

Quantum Genomics Launches Phase III Pivotal REFRESH Study in Difficult-to-treat/Resistant Hypertension with Once-a-day Formulation of Firibastat

Quantum Genomics (Euronext Growth - FR0011648971 - ALQGC), a biopharmaceutical company specializing in developing a new drug class that directly targets the brain to treat difficult-to-treat and resistant hypertension and heart failure today announced the launch of its Phase III REFRESH study in difficult-to-treat⁽¹⁾ or resistant⁽²⁾ hypertension.

This new study is part of firibastat's Phase III clinical development and aims to assess long-term safety as well as the three-month efficacy after a single daily dose of firibastat 1000mg in treatment resistant hypertensive patients.

« We are thrilled to launch this new pivotal study as a precursor to potential market approval of single dose firibastat, which we believe to be the best regimen for chronic treatment of resistant of difficult-to-treat hypertension,» said Jean-Philippe Milon, Chief Executive Officer at Quantum Genomics. *“This study will also provide long-term safety data in accordance with Quantum Genomics’ development plan endorsed by the FDA”* ⁽³⁾

This multicenter, multinational study will enroll 750 patients with difficult-to-treat or resistant hypertension in Europe, Canada, US as well as collaboratively in Asia with our commercial partners in China, Taiwan and South-Korea.

For the first randomized three-month period, 750 patients will receive firibastat (1000mg once-a-day) or placebo, on top of their current therapy. The primary endpoint will be reduction in systolic automated office blood pressure (AOBP) from baseline. After this first period, subjects will be treated and followed-up for six months (and 12 months for 100 patients) to assess long-term safety, data that are mandatory for New Drug Application (NDA) for a chronic treatment.

Sites selection will start shortly, and regulatory submissions to competent authorities and ethics committees are in preparation for each country. First patient recruitment is planned in Q2 2021 and efficacy results and six-month safety results are expected for mid-2023, on time to submit New Drug Applications in 2023. Study costs are budgeted and financed thanks to the partnerships signed by Quantum Genomics.

⁽¹⁾ Patients not controlled despite two antihypertensive classes, including a diuretic, at maximum tolerated doses.

⁽²⁾ Patients not controlled despite at least three antihypertensive classes, including a diuretic, at maximum tolerated doses.

⁽³⁾ FDA: Food and Drug Administration, US Regulatory Authority.

About Quantum Genomics

Quantum Genomics is a biopharmaceutical company specializing in the development of a new class of cardiovascular medications based on brain aminopeptidase A inhibition (BAPAI). Quantum Genomics is the only company in the world exploring this innovative approach that directly targets the brain. The company relies on 20 years of academic research from the Paris-Descartes University and the laboratory directed by Dr. Catherine Llorens-Cortes at the Collège de France (French National Institute of Health and Medical Research (INSERM)/ the Scientific Centre for National Research (CNRS)). The goal of Quantum Genomics is to develop innovative treatments for complicated, or even resistant, cases of hypertension (around 30% of patients have poor control of their condition or receive ineffective treatment) and for heart failure (one in two patients diagnosed with severe heart failure dies within five years).



Based in Paris and New York, Quantum Genomics is listed on the Euronext Growth exchange in Paris (FR0011648971- ALQGC) and trades on the OTCQX Best Market in the United States (symbol: QNNTF).

For more information, please visit www.quantum-genomics.com, or follow us on [Twitter](#) and [LinkedIn](#)

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