OCT Clinical to Conduct a Bioequivalence Study in Eastern Europe

Leading mid-size European CRO approved to begin work on bioequivalence study; seeks marketing authorization for all member states of EAEU.

OCT Clinical announced it has successfully obtained a clinical trial approval to conduct a bioequivalence study on behalf of a European pharmaceutical company.

ST. PETERSBURG, RUSSIA, March 23, 2020 /EINPresswire.com/ -- OCT Clinical, a leading European CRO headquartered in Russia, today announced it has successfully obtained a clinical trial approval to conduct a bioequivalence study on behalf of a European pharmaceutical company.

The open-label, randomized, single-dose, two-treatment, two-sequence, two-way crossover, pivotal bioequivalence study will test an investigational drug: a film-coated tablet composed of a combination of rosuvastatin and ezetimibe. The primary objective of the study is to evaluate comparative pharmacokinetics and bioequivalence under fasting conditions.

110 healthy volunteers are to be screened, and 88 of them will be randomized within a specialized Phase I unit in Russia. The planned duration of the study is six months, with the ultimate goal to obtain a marketing authorization valid within all the member states of the Eurasian Economic Union (EAEU).

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> *Irina Petrova, Director of Medical Operations, OCT Clinical*

"We see growing interest among sponsors from all over the world for their drugs to have marketing authorization across the entire Eurasian Economic Union while having registered them in only one of the member countries," said Irina Petrova, Director of Medical Operations, OCT Clinical. "We are positive that our experience will allow us to meet all the Sponsor's goals. We are very excited about this project and we are committed to delivering excellence during every stage of the study."

Within this project, the OCT Clinical team is responsible for a wide scope of clinical trial services: project management, pharmacovigilance and medical monitoring, data management and biostatistics, medical writing, logistics support, and regulatory support, including CSR submission to regulatory authorities.

“We have high expectations for the outcome of this project through our collaboration with OCT Clinical,” said a representative from the study Sponsor. “Throughout our experience of working with OCT they have demonstrated a consistent level of competence, thus matching our highest aspirations by keeping timelines, delivering effective communication on a 24/7 basis, and providing continuous assistance.”

About OCT Clinical
OCT Clinical is the leading CRO in Russia, with operations in Central and Eastern Europe and the CIS region. With a team of over 200 professionals, the company provides a full range of high-quality clinical research services for phase I-IV and BE studies. With strong local expertise and focus on quality, OCT ensures seamless clinical trial conduct and drug registration on time and within budget. OCT’s experienced team delivers both standalone services such as medical writing, consultancy, project management/monitoring, data management/biostatistics and turnkey service for clinical development. Since 2005, OCT Clinical Trials has worked on over 300 full-service and functional service projects in more than 20 therapeutic areas. Learn more at www.OCT-ClinicalTrials.com.

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