EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA), Scientific Committee members and experts

Public declaration of interests

I, **Jonas Bergh**

Organisation/Company: Karolinska Institutet

Country: Sweden

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

Period	Company	Products	Therapeutic Indication
05/2017-03/2020	Merck, International Steering Committee (reported previously) for KN 522 (No personal payments)	Neoadjuvant randomized study	No indication, interim data was reported 2019 and accepted for publication 2020. Not member of Steering Committee from March 27, 2020.

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

Period	Company	Products	Therapeutic Indication
10/2012-(current)	Roche	BEVPAC. Paclitaxel and bevacizumab.	Breast Cancer. Biopsy + PET/CT study. Study Director.
11/2014-10/2016	Boehringer-Ingelheim	BI BrEEast, phase 1b study, exemestane + everolimus vs exemestane and everolimus alone.	Locally advanced/metastatic breast cancer. Follow up ongoing. National Co-ordinator, Steering Committee.
11/2014-(current)	Roche	PREDIX HER2, part of a set of translational phase II trials based on molecular subtypes.	Neoadjuvant response-guided treatment of HER2-positive breast cancer. Study Director.
10/2014-(current)	BIG, sponsors NCI-NRG, AstraZeneca, Merck	BIG 6-13, OlympiA, phase III study, olaparib versus placebo	BRCA mutated high risk HER2-negative breast cancer. Member of the International Steering Committee.
09/2015-10/2017	Pfizer	PREDIX-Luminal A. Endocrine therapy +- palbociclib. Academic study.	Neoadjuvant response-guided treatment. JB co-investigator and study director.
01/2016-(current)	Pfizer	PREDIX-Luminal B. Endocrine therapy +- palbociclib. Academic study.	Neoadjuvant response-guided treatment. JB co-investigator and study director.
01/2016-(current)	Merck	MK-3475. Randomised multicenter study with pembrolizumab.	First line metastatic disease TNBC. JB National co-ordinator.
01/2016-(current)	Merck	Neoadjuvant study with pembrolizumab.	Breast cancer. JB co-investigator.
09/2015-10/2016	Roche	Sandpiper GO29058. Phase III study, taselisib + fulvestrant vs placebo + fulvestrant.	ER-positive and HER2-negative locally advanced or metastatic breast cancer. JB National co-ordinator. The study is closed at Radiumhemmet.
09/2017-(current)	Pfizer	Pasiphae. Phase II study, palbociclib+fulvestrant vs capecitabine	HER-positive/HER2-negative advanced breast cancer and endocrine resistance. JB Study Director.
05/2017-(current)	Merck	Keynote-522. Phase III study, pembrolizumab+chemotherapy vs placebo+ chemotherapy as neoadjuvant treatment, followed ny pembrolizumab vs placebo as adjuvant treatment.	Locally advanced triple-negative breast cancer. JB local investigator at Karolinska and member of the international steering committee.
04/2019-(current)	Academic study supported by the Swedish Research Council and drug support by Roche	PREDIX 2, HER2. Randomised, neoadjuvant phase II study, trastuzumab + pertuzumab + carboplatin + docetaxel + epirubicin + cyclophosmonide +- ateziolizumab	Neoadjuvant breast cancer therapy. Renske Altena PI, JB study Director.

01/2012-(current)	BIG and US Intergroups, Roche	BIG 4-11, Aphinity. CT + trastuzumab + pertuzumab, Adjuvant use.	JB country representative for SweBCG, member of the International Steering Committee.

2.7 Grant / Funding to organisation /institution

Company	Subject Matter
Sanofi Aventis	Clinical Study
Amgen	Clinical Study
Merck	Gene Expression and SNP studies
Roche	Clinical Study + Biopsy + CT/PET study (start date 30/1 2013).
Pfizer	Biopsy + PET/CT Substudy
Bayer	Biopsy + CT/PET substudy
AstraZeneca	AstraZeneca-Karolinska Institutet research collaboration. Studies on molecular markers and early drug development.

2.8 Close family member interest

No interest declared

2.9 Any other interests or facts

- Regarding research funding and grants - all payments are to Karolinska University Hospital and/or Karolinska Institutet.
- Regarding previous 'consulting' role - all payments made to Asklepios Medicin.
- Elected member of the Ethics Committee, Karolinska Institutet 2007-2009 and from 2014-2019.
- Chairman for the National Breast Cancer Guidelines produced by the Swedish Board for Health and Welfare 2013-2019.
- External expert to the Swedish Medical Product Agency 2000-.
- Member of consensus panels for early and advanced breast cancer, respectively.
- Previous member of ESMO/ASCO task force for an "Oncology Curriculum".
- Chairman Research & Education Karolinska Oncology/Cancer Centre Karolinska 2011-2018.
- Has participated as lecturer in meetings organized by FDA/ASCO/NCI and ESMO/ECCO/EBCC.
- Author on a chapter "Prognostic and predictive factors in early, non-metastatic breast cancer" for "UpToDate", www.uptodate.com. Author honoraria to Askleipos Medicin.
- Member of the Scientific Council WHO/IARC, Lyon, France 2016-2019.
- Member of the Editorial Board, Journal of Clinical Oncology, 2016-
- Since the most recent directives for SAG; no personal payments for lectures and/or chairmanships, if the meeting is arranged or sponsored by the pharmaceutical and/or diagnostic industries.
- Member of ASCO International Affairs Committee" 2016-2019.
- Member of the Nobel Assembly 2017- and the Nobel Committee 2019-.
- Visiting Professor of Breast Cancer Research, Oxford University, 2017-2019.
- Visiting Professor of Oncology, Oxford University, 2019-2024.
- Director Strategic Research Program in Cancer, Karolinska Institutet, 2016-2019.
- Director of Cancer Research KI, Karolinska Institutet, 2019-

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance

development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.
- Not to disclose (or authorise any other person to disclose) in any way to any third party any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full Name:	Jonas Bergh
Date:	2020-05-31

For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template