

Press Contact: Kimberly Gerweck Bracco Diagnostics Inc. Kimberly.Gerweck@diag.bracco.com 609.514.2249

# Bracco's CT Exprès<sup>™</sup> 3D Contrast Media Delivery System is the First and Only Syringe-Less Computed Tomography (CT) Power Injector Available in the U.S.

#### CT Exprès Multi-Patient, Multi-Use Technology Improves Efficiency and Reduces Contrast Media Waste in the CT Suite

**Monroe Township, NJ, November 28, 2016 –** Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a global leading company in the diagnostic imaging business, today announced that CT Exprès, the first and only multi-dose, multi-patient, syringe-less injector for CT, is now available in the United States. The CT Exprès 3D Contrast Media Delivery System is designed to streamline workflow and optimize patient care within the CT department.

"As a leader in the imaging marketplace, we are proud to offer CT Exprès, an innovative solution that can significantly increase the number of scans clinicians can perform in a day," said Vittorio Puppo, President and CEO, Bracco Diagnostics Inc. "This is critical because the volume of CT exams continues to grow and we want to help technologists meet current demand. We recognize that imaging centers and radiology departments need to control costs, maintain productivity, and preserve workflow efficiency. CT Exprès does this while providing a more user-friendly experience and delivering the same high-quality imaging results, as dual syringe systems. Our work continues to demonstrate Bracco's commitment to innovation."

CT Exprès was cleared by the U.S. Food and Drug Administration for controlled automatic administration on the venous side, of contrast media and saline. CT Exprès is used in combination with Isovue<sup>®</sup> (lopamidol injection) Imaging Bulk Package (IBP) and saline (0.9% Sodium Chloride Injection USP). Use of saline with this innovative contrast medium injector allows multi-dosing from a saline container.

#### About CT Exprès

In a prospective study of 275 consecutive outpatients, the utility of CT Exprès was compared with a dual-syringe system. The comparison was carried out in a single center utilizing two scanner rooms, which shared a common console room. Patients and technologists were randomized between the rooms, and two radiologists evaluated image quality. Results showed that CT Exprès improved throughput and provides added benefits over dual syringe-based systems including<sup>i</sup>:

more -

- 65 percent less preparation time
- 75 percent less releasing time
- Saved over 2 minutes / exam and increased throughput by 2.6 patients / day
- Reduced contrast media waste
- Increased technologists' satisfaction
- Equivalent image quality

Please see Important Safety Information below.

### IMPORTANT SAFETY INFORMATION CT Exprès 3D Contrast Media Delivery System

#### INDICATIONS

The CT Exprès 3D Contrast Media Delivery System is indicated for controlled automatic administration, on the venous side, of contrast media and saline, to human subjects while undergoing examination by means of a computed tomography (CT) scanner.

The CT Exprès 3D Contrast Media Delivery System is specifically indicated for use in CT procedures for the delivery of ISOVUE<sup>®</sup> (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media or a maximum of ten (10) hours, whichever comes first, per Day Set III HP disposable. The Bottle Spike disposable is for single-bottle use only and must be discarded with the contrast media bottle. The Patient Set must be discarded after each patient procedure.

The CT Exprès 3D is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

#### CONTRAINDICATIONS

This device is not intended for injection of contrast media for coronary arteriography, or for any other use for which the device is not indicated.

Not all products are available in all countries. Please contact your Bracco representative.

Bracco Injeneering S.A. reserves the right at any time and without notice, to change the specifications and features described herein, or to change the production or adjust the product described.

CT Exprès is manufactured for Bracco Injeneering S.A., Avenue de Sévelin 46, CH-1004 Lausanne, Switzerland; http://imaging.bracco.com

CT Exprès is distributed by Bracco Diagnostics Inc., 259 Prospect Plains Road, Bldg. H, Monroe Township, NJ 08831 USA; Phone: (800) 631-5245; Fax: (609) 514-2424; Customer Service: 1-877-BRACCO 9 (1-877-272-2269).

CT Exprès is a trademark of Bracco Injeneering S.A.

more -

## Indications and Usage for ISOVUE<sup>®</sup>-300 (Iopamidol Injection 61%) Imaging Bulk Package and ISOVUE<sup>®</sup>-370 (Iopamidol Injection 76%) Imaging Bulk Package<sup>‡</sup>

Isovue (Iopamidol Injection) Imaging Bulk Package (IBP) is indicated for intravenous contrast enhancement of computed tomographic (CECT) imaging of the head and body in adult and pediatric patients.

#### **IMPORTANT SAFETY INFORMATION:**

Isovue IS NOT FOR INTRATHECAL USE. Iopamidol Injection is available as Isovue-M<sup>®</sup> for intrathecal administration.

Caution must be exercised in patients with severely impaired renal function, those with combined renal and hepatic disease, or anuria, particularly when larger and repeat doses are administered. Radiopaque diagnostic contrast agents are potentially hazardous in patients with multiple myeloma or other paraproteinemia, particularly in those with therapeutically resistant anuria. Caution should be exercised in hydrating patients with underlying conditions that may be worsened by fluid overload, such as congestive heart failure. Diabetic nephropathy may predispose to acute renal impairment following intravascular contrast media administration. Acute renal impairment following contrast media administration may precipitate lactic acidosis in patients who are taking biguanides. Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, diabetic patients, and in susceptible nondiabetic patients (often elderly with preexisting renal disease). Patients should be well hydrated prior to and following iopamidol administration.

The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions, should always be considered. Patients at increased risk include those with a history of a previous reaction to a contrast medium, patients with a known sensitivity to iodine per se, and patients with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies).

‡The Isovue Imaging Bulk Package is for use with an automated contrast injector or a contrast management system approved or cleared for use with it.

Please see full Prescribing Information for ISOVUE IBP at <u>http://imaging.bracco.com/us-</u>en/products-and-solutions/x-ray-computed-tomography/isovue/prescribing-information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

For additional information about Bracco's products, and for full prescribing information, please visit <u>http://imaging.bracco.com/us-en</u>. If you have any questions or require additional information about any Bracco product, please contact Bracco Professional Services at 1-800-257-5181, option 2.

Isovue and Isovue-M are currently manufactured for Bracco Diagnostics Inc. at two locations: BIPSO GmbH, Singen (Germany) and Patheon Italia S.p.A., Ferentino (Italy).

Isovue and Isovue-M are registered trademarks of Bracco Diagnostics Inc.

more -

#### **About Bracco Imaging**

Bracco Imaging S.p.A., part of the Bracco Group, is one of the world's leading companies in the diagnostic imaging business. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions that meet medical needs.

Bracco Imaging offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray Imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers. The diagnostic imaging portfolio is completed by a range of medical devices and advanced administration systems for contrast imaging products.

The Company operates in over 100 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. With on-going research covering all key modalities, Bracco Imaging has a strong presence in key geographies: North America, Europe and Japan operating through the Joint Venture Bracco-Eisai Co. Ltd. The Company also operates in Brazil, South Korea, and China through the Joint Venture Bracco Sine Pharmaceutical Corp. Ltd.

Operational investments have been made in order to achieve top quality, compliant and sustainable eco-friendly production. Manufacturing activities are located in Italy, Switzerland, Japan, China, and Germany.

Bracco Imaging is an innovative Research and Development (R&D) structure with an efficient process oriented approach and a track record of innovation in the diagnostic imaging industry. R&D activities are managed in the three Research Centers located in Italy, Switzerland, and the USA.

To request a demonstration of CT Exprès go to: <u>http://www.ct-expres.com/</u>

To learn more about Bracco Imaging, visit <u>www.braccoimaging.com</u>.

###

<sup>&</sup>lt;sup>i</sup> Ma X, Sing A, Fay J, Boland G, Sahani DV. Comparison of Dual-Syringe and Syringeless Power Injectors in Outpatient MDCT Practice: Impact on the Operator's Performance, CT Workflow, and Operation Cost. *Journal of the American College of Radiology*.2012; 9(8):578-582.