PRESS RELEASE 3 November 2020, 07:00 CET

# Biocartis and GeneproDx To Collaborate on Fully Automated ThyroidPrint® test on Idylla™

**Mechelen, Belgium, 3 November 2020** – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces it has signed a license, development and commercialization agreement with GeneproDx, a molecular diagnostics company based in Santiago, Chile, for the development of GeneproDx's novel genomic test ThyroidPrint® on Biocartis' rapid and easy to use molecular diagnostics platform Idylla™.

Under the terms of the agreement, GeneproDx will take the lead in the development of the Idylla™ ThyroidPrint® test, whereas Biocartis will be responsible for the distribution of the ThyroidPrint® on Idylla™ through its growing commercial infrastructure of Idylla™ instruments across the globe.

Thyroid nodules are very common and are often detected during routine medical exam or by patient self-assessment. Only some 10% of fine needle aspirate (FNA) biopsy procedures[1] reveal the presence of malignant cells, while approximately 70% confirm a benign (non-cancerous) diagnosis. The remaining 20% are reported as indeterminate, meaning that no certain diagnosis can be provided to physician and patients[2]. Annually, over 1.2 million thyroid cytology evaluations are reported as indeterminate[3]. In patients with such result, diagnostic surgery of the thyroid gland is frequently recommended[4]. The risk of malignancy in these indeterminate cases is estimated to be between 15-35%, meaning that surgical intervention is unnecessary in up to 65-85% of these cases[4].

ThyroidPrint® is a qRT-PCR[5] based mRNA-expression classifier[6] test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant[7]. A benign test result[8] allows physicians to recommend watchful waiting as an alternative to diagnostic surgery. This prevents exposing patients to surgical risks and permanent thyroid hormone supplementation. Moreover, it significantly reduces health costs associated with unnecessary surgery[3].

GeneproDx's ThyroidPrint® was initially clinically validated in a multicenter trial in Chile, after which it was launched in Latin America[3] in September 2018. Furthermore, the test was clinically validated in a second independent multicenter, prospective trial in the US in December 2019, demonstrating that ThyroidPrint® performs in the same manner in populations with different ethnicities and genetic backgrounds[9]. Currently, a new international validation study is ongoing, including an estimated 200 individuals with indeterminate cytology results[10], in leading academic sites in Europe, the US and Latin-America.

**Herman Verrelst, Chief Executive Officer of Biocartis, commented:** *"We are very pleased to enter into a new collaboration where a high value gene signature test is ported on Idylla™. By developing an Idylla™ version of ThyroidPrint®, GeneproDx and Biocartis may enable broad availability of this test to laboratories and hospitals around the world, to help address this high clinical unmet need in thyroid patients. For Biocartis, this also means further expansion of the oncology menu into thyroid cancer."*

**Hernán González MD, PhD, Professor of Surgery at the Pontifical Catholic University of Chile and Founder of GeneproDx, reacted:** *"As clinicians, an important challenge today is to determine whether a thyroid nodule is malignant and a patient really needs to undergo surgical resection of the thyroid gland. In our first real world clinical utility experience, ThyroidPrint® revealed a meaningful impact on the physician decision by reducing diagnostic surgery by more than 70% in patients with indeterminate cytology[11]. We are excited to use the rapid and easy-to-use Idylla™ technology to develop a ThyroidPrint® test that physicians can request to be performed in their local laboratories. As such, patients across the world can have the first of its kind, fast and easy-access diagnostic solution for indeterminate thyroid cytology results."*

Development of the ThyroidPrint® on Idylla™ will be initiated in Q4 2020.

**--- END ---**

[1] In FNA biopsy procedures, approximately 350,000 of which are performed annually in the US alone (Popoveniuc G, Jonklaas J. Thyroid nodules. Med Clin North Am. 2012;96(2):329-349. doi:10.1016/j.mcna.2012.02.002), cells are collected from the thyroid nodule for microscopic examination
[2] Faquin WC, Bongiovanni M, Sadow PM 2011 Update in thyroid fine needle aspiration. Endocrine pathology 22:178-183.
[3] S. Vargas-Salas et al., Genetic testing for indeterminate thyroid cytology: review and meta-analysis, 2018, Endocrine-Related Cancer, https://erc.bioscientifica.com/
[4] To determine the true nature of the nodule as standard practice. Haugen BRM, Alexander EK, Bible KC, Doherty G, Mandel SJ, Nikiforov YE, Pacini F, Randolph G, Sawka A, Schlumberger M, Schuff KG, Sherman SI, Sosa JA, Steward D, Tuttle RMM, Wartofsky L 2015 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid: official journal of the American Thyroid Association
[5] Quantitative Reverse Transcription PCR. PCR or Polymerase chain reaction is an efficient and cost-effective way to copy (amplify) small segments of DNA or RNA. As such, millions of copies of a section of DNA are made in just a few hours, allowing further analysis for clinicians to diagnose and monitor diseases using a minimal amount of sample, such as blood or tissue. Source: www.genome.gov, last consulted on 22 October 2020
[6] Based on RTqPCR analysis, combined with an advanced machine learning algorithm
[7] This means that the probability of the nodule being malignant drops from 25% to less than 5%, allowing follow-up to be recommended as an alternative to surgery. Info and source: https://thyroidprint.com/en/home-us/, last consulted on 22 October 2020
[8] NPV (Negative Predictive Value) > 95%
[9] M. Zafereo et al., A Thyroid Genetic Classifier Correctly predicts benign nodules with indeterminate cytology: two independent multicenter, prospective validation trials
[10] Results are expected end of October 2021
[11] Dominguez et al., ThyroidPrint: Preliminary Clinical Utility Experience. *Archives of Endocrinol & Metab* Vol 63, Suppl 02, pp 81 – 2019

**More information:**

**Biocartis**
Renate Degrave
Head of Corporate Communications & Investor Relations Biocartis
e-mail rdegrave@biocartis.com
tel +32 15 631 729
mobile +32 471 53 60 64
@Biocartis_ www.linkedin.com/Biocartis

**GeneproDx**
Francisca Mena
Head of Corporate Communications GeneproDx
email fmena@geneprodx.com
tel +569 5608 654

**About Biocartis**

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as tests for SARS-CoV-2 and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

**About GeneproDx**

GeneproDx's mission is to offer patients with indeterminate thyroid nodules the highest quality of precision medicine through ThyroidPrint®. GeneproDx's vision is to be pioneers and leaders in the diagnosis of patients with indeterminate thyroid nodules in Latin America, through permanent innovation and the highest quality standards. GeneproDx's ThyroidPrint® is the first molecular test for indeterminate thyroid nodules clinically validated in Latin America and the US. More info on www.thyroidprint.com.