Press Release
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Quantum Genomics Announces Interim Analysis from Study of Firibastat in Renal Failure Patients

Results demonstrate that firibastat could be used in hypertensive and heart failure patients with concomitant renal dysfunction, subject to dose adjustment.

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, announced results from an interim analysis of findings from QGC001/1QG4, its study of firibastat in end-stage renal failure (ESRD) patients.

The interim analysis shows that, because of a slower elimination (longer half-life [t ½]), exposure (AUC) to firibastat and its main metabolites is relatively more important in ESRD patients compared to healthy volunteers, without any significant increase in peak concentration (Cmax). Firibastat was well tolerated in the study and no related adverse event was recorded. No significant deterioration of the renal function was observed in ESRD patients, which strengthen safety conclusions of the previous studies, particularly the NEW-HOPE trial conducted in hypertensive patients without renal dysfunction. The pharmacokinetic parameters obtained and the good tolerance of the product suggest that a simple dose adjustment could allow the use of firibastat in patients with chronic renal failure.

"These interim results provide important insights since we know now how to adapt the firibastat dose to enroll patients with severe to end-stage renal failure in our clinical studies," said Bruno Besse Chief Medical Officer of Quantum Genomics. *"this will confirm that firibastat could be used to treat heart failure patients and treatment-resistant hypertensive patients even in the case of concomitant renal dysfunction, including end-stage, where very limited options are available."*

Jean-Philippe Milon, Chief Executive Officer of Quantum Genomics commented: *"Renal failure is a common comorbidity in patients with hypertension and with heart failure. The use of firibastat in these patients could expand its market in resistant hypertension and heart failure by 15 to 20%.*

Study QGC001/1QG4 was designed to compare pharmacokinetic parameters of firibastat and its main metabolites in patients with ESRD (estimated glomerular filtration rate [eGFR] <15 mL/min/m²) to those of healthy volunteers after a single oral dose of firibastat (500 mg).

All 14 patients with ESRD have been recruited in the study and had a mean age of 46±2 years with mean eGFR of 12±3 mL/min/m². To date, six of 14 healthy volunteers have been recruited and treated, and had a mean age of 43±12 years with a mean eGFR of 99±22 mL/min/m².

According to the Health Authorities recommendation, healthy volunteers' enrollment was stopped because of the COVID-19 pandemic and will resume after the crisis. Final analysis will be performed once all healthy volunteers have been enrolled, but since data for all ESRD patients are already available, this is not expected to significantly change the study conclusions.

Chronic kidney disease (CKD) is a well-known complication of hypertension, especially when blood pressure is uncontrolled. Renal dysfunction occurs in roughly 20% of patients with treatment-resistant hypertension.[1] This feature comorbidity makes these patients' treatment even more difficult because several classes of hypertension drugs are not recommended or are contra-indicated, for example with spironolactone.

CKD is also a frequent comorbidity in heart failure (HF). A prospective study found that 16% and 40% of HF patients have concomitant severe or moderate renal dysfunction, respectively.[2] This is also a factor of poor prognosis, with each 1 mL/min/m^2 decrease in eGFR resulting in a 1% mortality increase. Similarly, for myocardial infarction (MI), there is a 20% higher mortality rate following MI in patients ESRD.[3]

[1] Acharya T et al. Resistant Hypertension and Associated Comorbidities in a Veterans Affairs Population J Clin Hypertens (Greenwich). 2014;16:741–745.

[2] Mc Alister F. et al. Renal Insufficiency and Heart Failure. Prognostic and Therapeutic Implications From a Prospective Cohort Study. Circulation. 2004;109:1004-1009

[3] Sundaram V. et al. Impact of comorbidities on peak troponin levels and mortality in acute myocardial infarction. Heart 2020;106:677–685.

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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