Circassia Announces Duaklir® New Drug Application (NDA) and Tudorza® Supplemental NDA Accepted for Review by FDA

- **PDUFA target action date of 31 March 2019 confirmed for both filings**

Oxford, UK – 13 August 2018: Circassia Pharmaceuticals plc ("Circassia" or "the Company"; LSE: CIR), a specialty pharmaceutical company focused on respiratory disease, today announces that the United States Food and Drug Administration (FDA) has confirmed it has completed its validation for completeness, and accepted for filing and review, the previously submitted Duaklir® New Drug Application (NDA) for the treatment of chronic obstructive pulmonary disease (COPD). The FDA has also accepted for review the Tudorza® supplemental NDA (sNDA) requesting the inclusion of new clinical data demonstrating cardiovascular safety and the reduction of COPD exacerbations in the product's prescribing information. The FDA confirmed target action dates of 31 March 2019 for completion of the review of both filings under the Prescription Drug User Fee Act (PDUFA).

Steve Harris, Circassia's CEO, said: *"The acceptance of the Duaklir® and Tudorza® filings is an important milestone for Circassia, and we look forward to the outcome of the FDA's reviews in the coming months. We believe that based on its broad clinical database, Duaklir®, if approved, has the potential to become an important new treatment option for COPD patients in the United States. In addition, the inclusion of clinical data in Tudorza®'s prescribing information demonstrating cardiovascular safety and reductions in COPD exacerbations, if approved, would provide physicians with unique new information."*

About Duaklir®
Duaklir® is a fixed-dose combination of the long-acting muscarinic antagonist (LAMA) aclidinium and the long-acting beta agonist (LABA) formoterol. It is administered twice daily via the easy-to-use, breath-actuated, multi-dose inhaler, Pressair®. The product is approved in approximately 50 countries worldwide, including in the European Union, under a number of brand names. In April 2017, Circassia and AstraZeneca established a commercial collaboration in the United States under which Circassia has exclusive US commercialisation rights to Duaklir® and AstraZeneca is responsible for the product's development and regulatory submission.

The Duaklir® NDA is supported by a broad clinical database, and includes data from the AMPLIFY study, results from two previous Duaklir® phase III studies, ACLIFORM and AUGMENT, and exacerbation data from the ASCENT trial.

About Tudorza®
Tudorza® contains the LAMA aclidinium administered twice daily via the Pressair® inhaler. Tudorza® was first approved in the United States in 2012 for use in the treatment of COPD, and under Circassia's commercial collaboration with AstraZeneca, Circassia is responsible for the product's promotion and AstraZeneca for completing its clinical studies and regulatory submissions.

Tudorza®'s sNDA includes data from the recently completed phase IV ASCENT study. The study, which was conducted in patients with moderate to very severe COPD and cardiovascular disease and / or risk factors, demonstrated Tudorza® is effective at reducing COPD exacerbations with no increase in cardiovascular events, and reducing hospitalisations due to COPD exacerbations, in this at-risk population. If the sNDA is approved, Tudorza® will be the only LAMA in the United States with these data in its label.

About Circassia
Circassia is a world-class specialty pharmaceutical business focused on respiratory disease. Circassia sells its novel, market-leading NIOX® asthma management products directly to specialists in the United States, United Kingdom and Germany, and in a wide range of other countries through its network of partners. In 2017, the Company established a commercial collaboration with AstraZeneca in the United States in which it promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza®, and has the commercial rights to NDA-stage COPD product Duaklir®. For more information please visit www.circassia.com.

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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.