverse event rate, and preparation errors.
- 2. Operational Efficiency
 - Procedure completion rate, time to completion, repeat study rate, and supply utilization.
- 3. Patient-Centered Outcomes
 - Patient satisfaction, and compliance rate,

After review of the data, the products may be adjusted for performance improvement and then released to market. The second phase of testing for FDA licensing, will commence in Q2 2025. Voyageur's products will be used with patients and the data will be accumulated for the FDA under the new drugs 505(2)(b) drug guidelines. The KPIs for phase two will include ensuring clinical safety, efficacy, pharmacokinetic and pharmacodynamic data, operational efficiency, market and stakeholder readiness and regulatory compliance.

Voyageur's advanced formulations, such as SmoothX®, SmoothHD®, SmoothLD®, VisionHD®, and VisionLD®, are designed to enhance radiographic examinations of the gastrointestinal tract with clarity, detail, and versatility for both adult and pediatric patients. The Company's primary goal is to get these products into the Canadian market in 2025.

To summarize, Voyageur's products that will be undergoing testing will include:

- SmoothHD® 105%: Designed for upper GI esophagogram and double contrast studies of the upper and lower gastrointestinal tract and colon, SmoothHD delivers unmatched clarity and detail with its high-density (105% w/v, 58% w/w) barium suspension formulation, catering to the diagnostic needs of both adults and children.
- SmoothLD® (60% w/v): Offering a low-density (60% w/v) barium suspension solution, SmoothLD is tailored for single contrast radiographic examinations of the esophagus, stomach, and small bowel to visualize the gastrointestinal (GI) tract.
- VisionHD® (98% w/w): Engineered as a high-density (98% w/w) barium powder suspension, VisionHD is tailored for double-contrast radiographic examination of the gastrointestinal tract, esophagus, stomach and duodenum.

- VisionLD® (96% w/w): Boasting exceptional versatility, VisionLD is a high-density (57% w/v to 156% w/v) barium powder suspension for single contrast radiographic examinations of the esophagus, stomach, duodenum and small bowel to visualize the gastrointestinal tract (GI).
- SmoothX (2%w/v): Is a contrast medium for use in Computed Tomography (CT) of the gastrointestinal tract. Our barium supports high-quality imaging with reproducible results for accurate diagnosis and image comparison. In clinical tests a majority of patients preferred the taste of SmoothX over the product currently used in CT imaging.
- V-Gas Effervescent Granules (4g): An innovative antacid and anti-flatulent solution poised to alleviate common digestive discomforts while also serving as an integral component in double contrast studies. V-Gas is indicated for use in adults and children.

Diagnostic centres wishing to update their suite of barium product lines with Voyageur's new products should contact Ethan Mohan at Ethan@Vpharma.ca.

About Voyageur Pharmaceuticals Ltd.

Voyageur, a Canadian public company trading under the symbol VM on the TSXV, is in development of barium and iodine Active Pharmaceutical Ingredients (API) and offers high-performance, cost-effective imaging contrast agents. With a strategic focus on vertically integrating the barium and iodine contrast markets, Voyageur aims to become a key player by producing its own barium, iodine, and new endo fullerene drugs. Voyageur's business plan is set to generate cash flow by partnering with established third-party GMP pharmaceutical manufacturers in Canada thereby ensuring the validation of its products by regulatory agencies worldwide. As Voyageur solidifies its presence in the market, it plans to transition into a high-margin domestic manufacturer of radiology drugs, further expanding its revenue streams.

Voyageur is committed to sustainability and environmental stewardship. Voyageur envisions a future where reducing carbon emissions is the norm, and to achieve this, it will build state-of-the-art carbon-capture infrastructure utilising the Rain Cage $EDEN^{\text{TM}}$ system. By investing in carbon capture energy sources and sustainable manufacturing practices, Voyageur aims to generate revenue from carbon captured "advanced carbon production" to accelerate revenue growth. Voyageur's unwavering commitment to the environment sets it apart as a pioneer in the industry.

At the core of its operations, Voyageur owns a 100% interest in the Frances Creek barium sulphate (barite) project. Currently, the worlds pharmaceutical barium sulphate is almost entirely synthetically produced resulting in a less effective imaging quality product. Voyageur's Frances Creek resource boasts a rare and exceptional grade mineral suitable for the pharmaceutical marketplace that Voyageur believes will replace the current synthetic products with higher quality imaging products.

Voyageur's ambitious vision is to become the first vertically integrated company in the radiology contrast media drug market. By controlling all primary input costs, from the sourcing of raw materials to final production, Voyageur ensures quality and cost efficiency. With its approach, it embodies the motto of "From the Earth to the Bottle," highlighting Voyageur's commitment to responsible sourcing and manufacturing practices. For Further Information:

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This news release may contain certain forward-looking information and statements, including without limitation, statements pertaining to: the successful completion of clinical testing; Canadian, FDA and other regulatory approvals; and the effectiveness, efficiency and market acceptance of the four new barium contrast drugs and one gas agent. All statements included herein, other than statements of historical fact, are forwardlooking 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.sedarplus.ca. Voyageur does not undertake to update any forward-looking information except in accordance with applicable securities laws.