NEWS RELEASE

Onco-Innovations' Inka Health Publishes Roche-Sponsored Study Advancing Real-World Oncology Research

Vancouver, Canada – April 10, 2025 – Onco-Innovations Limited (CSE: **ONCO**) (OTCQB: **ONNVF**) (Frankfurt: **W1H**, WKN: **A3EKSZ**) ("**Onco**" or the "**Company**") is pleased to announce that its subsidiary, Inka Health Corp. ("**Inka Health**"), has published a significant and novel study titled *Quantitative Bias Analysis for the Assessment of Bias in Comparisons between Synthetic Control Arms* (the "**Study**") published in *JAMA Network Open*[1] in March 2025, addressing a critical methodological gap in real-world oncology research. The Study[2], sponsored by F. Hoffmann-La Roche (**Roche**), the fifth-largest pharmaceutical company in the world by revenue[3], presents a novel approach to improving the validity of clinical comparisons drawn from real-world data. Specifically, it provides a method to adjust for unseen differences between patient groups that can lead to misleading results when randomized trials[4] are not possible.

As regulatory bodies increasingly turn to real-world evidence in evaluating new treatments[5], the Study contributes a significant tool for addressing underlying bias in real-world data sources, helping ensure that treatment effects observed outside of traditional trials can be interpreted with greater scientific rigor and confidence.

The Study was led by Alind Gupta, co-founder of Inka Health, in collaboration with Roche and internationally recognized experts in medical research, including Harvard Professor Miguel Hernán[6]. This research builds on Inka Health's efforts to address real-world challenges in oncology trial design, particularly in settings where traditional randomized trials are not feasible. Q-BASEL applies Quantitative Bias Analysis (QBA) to external control arm[7] (ECA) studies, which compare single-arm trial results to outcomes derived from historical or real-world data. These types of studies are increasingly used when randomized controlled trials are not feasible, such as in advanced non-small cell lung cancer (aNSCLC).

The Q-BASEL study emulated 15 treatment comparisons in advanced non-small cell lung cancer (aNSCLC) by using real-world patient data to recreate experimental arms from previously conducted randomized trials. The research team applied Quantitative Bias Analysis (QBA) after adjusting for known baseline differences, using evidence from medical literature, clinical trial data, and expert input to account for unmeasured or mismeasured factors. The Study then compared the results from these real-world emulations to the original randomized trial outcomes. The findings showed that applying QBA meaningfully improved the alignment between the two, demonstrating its ability to reduce bias and enhance the reliability of external control arm analyses.

By incorporating external evidence from clinical trials, expert opinion, and published literature, the QBA approach adjusts for potential bias introduced by unmeasured or mismeasured variables. In simpler terms, it helps account for hidden differences between patient groups that could otherwise lead to misleading comparisons. The Study showed that this method substantially improves the alignment of real-world data with randomized trial outcomes, offering a more reliable foundation for clinical decision-making and regulatory assessment.

The application of QBA in this context is particularly relevant as regulatory agencies such as the U.S. Food and Drug Administration[8] (FDA), European Medicines Agency[9] (EMA), National Institute for Health and Care Excellence[10] (NICE), and Canada's Drug Agency [11] (CDA-AMC) continue to support the use of ECAs in evidence submissions. The methodology demonstrated in Q-BASEL offers a scalable solution with potential application across a broad range of therapeutic areas. Onco-Innovations and Inka Health intend to integrate this capability into Inka's SynoGraph

platform, enhancing its ability to support pharmaceutical partners in optimizing real-world evidence strategies and advancing access to innovative treatments in settings where traditional trials remain challenging.

"By addressing a longstanding gap in the way we evaluate treatments using real-world data, this work brings us closer to making faster, evidence-based decisions in areas where patients often cannot wait for traditional trials. It also lays the foundation for how SynoGraph can support the next generation of real-world studies with greater methodological integrity. Integrating these tools into our platform enables us to help biopharma partners generate more credible evidence, streamline regulatory submissions, and expand access to innovative therapies in difficult-to-study cancer populations," said Alind Gupta, Co-founder of Inka Health.

About Inka Health

Inka Health is an AI-driven analytics company revolutionizing oncology research and drug development through advanced causal AI. Its proprietary platform, SynoGraph, leverages AI-powered causal inference to identify which cancer patients are most likely to respond to specific treatments, advancing precision medicine. By integrating diverse multimodal medical data—including genomics, transcriptomics, and proteomics—SynoGraph uncovers hidden insights that can optimize treatment decisions and clinical trial design. With this cutting-edge technology, Inka Health helps pharmaceutical companies accelerate drug development, reduce trial failures, and bring life-saving therapies to market faster.

About Onco-Innovations Limited

Onco-Innovations is a Canadian-based company dedicated to cancer research and treatment, specializing in oncology. Onco's mission is to prevent and cure cancer through pioneering research and innovative solutions. The company has secured an exclusive worldwide license to patented technology that targets solid tumours, setting new standards in cancer treatment. Onco's commitment to excellence and innovation drives it to develop advanced therapies that improve patient outcomes and offer hope in the fight against cancer.

ON BEHALF OF ONCO-INNOVATIONS LIMITED,

"**Thomas O'Shaughnessy**"
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Forward-Looking Statements Caution. This news release contains forward-looking statements relating to the further development, potential commercialization and benefits of the Company's technologies, including SynoGraph, and the Company's other research initiatives, and the prospects of the Company, including its ability to safeguard its technologies, and the Company's business and plans generally, and other statements that are not historical facts. Forward-looking statements are often identified by terms such as "will", "may", "potential", "should", "anticipate", "expects" and similar expressions. All statements other than statements of historical fact, included in this release are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ

materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the failure to further develop, prove out or commercialize the Company's technologies, the failure to receive a patent or to otherwise safeguard the Company's intellectual property rights, the failure to successfully complete further trials and studies, and other risks detailed from time to time in the filings made by the Company with securities regulators. The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company will update or revise publicly any of the included forward-looking statements as expressly required by applicable law.

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[1] *JAMA Network Open* is an international, peer-reviewed, open access, general medical journal that publishes research on clinical care, innovation in health care, health policy, and global health across all health disciplines and countries for clinicians, investigators, and policy makers. (see https://jamanetwork.com/journals/jamanetworkopen/pages/for-authors#fa-about for more information)

[2] Gupta A, Hsu G, Kent S, et al. Quantitative Bias Analysis for Single-Arm Trials With External Control Arms. JAMA Netw Open. 2025;8(3):e252152. doi:10.1001/jamanetworkopen.2025.2152

[3] https://www.proclinical.com/blogs/2024-7/who-are-the-top-10-pharma-companies-in-the-world-2024

[4] Randomized trials, also known as randomized controlled trials (RCTs), are a type of study where participants are randomly assigned to different groups to compare the effects of different treatments or interventions. This random assignment helps ensure that groups are similar, allowing for a more fair comparison of treatment effects (see https://pmc.ncbi.nlm.nih.gov/articles/PMC6235704/).

[5] The U.S. Food and Drug Administration's 2018 Real-World Evidence Framework explicitly outlines how RWE can be used to support regulatory decisions. The 21st Century Cures Act encourages the FDA to expand the use of RWE.(see https://www.fda.gov/media/120060/download for more information)

[6] Gupta A, Hsu G, Kent S, et al. Quantitative Bias Analysis for Single-Arm Trials With External Control Arms. JAMA Netw Open. 2025;8(3):e252152. doi:10.1001/jamanetworkopen.2025.2152

[7] In clinical trials, control arms are groups that receive either a placebo or standard treatment to compare against the experimental therapy.

[8] https://www.fda.gov/media/120060/download

[9] https://www.ema.europa.eu/en/about-us/how-we-work/big-data/real-world-evidence/data-analysis-real-world-interrogation-network-darwin-eu

[10] https://www.nice.org.uk/corporate/ecd9/resources/nice-realworld-evidence-framework-pdf-1124020816837

[11] https://www.cda-amc.ca/real-world-evidence-and-health-technology-assessment-past-present-and-future