QIAGEN and Incyte Announce Precision Medicine Collaboration to Develop Companion Diagnostics for Patients With Mutant CALR-expressing Myeloproliferative Neoplasms (MPNs)

June 15, 2025

- **QIAGEN to create a multimodal panel using next-generation sequencing (NGS) technology for detecting clinically relevant gene alterations in hematological malignancies**
- **Companion diagnostic to identify key disease-causing mutations in patients with MPNs, with an initial focus on mutant CALR the second most common driver of MPNs**
- **Panel to be validated on Illumina NextSeq 550Dx platform for use with whole blood samples**
- **Partnership supports Incyte's extensive portfolio in myeloproliferative neoplasms, including INCA033989, and enhances QIAGEN's onco-hematology diagnostics pipeline**

VENLO, Netherlands & WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 15, 2025-- QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) and Incyte (Nasdaq: INCY) today announced a new global collaboration to develop a novel diagnostic panel to support Incyte's extensive portfolio of investigational therapies for patients with myeloproliferative neoplasms (MPNs), a group of rare blood cancers, including Incyte's monoclonal antibody INCA033989, targeting mutant calreticulin (mutCALR), which is being developed in myelofibrosis (MF) and essential thrombocythemia (ET).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20250615075973/en/

Under the terms of the Master Collaboration Agreement with Incyte, QIAGEN will develop a multimodal panel using next-generation sequencing (NGS) technology for detecting clinically relevant gene alterations in hematological malignancies.

The panel will be validated using the next-generation sequencing (NGS) technology and the Illumina NextSeq 550Dx platform as part of QIAGEN's partnership with Illumina (NASDAQ: ILMN) to leverage its NGS diagnostic platforms for patient testing by laboratories worldwide. QIAGEN will support regulatory submission processes and market access activities across the United States, European Union and Asia-Pacific regions.

Myeloproliferative neoplasms are a group of diseases representing about 40% of hematological malignancies, characterized by chronic accumulation of different mature blood cell types in blood.

Identifying genomic aberrations in clinically relevant biomarkers like CALR are shown to be key, especially in MPNs. Incyte is at the forefront of developing novel therapies, including INCA033989 for patients with mutCALR ET or MF, that target only malignant cells, sparing normal cells. The use of companion diagnostics helps guide clinicians in making treatment decisions that can lead to better patient outcomes.

"Following our presentation of positive, late-breaking data from our first-in-class mutCALR-targeted antibody at EHA, we are excited to announce this partnership with QIAGEN, which will facilitate CALR testing for patients with MPNs on a global basis. The development of companion diagnostics for mutCALR, coupled with the potential for new medicines to selectively target disease-initiating cells, is a critical step toward changing the course of disease in patients with ET and MF," said Pablo J. Cagnoni, M.D., President and Head of Research and Development, Incyte. "As a partner, QIAGEN has the proven expertise in companion diagnostics development and approvals needed to support our ongoing work and commitment to transforming the treatment of patients with CALR-mutant MPNs."

"Together with Incyte we are building a multimodal companion diagnostic using a powerful technology like next-generation sequencing to facilitate highly accurate testing for several blood cancer genes at once," said Jonathan Arnold, Vice President and Head of Partnering for Precision Diagnostics at QIAGEN. "This new partnership strengthens our role in offering companion diagnostics for the growing number of biomarkers being discovered in onco-hematology and maximizing the clinical utility of the diagnostic for payor and patient benefit, thus supporting the work of innovative, science-driven companies like Incyte to improve patient outcomes."

About Mutations in Calreticulin (mutCALR)

Calreticulin (CALR) is a protein involved in the regulation of cellular calcium levels and normal protein production. Somatic, or non-inherited, DNA mutations in the CALR gene (mutCALR) can result in abnormal protein function and lead to the development of myeloproliferative neoplasms (MPNs),[i] a closely related group of clonal blood cancers in which the bone marrow functions abnormally, overproducing blood cells.[ii,iii] Among the two types of MPNs, essential thrombocythemia (ET) and myelofibrosis (MF), mutCALR drives 25-35% of all cases.[i,ii]

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions, enabling customers to extract and gain valuable molecular insights from samples containing the building blocks of life. Our Sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies prepare these biomolecules for analysis while bioinformatics software and knowledge bases can be used to interpret data to find actionable insights. Automation solutions bring these processes together into seamless and cost-effective workflows. QIAGEN serves over 500,000 customers globally in Life Sciences (academia, pharma R&D and industrial applications, primarily forensics) and Molecular Diagnostics for clinical healthcare. As of March 31, 2025, QIAGEN employed approximately 5,700 people in over 35 locations worldwide. For more information, visit https://www.qiagen.com.

QIAGEN is a pioneer in precision medicine and the leader in collaborating with pharmaceutical and biotechnology companies to develop companion diagnostics, having more than 30 master collaboration agreements with global pharmaceutical and biotechnology companies to develop and commercialize diagnostic tests. QIAGEN's offering to these companies encompasses technologies ranging from polymerase chain reaction (PCR),

near-patient testing and digital PCR (dPCR) to next-generation sequencing (NGS), and sample types from liquid biopsy to tissue. It also spans disease areas from cancer to non-oncology diseases such as neurodegenerative, inflammatory, and metabolic diseases – including 16 FDA-approved PCR-based companion diagnostics.

For more information about QIAGEN's efforts in precision medicine please visit https://www.qiagen.com/us/clp/partnering-for-precision-diagnostics.

About Incyte

A global biopharmaceutical company on a mission to *Solve On.,* Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

QIAGEN Forward-Looking Statement

Certain statements in this press release may constitute forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. These statements, including those regarding QIAGEN's products, development timelines, marketing and / or regulatory approvals, financial and operational outlook, growth strategies, collaborations and operating results - such as expected adjusted net sales and adjusted diluted earnings - are based on current expectations and assumptions. However, they involve uncertainties and risks. These risks include, but are not limited to, challenges in managing growth and international operations (including the effects of currency fluctuations, regulatory processes and logistical dependencies), variability in operating results, commercial development for our products to customers in the Life Sciences and clinical healthcare, changes in relationships with customers, suppliers or strategic partners; competition and rapid technological advancements; fluctuating demand for QIAGEN's products due to factors such as economic conditions, customer budgets and funding cycles; obtaining and maintaining regulatory approvals for our products; difficulties in successfully adapting QIAGEN's products into integrated solutions and producing these products; and protecting product differentiation from competitors. Additional uncertainties may arise from market acceptance of new products, integration of acquisitions, governmental actions, global or regional economic developments, natural disasters, political or public health crises, and other "force majeure" events. There is also no guarantee that anticipated benefits from restructuring programs and acquisitions will materialize as expected. For a comprehensive overview of risks, please refer to the "Risk Factors" contained in our most recent Annual Report on Form 20-F and other reports filed with or furnished to the U.S. Securities and Exchange Commission.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the potential for Incyte's mut-CALR targeted antibody (INCA033989) to provide a potential treatment option for patients with ET or MF, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA, EMA, and other regulatory authorities; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K and our quarterly report on Form 10-Q for the quarter ended March 31, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

Source: QIAGEN N.V.
Category: Precision Medicine

[i] Raghavan, M., Wijeyesakere S.J., Peters L.R., Del Cid N. (2013) Calreticulin in the immune system: ins and outs. *Trends in Immunology,* 34(1):13-21. Link to source (https://www.cell.com/trends/immunology/abstract/S1471-4906(12)00131-7?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1471490612001317%3Fshowall%3Dtrue)

[ii] Nangalia J. Massie C.E., Baxter E.J., Nice F.L., et al. (2013) Somatic CALR mutations in myeloproliferative neoplasms with nonmutated JAK2. *New England Journal of Medicine,* 369(25):2391-2405. Link to source (https://www.nejm.org/doi/10.1056/NEJMoa1312542?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov)

[iii] Klampfl T., Gisslinger, H., Harutyunyan A.S., et al. (2013) Somatic mutations of calreticulin in myeloproliferative neoplasms. *New England Journal of Medicine,* 369(25):2379-2390. Link to source (https://www.nejm.org/doi/10.1056/NEJMoa1311347?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov)

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