Zorginstituut Nederland
Eekholt 4
1112 XH DIEMEN

Amsterdam, 20 October 2017

Re: EUnetHTA assessment report MammaPrint

Dear Sir or Madam,

On September 29 we have received a draft of the EUnetHTA MammaPrint® Added value of using the gene-expression signature MammaPrint® for adjuvant chemotherapy decisions in early breast cancer Project ID: OTCA04 report authored by ZIN for our review. The report assesses the clinical utility of MammaPrint in early stage breast cancer. Clinical utility is the key driver for positive reimbursement decisions in Europe.

We understand that EUnetHTA intends to publish the report early 2018 and that ZIN (or the appropriate government authority) will use the report as a basis for its forthcoming advice (or decision making process) regarding the inclusion of Agendia's proprietary diagnostic test, MammaPrint, in the Dutch basic health insurance (*basisverzekering*).

This letter is addressed to you in your capacity of Dutch government agency, performing the tasks attributed and delegated to you, and as a member of the EUnetHTA network.

Considering topic and purpose of the report, you will appreciate that the impact of this report on not only on Agendia's business but also for early stage breast cancer patients will be significant and that it is therefore in Agendia's interest that the report is true and accurate and not misleading in any respect.

We have been given until 20 October 2017 to provide you with our review of the draft report. Our request to extend this deadline until 10 December 2017 has been denied. Our enclosed reaction is submitted timely.

We have carefully reviewed the draft report. In the enclosed document we have amalgamated our findings. We must conclude that the shortcomings of the draft report are many and of such magnitude that we fear that uncorrected publication of the report will be seriously detrimental to the business

Agendia NV | Science Park 406 | 1098 XH Amsterdam | The Netherlands | Phone: +31 20 4621500 | Fax +31 20 4621505
Agendia, Inc. | 22 Morgan | Irvine | California 92618 | United States | Phone: 888.321.2732 | Fax: 888.756.7548
info@agendia.com | www.agendia.com

interests of Agendia and its stakeholders. As such, publication of the report, disregarding Agendia's detailed rebuttal, would be unlawful (*onrechtmatig*) and breach a duty of care owed by ZIN to Agendia.

Please note that Agendia encourages debate and participates in high ranking and widely publicized clinical studies that include its tests. Agendia welcomes publications regarding any of its products and services, always provided that such publications are consistent with academic standards, are not false or misleading. The draft report in its current form fails to conform to these widely accepted standards. In any event, we feel that the current draft report fails to meet the standards that apply to documentation underlying any advice or decision (making process) regarding the inclusion of any care into the basic insurance.

It is imperative therefore that the report be corrected, before publication, taking into account Agendia's findings.

Considering the remaining short term before the intended publication of the report, the intended purpose of the report and the extent of Agendia's comments, we hereby invite ZIN to meet with representatives of Agendia to discuss the arisen situation on the shortest possible date. Please contact Mark Straley at mark.straley@agendia.com to arrange this meeting.

We look forward to your reply.

Yours sincerely,
Agendia N.V.

Mark Straley
Chief Executive Officer