SAMPLE QUALITATIVE PRESS RELEASE (annex to ESC Media and Embargo Policy)

Should not include any information that is not publicly available (for example on https://clinicaltrials.gov/)

Company X announces that phase X clinical trial of compound X for XXX met/did not meet XXX endpoint(s)

Date, place

XXX announced today that its phase X trial of XXX met/did not meet its endpoint(s) of XXX, for patients with XXX when compared with patients receiving a placebo (no interpretation of the data or its implications for clinical practice allowed).

In this multi-center, phase X, randomised XXX trial, more than XXX patients with XXX who had no prior therapy were randomised to receive either XXX or a placebo. The trial's objective was to determine XXX

"It is the first study to XXX" said XXX

"We thank patients and researchers who participated in this trial and look forward to presenting full results at a Hot Line session during the upcoming ESC Congress in XXX," said XXX.

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NOT ALLOWED

<u>Positive results from XXX five-year XXX study in XXX demonstrate long-term clinical benefits of early combination</u> <u>treatment with XXX and XXX</u>

Date, place

- Early combination treatment with XXX and XXX was superior to standard of care in XXX patients (ref)
- The landmark XXX study is the first to investigate long term clinical benefits of this strategy in XXX

XXX announced key results from the phase XXX study evaluating the long-term efficacy and safety of early combination treatment with XXX plus XXX to the traditional approach with XXX.

The study was conducted across 100 centres in 32 countries and involved 1820 treatment-naïve individuals diagnosed with XXX.

In the randomised, double-blind phase X study (ClinicalTrials.gov Identifier: XXX), early combination therapy of XXX and XXX met the primary endpoint with a statistically significant 52% reduction in XXX versus XXX alone.

The combination treatment strategy also showed XXX when all patients received combination therapy. Furthermore, patients treated with early combination had consecutively lower XXX levels (below XX%, XX% or XX%) for four years versus those receiving combination therapy only after XXX.

"Findings from the XXX study show without doubt that early intervention with a combination therapy provides greater and long-term benefits for patients. The currently recommended XXX approach with XXX is shown to be an inferior strategy," said Professor XXX of XXX.

No new safety findings were reported on the overall safety and tolerability profile.

Notes for editors

Full results from this study will be presented at ESC Congress in XXX next month.

About XXX

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Forward Looking Statements

References