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Contact:

Peter Evers
Natron Communications
(415) 524-8899
pr@irapid.com

iSchemaView's RAPID™ Approved for Use in Brazil

iSchemaView Expands RAPID's South American Footprint by Bringing Brazil the Only Clinically Validated, Next-Generation Imaging Platform for Assessing Ischemic Stroke

Menlo Park, Calif. — February 21, 2019 – iSchemaView, the worldwide leader in advanced imaging for stroke, has received approval from ANVISA (the Brazilian Health Regulatory Agency), for the use of the RAPID imaging platform across Brazil. RAPID is designed to provide physicians with fast, fully automated, elegant and easy-to-interpret imaging that facilitates clinical decision-making around stroke. The approval comes after iSchemaView's quality system was also certified through the Medical Device Single Audit Program (MDSAP) — a global approach to auditing and monitoring the manufacturing of medical devices, in an effort to improve safety and oversight on an international scale.

Hospitals and clinics that treat ischemic stroke in Brazil will now have access to RAPID's automated CTP, MR, CTA and ASPECTS solutions. RAPID's expansion into Brazil represents significant market growth in South America, and is another sign that RAPID has become the de facto standard in stroke imaging around the world.

"RAPID signifies the massive leaps medical technology has made in the last two years to better diagnose and treat stroke patients," said Dr. Francisco Mont'Alverne, MD, PhD, Director of Interventional Neuroradiology Hospital Geral de Fortaleza. "This ANVISA clearance means hundreds of thousands of Brazilians may now benefit from RAPID's state-of-the-art, AI-powered imaging technology."

Developed by leading stroke experts, the RAPID Artificial Intelligence framework combines deep learning, machine learning and expert feature extraction. Together these provide unparalleled sensitivity and specificity across stroke modules (CT perfusion, MR diffusion and perfusion, CTA and CT ASPECT scoring). Results are then delivered by the RAPID Intelligence Services Platform via PACS, email, text, the RAPID APP or corporate partner workflow systems.

"Patients often arrive at the hospital several hours after stroke symptom onset," said Dr. Fabricio Oliveira Lima, MD, MPH, PhD, Director of the Stroke Unit Neurology Service Hospital Geral de Fortaleza. "RAPID allow us to see the status of the brain upon arrival and to quickly identify patients who are eligible for clot removal, even as late as 24 hours after stroke onset. This increases the chances for recovery for our patients, reduces disability and saves lives.

The Complete RAPID Platform includes:

- **RAPID MRI** provides fully automated, easy to interpret diffusion and perfusion maps that identify brain areas with low ADC values, as well as delayed contrast arrival. RAPID MRI perfusion automatically quantifies regions of reduced cerebral blood flow, volume and transit time that exceed pre-specified thresholds.

- **RAPID CT** perfusion automatically quantifies regions of reduced cerebral blood flow, volume and transit time that exceed pre-specified thresholds. Regions are color coded and the volumes of interest are automatically measured. Maps (including mismatch maps) of the severity of Tmax delays are provided using a four-color-coded scale.

- **RAPID CTA** automatically provides clear, easy to interpret CTA maps which include a colored overlay to identify brain regions with reduced blood vessel density. The severity of reduction can be readily visualized by a simple, four-color-coded scale. Additionally, a 3D reconstruction of the vasculature allows physicians to rotate the image for optimal viewing of the vessels from multiple angles.

- **RAPID ASPECTS** automatically generates a standardized score — based on clinically validated machine learning algorithms — that enables physicians to easily communicate about the extent of a patient's ischemic changes and to determine eligibility for thrombectomy (clot removal). In addition, RAPID ASPECTS provides clear visualization of the brain so that clinicians can better scrutinize each region and confirm the automated score.

"Over 1,000 stroke centers in more than 40 countries across North America, South America, Europe, Asia and Australia have committed to using the RAPID platform for stroke imaging," said Don Listwin, CEO of iSchemaView. "We are excited we can now bring RAPID to Brazil, give hospitals of all sizes the tools they've needed, and help address more patients than ever before. In addition, we have secured the support of some of the best RAPID experts in Brazil to provide clinical training."

For more information about working with RAPID in Brazil, contact info@irapid.com.

About iSchemaView

iSchemaView is the world-wide leader in advanced imaging for stroke. Installed in over 1,000 stroke centers, iSchemaView's RAPID (automated CTP, MR, CTA and ASPECTS), with enhanced AI framework, is the most advanced stroke imaging platform. In clinical trials, RAPID has been shown to aid in the selection of patients in early and late-window stroke trials, including SWIFT PRIME, EXTEND IA, DAWN, DEFUSE 3 and EXTEND. In addition to achieving the best clinical outcomes and largest treatment effects ever obtained, these landmark studies led to new American Heart Association and American Stroke Association guidelines and have dramatically altered the management of acute stroke around the world. For more information, visit www.iRAPID.com.

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