# Circassia Announces FDA Approval of Duaklir® for Maintenance Treatment of Chronic Obstructive Pulmonary Disease

- **Duaklir® launch planned H2 2019**
- **Duaklir® to join Tudorza® in Circassia's portfolio of US COPD products**

**Oxford, UK – 1 April 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 Duaklir® for the maintenance treatment of chronic obstructive pulmonary disease (COPD). Duaklir® is a fixed-dose combination of the long-acting muscarinic antagonist (LAMA) aclidinium bromide (400 mcg) and long-acting beta-agonist (LABA) formoterol fumarate (12 mcg) administered twice-daily via the breath-actuated inhaler Pressair®. Circassia is on track to launch Duaklir® in the United States in the second half of 2019 via its dedicated COPD sales force.

The Duaklir® approval is based on a broad clinical database, including data from three phase III studies, ACLIFORM, AUGMENT and AMPLIFY. The label also includes clinical data from the phase IV ASCENT study, which shows aclidinium therapy is effective at reducing COPD exacerbations. As a result, Duaklir® is the only twice-daily LAMA / LABA in the United States with COPD exacerbation data included in its prescribing information.

**Steve Harris, Circassia's Chief Executive**, said: *"We are delighted with the FDA approval of Duaklir®, which we believe will provide a valuable treatment option for the significant number of patients with COPD in the United States. The addition of Duaklir® to our portfolio further strengthens our range of marketed respiratory products and we look forward to launching it in the US in the coming months alongside our aclidinium monotherapy, Tudorza®, as part of the significant LAMA / LABA market that is predicted to grow rapidly over the coming years."*

**Michael Asmus, Circassia's Vice President, US Medical Affairs**, said: *"With guidelines recommending combined LAMA and LABA therapy for a number of COPD patient groups, we believe Duaklir® will make an important contribution to the treatment of this debilitating disease. Dukalir®'s approval is based on a broad clinical database, including data demonstrating a reduction in the risk of COPD exacerbations driven by its aclidinium component, and we look forward to making this new therapeutic option available to patients across the United States."*

**AstraZeneca partnership**

In 2017, Circassia and AstraZeneca established a collaboration for the commercialisation of Tudorza® and Duaklir® in the United States. At the end of 2018, Circassia exercised its option over Tudorza® and the Company now has the full US commercial rights to both products. Under the companies' agreement, a contingent option fee of $20 million becomes due to AstraZeneca within 30 days of the FDA approval of Duaklir®, and final deferred consideration of $100 million is due by 30 June 2019. The Company is in discussions with third-party finance providers to satisfy all or part of these payments. If this financing is not forthcoming, Circassia plans to use a loan facility provided by AstraZeneca under the companies' agreement to satisfy the outstanding amount.



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**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.*