

The following content is a mock (fictional) market announcement to illustrate the application of the BIA's best practice principles for communicating R&D progress. It is for guidance purposes only and should not be relied upon. Specific advice from qualified professionals should be taken in individual circumstances.

### **Biotech Co Announces Headline Results from Phase III Study in Disease B**

- Primary endpoint not reached
- Trend towards efficacy seen in primary and secondary endpoints
- Biotech Co to focus on development of Therapy D

Town, UK – Date: Biotech Co plc (“Biotech”), a company developing an innovative new therapy for a range of diseases, today announces headline results from its Phase III study of Therapy C for the treatment of disease B. The primary endpoint, a reduction in Symptom D compared to baseline, was not reached.

The Phase II study was a double-blind placebo controlled trial in 13,000 patients. Patients received two doses of Therapy C per day for 12 weeks. The primary endpoint measurement was the MEASURE index, and the primary endpoint outcomes were the difference between placebo and active groups six months after the start of dosing.

#### **Results**

- In the treatment arm Symptom D was reduced by 360 units vs 350 units in the placebo arm ( $p=0.13$ )
- Secondary endpoints showed that Therapy C reduced Symptom E and F
- Therapy C was seen to be well-tolerated with no safety concerns

Dr X, CEO of Biotech Co said: “The results we have seen in this study are disappointing for all at Biotech Co and, more importantly, for patients suffering from Disease B which is currently poorly treated. While a trend towards efficacy was seen in line with results observed in Phase II, we do not anticipate further development of Therapy C and will focus our efforts on Therapy D which is currently in Phase II.”

The company plans to submit the full data for peer reviewed publication later this year. Details of the trial are available at [www.clinicaltrials.gov/xxx](http://www.clinicaltrials.gov/xxx)

#### **Quality notes:**

- The headline does not suggest a different result to that presented in the content
- The first bullet is clear on the primary endpoint
- The methodology and results are included
- The quote is clear on the bad news of the results
- It provides an explanation of the positive trend consistent with a previous announcement of Phase II results
- Despite ‘negative’ result company intends to publish and gives link to clinicaltrials.gov