Circassia Announces Top-Line Results from Cat Allergy Phase III Study

- **Primary endpoint not achieved**
- **Treatment groups had dramatically reduced Combined Score and symptoms**
- **Powerful placebo response eliminated ability to identify treatment effect**
- **Wider NIOX® and respiratory franchises unaffected by results**

Oxford, UK – 20 June 2016: Circassia Pharmaceuticals plc ("Circassia" or "the Company"; LSE: CIR) today announces top-line results from its investigational cat allergy immunotherapy phase III study. In the study, both treatment regimens and placebo greatly, and equally, reduced subjects' combined allergy symptom and rescue medication use score from baseline. As a result of the very marked placebo effect the treatment did not meet the study's primary endpoint. The treatment was well tolerated with a highly favourable safety profile.

Steve Harris, Circassia's Chief Executive, said: *"We are surprised and disappointed by these results. Such a dramatic placebo effect was not a feature of our earlier phase II studies. However, in this large-scale trial it eliminated the ability to identify a treatment effect despite dramatic improvements in subjects' allergy symptoms and rescue medication use. We will now rapidly analyse the full dataset, address the implications for our wider allergy pipeline and provide an update on the development plans for our broader business at our interim results. At the same time, we will continue to focus resolutely on our wider portfolio, rapidly growing the sales of our market-leading NIOX® asthma management products and advancing our pipeline of respiratory products."*

Efficacy

The study compared a four-dose course of Fel d 1 allergen peptides, two sequential courses (eight doses) and placebo. The primary endpoint measure was the mean Combined Score (combined total rhinoconjunctivitis symptom score [TRSS] and rescue medication use score); mean TRSS was a secondary endpoint measure. The study's endpoint outcomes were the difference between placebo and active groups one year after the start of dosing.

- All groups had greatly improved Combined Score vs baseline
  (4 x 6nmol reduction = 58.2%; 8 x 6 nmol reduction = 59.8%; placebo reduction = 58.5%).
- All groups had greatly improved TRSS vs baseline
  (4 x 6nmol, 14.5 TRSS points decreased to 5.7 points [-61.0%]; 8 x 6 nmol, 14.2 decreased to 5.5 points [-61.1%]; placebo, 14.5 decreased to 5.9 points [-59.5%]).
- The Combined Score in the active treatment groups were not significantly different to placebo.

Next steps

Circassia will now review the study's full dataset to understand the detailed results and assess whether any other confounding factors affected the outcome, as well as the implications for its allergy portfolio. In the meantime, the Company will stop the recently initiated registration study of its grass allergy treatment and the preparatory work for a dose-ranging study of its ragweed allergy therapy. The phase IIb study of Circassia's house dust mite allergy product is well advanced and the Company will assess the implications associated with continuing the trial. Circassia's birch allergy product is nearing completion of a phase II study, which will therefore continue.

Maintain focus on broader business

In parallel, the Company will continue its focus on maintaining strong sales growth in its NIOX® asthma management franchise and firmly establishing its specialty commercial infrastructure in the US and Europe as a strategic growth platform. Circassia will also continue to progress its respiratory portfolio. The Company anticipates providing an update on its wider development plans and robust financial position at its interim results. As at 31 May 2016, the Company's unaudited cash balance remained over £139 million.

Analyst conference call and webcast

Circassia will host an analyst conference call today at 08:30 BST. For further details please contact Matthew Moss on +44 (0) 20 3727 1373. Following the conference call it will be available as an audio webcast in the Media section of the Company's website at www.circassia.com.

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About the study

The double-blind, placebo-controlled, multi-centre field study enrolled cat allergic subjects aged 12 to 65 years old with moderate or severe allergy symptoms (mean Total Rhinoconjunctivitis Symptom Score [TRSS] ≥ 10) and a cat at home. The study was conducted in over 100 centres in North America, Europe and Russia in an intention-to-treat population of 1,245 subjects. It compared 4 x 6nmol (n=417) and 8 x 6nmol regimens (n=414) of investigational immunotherapy with placebo (n=414). The primary endpoint was the difference in the mean combined TRSS and rescue medication scores (the Combined Score) between the treatment and placebo groups one year after the start of dosing. Additional pre-specified endpoints included a range of symptom, rescue medication and quality-of-life improvement measures.

About Circassia

Circassia is a specialty biopharmaceutical business with an established commercial infrastructure, marketed products, a pipeline of near-term therapies and a portfolio of next generation treatments targeting major market opportunities. Circassia sells its novel, market-leading products for asthma management directly to allergy / asthma specialists in the United States and Germany. Its products are also promoted in a number of other countries by the Company's network of partners.

Circassia's broad-based development pipeline includes a range of treatments for respiratory disease and allergy. Circassia's lead asthma treatment, which targets substitution of GSK's Flixotide® pMDI, is approved in the UK, and the Company is developing therapies targeting direct substitution of Seretide® pMDI and Serevent® pMDI. The Company is also developing a number of novel treatments, including a fixed dose 'triple' combination containing an inhaled corticosteroid, long-acting beta agonist and long-acting muscarinic antagonist. Circassia's allergy immunotherapies target cat, house dust mite, ragweed and grass allergies. For more information on Circassia please visit www.circassia.com.

Forward-looking statements

This press release contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Circassia. The use of terms such as "may", "will", "should", "expect", "anticipate", "project", "estimate", "intend", "continue", "target" or "believe" and similar expressions (or the negatives thereof) are generally intended to identify forward-looking statements. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors that could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Nothing contained in this press release should be construed as a profit forecast or profit estimate. Investors or other recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. Circassia undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.