

This announcement contains inside information for purposes of Article 7 of Market Abuse Regulation 596/2014

Circassia Announces FDA Approval of Tudorza® Supplemental New Drug Application

- **Data showing reduction in COPD exacerbations and no increase in major cardiovascular events vs placebo added to label**
- **Tudorza® is the only product in its class with these data in the label**

Oxford, UK – 29 March 2019: Circassia Pharmaceuticals plc (“Circassia” or “the Company”; LSE: CIR), a specialty pharmaceutical company focused on respiratory disease, today announces the US Food and Drug Administration (FDA) has approved Tudorza®’s supplemental New Drug Application (sNDA) for the inclusion of unique new clinical data in the product’s label. Tudorza® is indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) and contains the long-acting muscarinic antagonist (LAMA) aclidinium bromide (400 mcg) administered twice-daily via the breath-actuated inhaler Pressair®.

Tudorza®’s expanded label now includes data from the phase IV ASCENT study, which was conducted in patients with moderate to very severe COPD and cardiovascular disease and / or significant cardiovascular risk factors. The study demonstrated that Tudorza® is effective at reducing COPD exacerbations with no increase in major cardiovascular events, and at reducing hospitalisations due to COPD exacerbations, in this at-risk population. Cardiovascular disease is the most common and significant co-morbidity of COPD, with approximately 30% of COPD patients dying from cardiovascular conditions. Tudorza® is the only LAMA in the United States with these data in its label.

Steve Harris, Circassia’s Chief Executive, said: *“This approval adds unique new clinical data to Tudorza®’s label, which further differentiates this important COPD treatment option within the \$2 billion US LAMA market. Cardiovascular disease is a major co-morbidity of COPD, and the inclusion of comprehensive data demonstrating COPD exacerbation reductions and cardiovascular safety provides physicians with important new information, helping to further serve this significant patient group. Following our recent option exercise acquiring the full US commercial rights to Tudorza®, and this subsequent label expansion, we look forward to implementing our strategy targeting product growth in this major market.”*

Tudorza® is a registered trademark of Almirall S.A.
Pressair® is a registered trade mark of the AstraZeneca group of companies

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Contacts

Circassia

Steve Harris, Chief Executive Officer
Julien Cotta, Chief Financial Officer
Rob Budge, Corporate Communications

Tel: +44 (0) 1865 405 560

Peel Hunt (Nominated Adviser and Joint Broker)

James Steel / Dr Christopher Golden

Tel: +44 (0) 20 7418 8900

Numis Securities (Joint Broker)

James Black / Freddie Barnfield

Tel: +44 (0) 20 7260 1000

FTI Consulting

Simon Conway / George Kendrick

Tel: +44 (0) 20 3727 1000

About Circassia

Circassia is a world-class specialty pharmaceutical business focused on respiratory disease. The Company sells its novel, market-leading NIOX® asthma management products directly to specialists in the United States, United Kingdom, China and Germany, and in a wide range of other countries through its network of partners. In the United States, Circassia has a commercial collaboration with AstraZeneca in which it has the commercial rights to chronic obstructive pulmonary disease (COPD) treatments Tudorza® and Duaklir®. Circassia also has the

US and Chinese commercial rights to the late-stage ventilator-compatible nitric oxide product AirNOvent. For more information 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.