

**TAKEDA LAUNCHES CDPATH™, A PERSONALIZED PROGNOSTIC TOOL, ADVANCING INNOVATION FOR PATIENTS WITH CROHN'S DISEASE**

*CDPATH supports shared decision-making between patients and healthcare providers; provided at no cost to eligible adult patients who have not yet experienced serious complications\**

CAMBRIDGE, Massachusetts, September 14, 2022 – Takeda (TSE:4502/NYSE:TAK) announced the national launch of the CDPATH™ program, which includes an innovative, validated personalized prognostic tool that uses blood tests† to help predict the potential risk of developing serious Crohn's disease-related complications within three years.<sup>1,2</sup> CDPATH is available for use by US-based physicians and offered at no cost to eligible patients††, providing an opportunity for patients to partner with their physicians to map out a personalized disease management plan.

CDPATH is for adult patients (≥18 years old) diagnosed with Crohn's disease (CD) within the past 10 years who have yet to experience serious complications defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).<sup>1,2</sup> Patients can have blood drawn for the CDPATH test at one of more than 2,500 participating locations nationwide.

“At Takeda, we are driven by the challenge of making a meaningful difference in the lives of patients with inflammatory bowel disease, and working with partners to provide solutions that can help transform their care,” said Gamze Yüceland, Head, Gastroenterology Business Unit, Takeda Pharmaceuticals, U.S.A., Inc. “Offering CDPATH at no cost to eligible patients with CD will help deliver an innovative tool to the community that can help inform and personalize CD management.”

CD is a chronic inflammatory disease that affects the gastrointestinal (GI) tract. CD is one of the two most common types of inflammatory bowel disease (IBD). In the U.S., IBD impacts approximately three million people.<sup>3</sup> CD may be progressive and has the potential to lead to irreversible and destructive complications, which may require surgery.<sup>4</sup> Complications—which may include fistulas, abscesses and strictures—can occur, yet the course of CD is variable and difficult to predict.<sup>5,6,7</sup>

CDPATH integrates patient-specific serologic markers and genetic marker status, identified via a

blood sample, with a patient's CD characteristics to predict a low, medium or high risk for potentially developing serious CD complications over a three-year period. Test results are intended to be used in combination with a physician's clinical assessment and should not be the primary factor in diagnosing or making treatment decisions. Healthcare providers will receive a CDPATH test report with a graphical risk profile that can then be used to facilitate discussions with patients.<sup>1,2</sup>

To learn more and find a participating location for the required blood draw, visit:

**CDPATH.com**

Takeda has partnered with MiTest Health (“MiTest”) and Prometheus Laboratories Inc. (“Prometheus”) to establish the CDPATH program. MiTest Health defined and established the clinical relevance of the CDPATH model through an independent clinical study. Prometheus, a certified Clinical Laboratory Improvement Amendments (CLIA) laboratory, validated the model, and has received approval from the New York State Department of Health (NYS DoH) for CDPATH as a Laboratory Developed Test (LDT). Prometheus is the processing laboratory for the CDPATH program.

“Prometheus Laboratories is pleased to partner with Takeda on the CDPATH program as they share our commitment to patients,” said Mike Walther, President of Prometheus Laboratories Inc. “CDPATH is a prognostic tool that we believe can be important when considering an appropriate management approach for an individual patient.”

“Having a better understanding of their underlying disease can help patients take a more proactive role in their Crohn's disease management,” said Corey Siegel, MD, MS, MiTest Co-Founder, Section Chief of Gastroenterology and Hepatology and Co-Director of the IBD Center at the Dartmouth Hitchcock Medical Center. “For physicians, shared decision-making is a key component to a patient-centric management approach. CDPATH will allow healthcare providers to evaluate the potential variability and complexity of Crohn's disease for each individual patient, and support a more collaborative approach to managing their patient's CD.”

\*Serious complications are defined as bowel strictures,

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internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).

†The CDPATH risk assessment tool was developed and validated by Prometheus Laboratories Inc., a partner of Takeda, and has received approval from the New York State Department of Health (NYS DoH) as an LDT. Test results are provided via Prometheus Laboratories Inc. to physicians.<sup>2</sup>

### **About CDPATH**

††CDPATH is only validated in, and can only be performed on, adult Crohn's disease patients (≥18 years old) diagnosed within the past ten (10) years, who have not experienced a Crohn's disease complication, defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty). Beneficiaries must be covered by a commercial insurance plan or be uninsured. Those with state or federal health insurance program (including, but not limited to, Medicare, Medicaid, Department of Veteran's Affairs, Coast Guard, Public Health Service, or Department of Defense) are excluded from participating in this program. No insurance claims should be collected or processed, and no charges should be billed to the patient for CDPATH and shipping. Takeda has made arrangements to directly cover these charges. The cost of the blood draw, CDPATH, and shipping will be covered, provided a participating location is used for the blood draw. Participating locations include Quest Diagnostics (NYSE:DGX) Patient Service Centers, Prometheus-contracted phlebotomy locations and a mobile phlebotomy program. To find a participating location, please call CDPATH client services at 1-877-556-8766<sup>2</sup> or visit [www.CDPATH.com](http://www.CDPATH.com). Only the cost of CDPATH and blood sample shipping will be covered if the blood draw is completed in a physician's office and it is shipped to Prometheus, the processing laboratory, with the provided shipping label.

Due to the nature of clinical testing, there are limitations to consider for the CDPATH model:<sup>1</sup>

- Testing was conducted with only patients from North America; the results for patients from other regions have not been established.<sup>1</sup>
- Patients were recruited from large referral centers and may not be representative of all CD patients.<sup>1</sup>

- The model was built and validated in CD patients with 15 years as the maximum duration of disease; as such, it is not understood whether the model is applicable for patients with long-standing CD beyond 15 years from diagnosis.<sup>1</sup>
- The validity of the model after the first complication or surgery has not been tested or established; therefore, CDPATH is not intended to be used as a monitoring tool and may only be used one time for each patient.<sup>1</sup>

Healthcare Providers should not rely primarily on the risk predictions from CDPATH to make a clinical diagnosis or treatment decision regarding an individual patient. CDPATH should only be considered an additional piece of information in combination with a doctor's evaluation of a patient's CD. Doctors can decide if this tool is appropriate for individual patients as part of their overall assessment.

More information is available at

**CDPATH.com**

### **About Crohn's Disease**

Crohn's disease (CD) is one of the most common forms of inflammatory bowel disease.<sup>8</sup> It is a chronic, relapsing, remitting, inflammatory condition of the gastrointestinal (GI) tract that is often progressive in nature.<sup>4,9,10</sup> CD can affect any part of the GI tract from mouth to anus, and can affect the entire thickness of the bowel wall.<sup>11</sup> CD can present with symptoms of abdominal pain, diarrhea, and weight loss.<sup>10</sup> The cause of CD is not fully understood; however, recent research suggests heredity, genetics, environmental factors, and/or an abnormal immune response to microbial antigens in genetically predisposed individuals can lead to CD.<sup>12,13</sup>

### **Takeda's Commitment to Gastroenterology in the United States**

Takeda sees an urgent need for improving patient care in gastroenterology (GI) and has focused on improving the lives of patients through the delivery of innovative medicines and dedicated patient disease support programs for more than 25 years. We push boundaries and work across modalities, taking on the most complex GI conditions and the most neglected patient needs, boldly advancing original thinking and creatively tackling barriers to make a meaningful difference

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for patients. Challenging expectations and enabling innovative thinking, Takeda is part of more than 200 collaborations connecting people with a mutual commitment to action. Takeda is leading in areas of gastroenterology associated with high unmet need, such as inflammatory bowel disease, short bowel syndrome and motility disorders. Our GI Research & Development team is also exploring solutions in immune-related diseases, motility and liver diseases.

**About Takeda**

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetics and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people’s lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries and regions.

For more information, visit:

**takeda.com**

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**METABOLON ANNOUNCES JOINT DEVELOPMENT AGREEMENT WITH MAYO CLINIC TO CREATE NEW DIAGNOSTIC TESTS**

***Metabolon and Mayo Clinic will jointly research disease biomarkers and develop novel diagnostic tests for use in Mayo Clinic’s nationwide reference laboratories***

MORRISVILLE, N.C. – August 9, 2022 – Metabolon, Inc., the global leader in metabolomics solutions advancing a wide variety of research, diagnostic, therapeutic development, and precision medicine applications, announced a joint development agreement with Mayo Clinic to develop novel metabolomic biomarker diagnostic tests. Metabolon will analyze Mayo Clinic patient clinical samples across multiple cohorts to look for disease biomarkers. New diagnostic tests for Mayo Clinic to use in its nationwide Mayo Clinic Laboratories will be designed using these biomarkers.

Metabolon and Mayo Clinic will initially focus their investigation on metabolite biomarkers indicating inflammatory bowel disease and non-alcoholic fatty liver disease (NAFLD). Additional potential collaboration areas include research into biomarkers revealing the presence of Alzheimer’s disease, pancreatic cancer, breast cancer, inflammatory arthritis, and others.

“We are incredibly excited to be working with Mayo Clinic, as they bring significant clinical strength and robust commercialization capabilities to this vital research. Mayo Clinic’s laboratories are the third-largest in the U.S., performing over 25 million diagnostic tests each year,” said Rohan Hastie, Ph.D., President and CEO of Metabolon. “Collaborating with Mayo Clinic has the potential to help both parties expand their cutting-edge research into the critical role of metabolomic biomarkers as valuable indicators of human health.”

**About Metabolon**

Metabolon, Inc. is the global leader in metabolomics, with a mission to deliver biochemical data and insights that expand and accelerate the impact of life sciences research. Over 20 years, 10,000+ projects, 2,800+ publications, and ISO 9001:2015 and CLIA certifications, Metabolon has developed industry-leading scientific, technology, and bioinformatics techniques. Metabolon’s Precision

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Metabolomics™ platform is enabled by the world's largest proprietary metabolomics reference library. Metabolon's industry-leading data and translational science expertise help customers and partners address some of the most challenging and pressing questions in the life sciences, accelerating research and enhancing development success. The company offers scalable, customizable metabolomics and lipidomics solutions supporting customer needs from discovery through clinical trials and product life-cycle management.

For more information, please visit:  
**metabolon.com**

**About Metabolomics**

Metabolomics, the large-scale study of all small molecules in a biological system, is the only 'omics technology that provides a complete current-state functional readout of a biological system. Metabolomics helps researchers see beyond the genetic variation of individuals, capturing the combined impact of genetic as well as external factors such as the effect of drugs, diet, lifestyle, and the microbiome on human health. By measuring thousands of discrete chemical signals that form biological pathways in the body, metabolomics can reveal important biomarkers enabling a better understanding of a drug's mechanism of action, pharmacodynamics, and safety profile, as well as individual responses to therapy.



**JOB DESCRIPTION: Gastroenterologist**

NYU Langone Health – Suffolk County - Long Island, New York

We are actively seeking a **Gastroenterologist for our Ambulatory Practices** in Suffolk County, Long Island. The ideal physicians are motivated with an interest in being part of a growing World-Class, Patient-Centered Network!

**Position Qualifications:** Medical License, Board Eligible or Board Certified

NYU Langone Health Faculty Group Practice (FGP) is a group of more than 3,500 physicians in more than 350 sites owned and operated as part of the NYU Langone Health and the NYU School of Medicine. Our rapidly growing portfolio of satellite sites and our expertise of care continues to expand throughout the New York boroughs and Long Island. We seek to create a platform for evidence-based health promotion and disease prevention at the neighborhood level.

Additionally, patients have enhanced access to our vast range of highly specialized medical and surgical care at our hospital campuses as well as the growing network of ambulatory facilities. When you join us, the Physician Network Development Office will work with you to build and maintain relationships that promote access to the world-class care and research available at NYU Langone Health.

For consideration, please send your CV to:  
**Networkdevelopment@nyulangone.org**

EOE including Disabled and Vets VEVRAA Federal Contractor