

Circassia Announces Successful Completion of FDA Pre-submission Meeting for Novel Nitric Oxide Product AirNOvent

Oxford, UK – 4 February 2019: Circassia Pharmaceuticals plc (“Circassia” or “the Company”; LSE: CIR), a specialty pharmaceutical company focused on respiratory disease, today announces its partner, AIT Therapeutics Inc. (“AIT”), has successfully completed a pre-submission meeting with the US Food and Drug Administration (FDA) for the ventilator-compatible nitric oxide product AirNOvent*. On 24 January 2019, Circassia announced it had entered a definitive agreement to acquire the exclusive commercialisation rights to AirNOvent in the United States and China from AIT. Under the companies’ agreement the successful completion of the FDA meeting triggers a milestone payment of \$3.15 million, which Circassia intends to satisfy through the issuance of new Ordinary Shares in the Company to AIT.

AIT anticipates submitting a Premarket Approval application (PMA) in Q2 2019 for AirNOvent for use in the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN). Circassia anticipates launching the product in the first half of 2020, once approved.

Steve Harris, Circassia’s CEO, said: *“Successful completion of this pre-submission meeting represents a further key milestone in advancing AirNOvent towards the market. We are excited at the potential benefits offered by AirNOvent, once approved, and look forward to AIT submitting this novel nitric oxide product for regulatory approval in the coming months.”*

About AirNOvent

AirNOvent is a portable system that utilises an electric voltage to produce precise quantities of nitric oxide from the nitrogen and oxygen in air. Inhaled nitric oxide is a pulmonary vasodilator, which is approved in the United States for use as part of a regimen in the treatment of hypoxic respiratory failure associated with PPHN. The currently available product, INOMAX®, is used in neonatal intensive care units (NICUs) and its delivery system administers nitric oxide from pressurised cylinders in conjunction with ventilator systems. The product generated estimated US revenues of over \$400 million in 2017.

AirNOvent offers a number of potential benefits over the existing competition. It is cylinder-free and is smaller, significantly lighter and more convenient, and unlike nitric oxide cylinder-based systems does not require special storage and handling. As a result, it has the potential for use by NICUs, as well as smaller clinics without the facilities required to manage nitric oxide cylinders.

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, China 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®. The Company also has the commercial rights to NDA-stage COPD product Duaklir®, and following the exercise of its option anticipates taking full commercial control of Tudorza® in the US in 2019. For more information please visit www.circassia.com.

Application for admission and total voting rights

Application has been made for admission of 5,271,844 new Ordinary Shares in the Company, in respect of the \$3.15 million milestone payment to AIT, to trading on AIM. Admission of the new Ordinary Shares is expected to occur at 8.00 a.m. on 5 February 2019. The new Ordinary Shares will, when issued, be credited as fully paid and will be issued subject to the Company’s articles of association and will rank pari passu in all respects with the existing issued Ordinary Shares in the capital of the Company, including the right to receive all dividends and other distributions declared, made or paid on or in respect of such shares by reference to a record date falling after their issue.

Following the issue of the new Ordinary Shares, the Company’s issued share capital will comprise 374,859,249 Ordinary Shares each of 0.08p, and each with equal voting rights. This figure may be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their interest in, or a change to their interest in, the share capital of the Company under the AIM rules.

*AirNOvent is not an approved name for the product and may not be the final name submitted for approval

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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.