

Servier Announces Partnership with QIAGEN to Develop New IDH1 Companion Diagnostic Test to Support Servier's Onco-hematology Portfolio

Paris (France), March 9, 2023 – Servier, a global pharmaceutical group, today announced it has entered into a strategic partnership with QIAGEN, a leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life, to develop a companion diagnostic test that detects IDH1 mutations. This test will be for use with Servier's marketed and investigational targeted treatments in Acute Myeloid Leukemia (AML).

QIAGEN and Servier are collaborating to develop a PCR-based companion diagnostic test that can be used to rapidly identify AML patients with IDH1 gene mutations. This partnership comes in the light of the published pivotal clinical phase 3 data of the AGILE study which showed that ivosidenib in combination with azacitidine as a first-line treatment for intensive chemotherapy ineligible AML patients with IDH1 gene mutations shows superior results compared to treatment with azacitidine alone.¹ The partnership with QIAGEN will lead to the development of a specific diagnostic test for IDH1 gene mutations with a rapid turnaround time.

Brian Lockhart, Global Head of Companion Diagnostics at Servier, said: *"In order to expand the global access for ivosidenib for patients, it is imperative that we leverage a partner such as QIAGEN with an established global footprint in oncology-driven diagnostics, and a proven expertise in companion diagnostics development and approvals."*

Jonathan Arnold, Vice President, Head of Partnering for Precision Diagnostics at QIAGEN, said: *"We are pleased to support Servier with a companion diagnostic in their mission to propose innovative treatment for IDH1 mutated AML patients. At the same time, we are further strengthening our role in developing companion diagnostics for the ever-growing number of biomarkers being discovered in onco-hematology."*

Under the Master Collaboration Agreement, QIAGEN will develop and validate a real-time PCR-based in vitro diagnostic test that can be used to detect IDH1 gene mutations in whole blood and bone marrow aspirates in AML.

The companion diagnostic will run on the QIAGEN Rotor-Gene Q MDx device, which is widely used by labs worldwide. QIAGEN's experienced regulatory teams will support clinical validation of the companion diagnostic and its approval in the US, the European Union and Japan.

Fabien Schmidlin, Global Head of Translational Medicine at Servier, concluded: *"Early biomarker testing for an IDH1 mutation has grown in importance for targeted therapies and can play a critical role in the treatment of acute myeloid leukemia (AML). This partnership with QIAGEN will help us further our mission to improve outcomes for patients with AML who test positive for an IDH1 mutation in both the relapsed/refractory and newly diagnosed intensive chemotherapy ineligible setting and for investigational purposes in AML patients in the front-line setting."*

¹ Results from the AGILE study were published in the [New England Journal of Medicine \(NEJM\)](#) in April 2022.

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About Servier

Founded to serve health, Servier is a global pharmaceutical group governed by a Foundation that aspires to have a meaningful social impact, both for patients and for a sustainable world. With its unique governance model, it can fully serve its vocation with a long-term vision: being committed to therapeutic progress to serve patient needs. The 21,400 employees of the Group are committed to this shared vocation, source of inspiration every day.

As a world leader in cardiology, Servier's ambition is to become a renowned, focused and innovative player in oncology by targeting hard-to-treat cancers. That is why the Group allocates over 50% of its R&D budget to developing targeted and innovative therapies in oncology.

Neuroscience and immuno-inflammatory diseases are the future growth drivers. In these areas, Servier is focused on a limited number of diseases in which accurate patient profiling makes it possible to offer a targeted therapeutic response through precision medicine.

To promote access to quality care for all at a lower cost, the Group also offers a range of quality generic drugs covering most pathologies, relying on strong brands in France, Eastern Europe, Brazil and Nigeria.

In all these areas, the Group includes the patient voice at each stage of the life cycle of a medicine.

Headquartered in France, Servier relies on a strong geographical footprint in over 150 countries and achieved a revenue of €4.9 billion in 2022. More information on the new Group website: servier.com

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