INOVIQ ENGAGES RESEARCHDX TO DEVELOP AND VALIDATE SUBB2M-BASED TESTS

- **INOVIQ's SubB2M technology detects the pan-cancer biomarker Neu5Gc found at elevated levels in multiple human cancers**
- **SubB2M-based tests are in early development for multiple uses including monitoring of breast and ovarian cancers, and for a general health panel**
- **ResearchDx, a US-based specialty contract diagnostics organisation, will undertake further development and validation of SubB2M-based tests**
- **Key milestones met to transfer SubB2M-based tests to an accredited CRO for commercial development and also for a potential LDT laboratory partner in the USA**

Melbourne, Australia, 5 April 2022: INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**) is pleased to announce that it has engaged US-based contract diagnostics organisation ResearchDx to further the development and validation of its SubB2M-based tests in the USA.

SubB2M technology and pipeline

INOVIQ is developing SubB2M-based tests for the monitoring and detection of cancer. The SubB2M technology is based on an engineered protein that specifically detects the pan-cancer biomarker Neu5Gc found in multiple human cancers including breast, ovarian, prostate and others. The SubB2M pipeline includes proof-of-concept stage **SubB2M-based immunoassays** for monitoring breast and ovarian cancers, and a **SubB2M-based SPR[1] test** for the detection of Neu5Gc levels in a general health panel.

Initial research on the SubB2M tests including assay design, prototype development and initial feasibility testing using RUO[2] reagents was conducted under a collaborative research agreement with the Institute for Glycomics at Griffith University. INOVIQ subsequently contracted the development of in-house CA15.3 and CA125 monoclonal antibodies for its breast and ovarian cancer immunoassays, respectively. Manufacturing of SubB2M was transferred from its licensor, University of Adelaide, to a contract manufacturer. These work programs are nearing completion and the SubB2M program is now in the process of being transferred to an accredited contract research organisation (CRO) for completion of feasibility testing using the new antibodies and commercial assay development.

Master Services Agreement signed with ResearchDx for diagnostic development services

INOVIQ has signed a Master Service Agreement (MSA) with ResearchDx to provide contract services under separate Task Order (TO) agreements to complete technology transfer, feasibility testing[3] and assay development, followed by the analytical validation and clinical validation of the SubB2M-based tests.

Task Order #1 is for the technology transfer, feasibility testing and assay development of the SubB2M-based tests including the SubB2M/CA15.3 test for monitoring breast cancer, SubB2M/CA125 test for monitoring ovarian cancer, and the SubB2M-SPR test for detection of Neu5Gc concentrations. This phase of work is expected to be completed within 6 months from commencement date. INOVIQ will pay agreed costs for the work undertaken and related sample, reagent, and consumable expenditure. Further analytical validation and clinical validation activities will be completed under future task orders.

ResearchDx is US-based full-service contract diagnostics organization (CDO) that offers a 'start-finish' partnership for the development of companion diagnostics (CDx), in vitro diagnostics (IVDs) and laboratory developed tests (LDTs). ResearchDx has built a strong reputation with biopharma and diagnostics companies in the US and internationally for its integrated diagnostics business model, capabilities and expertise in the design, development, validation, and registration of diagnostics.

[1] Surface plasmon resonance (SPR) is a non-invasive optical biosensing technology
[2] Research use only (RUO)
[3] Testing and optimisation in small sample cohorts

Future US laboratory partnering opportunity

ResearchDx operates a CAP[4]/CLIA[5] certified laboratory, PacificDx, that offers state-of-the-art facilities and expertise to undertake the design, analytical and clinical validation of Laboratory Developed Tests (LDTs) within a single laboratory (including high-complexity tests). This makes ResearchDx an ideal partner for our SubB2M-based LDTs in the USA where the tests can be developed and validated for their intended use in the PacificDx clinical laboratory and offered to hospitals, clinicians, and doctors' offices to aid in the detection of cancer. The LDT route provides a fast-to-market commercialisation path for the SubB2M tests in the USA.

INOVIQ CEO, Dr Leearne Hinch said, *"As a specialist contract diagnostic organisation with a US-based CAP/CLIA certified laboratory, ResearchDx is an ideal partner to help progress the development and commercialisation of our SubB2M-based tests in the USA. This agreement is important as it delivers two milestones-in-one with ResearchDx providing accredited CRO services and being a potential clinical laboratory partner for SubB2M-based lab developed tests in the USA."*

Authorised by the Company Secretary, Tony Di Pietro.

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ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) (**INOVIQ**) is developing and commercialising innovative diagnostic and exosome-based products to improve the diagnosis and treatment of cancer and other diseases. The Company has commercialised the hTERT test used as an adjunct to urine cytology testing for bladder cancer and the EXO-NET pan-exosome capture tool for research purposes. Our cancer diagnostic pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast, prostate, and other cancers. For more information on INOVIQ, see www.inoviq.com.

ABOUT RESEARCHDX

ResearchDx is US-based **full-service contract diagnostics organization (CDO) that offers a 'start-finish' partnership** for the co-development of **companion diagnostics**. Providing independent and unbiased guidance, we design, manage and coordinate all aspects of the diagnostics development process, concept through regulatory approval, based on your goals and objectives.

ResearchDx offers a custom **In Vitro Diagnostics** (IVD) experience from assay concept and biomarker discovery, through clinical validation and regulatory approval, to final kit manufacture, we can step in at any stage in the process to support your project needs. The ResearchDx team is highly skilled in all project phases associated with regulated and non-regulated environments in both the United States and abroad, supporting diagnostic development partnerships worldwide. We have broad development capabilities with a diverse array of platforms and technologies to support all development and testing needs, molecular and non-molecular.

ResearchDx also designs and performs analytical and clinical validations for **Laboratory Developed Tests** (LDTs) or custom assays through its PacificDx clinical laboratory. Our CAP/CLIA certified lab, PacificDx offers state-of-the-art facilities and expertise to meet your immediate clinical and pre-clinical needs for high-quality clinical and biopharmaceutical testing services.

[4] College of American Pathologists (CAP) accredited. CAP accreditation ensures laboratories meet industry standards from CLIA, FDA and OSHA for test accuracy and patient diagnosis.
[5] Clinical Laboratory Improvement Amendments (CLIA) certified. CLIA regulates laboratory testing and requires clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.

FORWARD LOOKING STATEMENTS

This announcement contains certain 'forward-looking statements' within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as 'may', 'should', 'expect', 'anticipate', 'estimate', 'scheduled' or 'continue' or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.