

## ESMO 2016 Congress Confidentiality Policy and Confidentiality Policy Exceptions

Abstracts submitted to ESMO 2016 Congress are considered confidential until publicly released in connection with the ESMO Congress. Prior to public release, the author, co-authors, research sponsors, journalists and others may not:

- Make the information public or provide it to others who can make it public (e.g. press);
- Publish or present the information or provide it to others who can make it public
- Use the information for trading purposes or provide it to others who can use it for trading purposes

When a publicly traded company is required to disclose data or other information from a confidential abstract in advance of the public release to satisfy requirements of the US Securities and Exchange Commission (SEC) or a corresponding body in another country, the abstract is still eligible for inclusion in the ESMO 2016 Congress Programme provided that the company submits to the ESMO Programme Manager (Programme@esmo.org) in advance of the release written notification of the requirement to issue information in accordance to SEC regulations.

In the interest of effective peer-reviewed presentation of data at the ESMO Congress, and particularly if the abstract has been tentatively included in the official ESMO 2016 Congress Press Programme, the company is required to get in contact with the ESMO Press Office in advance of the release to notify that a press release regarding an abstract included in the official ESMO 2016 Congress Press Programme will have to be issued in accordance to SEC regulations.

ESMO recommends that the company's press release adheres to the Sample Qualitative Press Release which is supposed to:

1. Summarize data cited in the abstract in a qualitative way rather than providing specific quantitative information, e.g. exact figures on the study
2. Avoid interpretations about the implications of the data for clinical practice
3. Note that full data has been submitted to, and will be presented at, ESMO 2016 Congress in an official Programme session.

### **SAMPLE QUALITATIVE PRESS RELEASE**

[DATE]

**[CompanyName] announces that phase [ ] trial of compound X for [DiseaseName] met [ ] endpoint(s)**

**QUALITATIVE:** [CompanyName] ([StockExchange info]) announced today that its Phase [ ] clinical trial of compound X met its [ ] endpoint(s) of [overall survival/progression-free survival, etc.] for patients with [DiseaseName], when compared with patients receiving a placebo. Further results will be presented at the ESMO 2016 Congress in Copenhagen, 07-11 October 2016

*QUANTITATIVE: [CompanyName] ([StockExchange info]) announced today that its Phase [ ] clinical trial of compound X met its [ ] endpoint(s) of [overall survival/progression-free survival, etc.] for patients with [DiseaseName], when compared with patients receiving a placebo. In the trial, [No. of] patients were randomized to either the treatment arm, receiving xx mg. of compound X every week, or the placebo arm. Overall survival for the treatment arm was xx%, compared with xx% for the placebo arm.*

**QUALITATIVE:** “[CompanyName] is pleased to report that compound X has shown significant results in the treatment of this difficult cancer,” said [Name], [position, affiliation]. “We are deeply appreciative of the cancer patients and clinical investigators and who participated in this trial, and look forward to presenting full/final/complete results at the ESMO 2016 Congress.”

*QUANTITATIVE: “[CompanyName] is thrilled to report that compound X has shown significant results in the treatment of this difficult cancer,” said [Name], [position, affiliation]. “The statistically significant xx%*

*difference in [overall survival/progression-free survival, etc.] between the treatment and placebo arms is promising news for patients, and will likely change the standard of care.”*

#### **About the compound X trial**

**QUALITATIVE:** In this [national/international/multi-center, etc], phase [ ], randomized, placebo-controlled trial, more than xxxx patients with [DiseaseName] who had (no) prior therapy were randomized to receive either compound X or a placebo. The trial’s objective was to determine [overall survival/progression-free survival, etc.] between the compound X and placebo arms.

*QUANTITATIVE: In the trial, [exact number of] patients were randomized to either the treatment arm, receiving xx mg. of compound X every week, or the placebo arm. [Overall survival/progression-free survival, etc.] for the treatment arm was xx%, compared with xx% for the placebo arm. There were no considerable differences regarding side effects between the treatment and placebo arms. The most serious side effects were [1, 2, 3, etc.]*

#### **About [CompanyName]**

[CompanyName boilerplate]

#### **Forward Looking Statements**

[CompanyName boilerplate]