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## ESMO Congress Confidentiality Policy and Confidentiality Policy Exceptions

Abstracts submitted to ESMO events are considered confidential by ESMO, the author, co-authors and research sponsors 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

*ESMO reserves the right to provide its press releases a few days before public release to a selected list of journalists who have previously agreed in writing to respect the ESMO embargo policy.*

If details or relevant information from the abstract or additional study data are disclosed in advance of public release in connection with ESMO events, the abstract will no longer be eligible for inclusion in the ESMO scientific programme and/or will be subject to removal.

**Confidentiality policy exceptions**

According to the Confidentiality policy, data and other information in a research abstract is confidential until public release in connection with the relevant ESMO congress.

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 Scientific Programme, provided that the company submits to the ESMO Programme Department (programme@esmo.org) written notification of the requirement to issue information in accordance to SEC regulations, in advance of the release.

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

ESMO recommends that the company's press release adheres to the Qualitative Sample Press Release (provided by the ESMO Press Office) and:

1. Summarises data cited in the abstract in a qualitative way rather than providing specific quantitative information, including exact figures on the study

2. Avoids interpretations about the implications of the data for clinical practice

3. Notes that full data has been submitted for presentation at the ESMO XXXX Congress.

The ESMO Press Office will review the company's press release to ensure it adheres to the Qualitative Sample Press Release and evaluate if the abstract can still be included in the official ESMO Press Programme.

If the press release includes significantly more information than ESMO's recommendations, the abstract's placement in the ESMO Congress is subject to change and can be withdrawn from the official ESMO Press Programme.

**Copyright**

ESMO holds copyright of all abstracts accepted for the ESMO XXXX Congress and therefore abstracts cannot be made public prior to official publication.

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The submission of abstracts accepted for ESMO XXXX to subsequent conferences, organised either by ESMO or third-parties, requires the permission of ESMO as copyright holder. Requests must be addressed to programme@esmo.org

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***SAMPLE QUALITATIVE PRESS RELEASE***

[DATE]

**[CompanyName] announces that phase [ ] trial of compound X for [DiseaseName] met/did not meet [ ] 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 [Name of ESMO event, i.e. *the ESMO XXXX Congress in Madrid, Spain, 08-12 September XXXX).*

*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 [Name of ESMO event]."

*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]

If you have any questions, please write to media@esmo.org