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iSchemaView's RAPID™ Approved for Use in Canada

Patients Suffering Ischemic Stroke in Canada Now Have Access to the Only Clinically Validated, Next-Generation Imaging Platform for Assessing Treatment

Redwood City, Calif. – August 16, 2018 – iSchemaView, the leader in cerebrovascular imaging analysis, today announced it has received final approval for the use of the RAPID platform in Canada. The RAPID platform is designed to provide physicians with fast, fully automated, elegant and easy-to-interpret imaging that facilitates clinical decision-making around cerebrovascular disease, such as stroke. Canadian approval comes after iSchemaView's quality system was 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.

iSchemaView's RAPID platform was recently used to select patients for two landmark stroke trials published in *The New England Journal of Medicine*, DAWN and DEFUSE 3, that successfully treated patients up to twenty-four hours after onset. RAPID was the exclusive imaging tool used to aid in patient selection in both studies. The results of the studies helped change the American Heart Association's and Canadian Heart and Stroke Foundation's stroke guidelines to include CT perfusion and MR perfusion. The prior treatment window for mechanical thrombectomy was up to six hours. Starting in 2018, select patients with salvageable brain tissue identified through advanced imaging are now eligible for treatment up to twenty-four hours after they were last seen well.

“Our research use of RAPID has shown that its speed and accuracy are very helpful in the management of patients with acute stroke,” said Dr. Frank Silver, Medical Director, Toronto West Stroke Network; Medical Director of the Ontario Telestroke Program and Professor of Neurology at the University of Toronto. “RAPID plays an important role in selecting which patients should be urgently transferred to regional stroke centers for endovascular therapy.”

RAPID technology assists physicians in the analysis of brain images using automated tools for CT ASPECTS, CT angiography, CT perfusion and MR diffusion and perfusion for more than 85,000 stroke cases per year. RAPID is also currently deployed in six multi-center clinical trials globally — adding 200 hospitals to RAPID’s global reach.

The RAPID neuroimaging platform creates high-quality images from non-contrast CT, CT angiography, CT perfusion and MRI diffusion and perfusion studies. The software provides an intuitive and easily interpretable real-time view of brain perfusion, allowing physicians to determine lesion volumes for a wide variety of different thresholds.

Also approved for use in Canada is RAPID ASPECTS, a validated solution that assists clinicians in assessing early signs of brain ischemia in stroke. 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.

“With approval for RAPID in Canada, we will be able to greatly expand the number of health care facilities that are able to assess stroke patients with the only clinically validated next-generation imaging technology,” said Don Listwin, CEO of iSchemaView. “Over 575 stroke centers in 22 countries around the world have now committed to using the RAPID platform, and we look to increasing that number substantially by the end of the year.”

For more information about working with RAPID in Canada, contact Cynthia Yang at +1 (949) 836-7402 or at yang@irapid.com.

About iSchemaView

iSchemaView is the leader in cerebrovascular imaging analysis, delivering the proven software tools that healthcare professionals around the world use to successfully identify and treat more stroke patients than ever before. Already installed in over 500 hospitals and stroke centers, iSchemaView’s RAPID (automated CTP, MR, CTA and ASPECTS) is the most advanced brain imaging platform. In clinical trials, under IRB, RAPID has been shown to aid in the selection of patients in early and late-window stroke trials, including SWIFT PRIME, EXTEND IA, DAWN and DEFUSE 3. 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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