

## **Circassia to Exercise Option for Full US Commercial Rights to COPD Treatment Tudorza® from AstraZeneca**

**Oxford, UK – 11 December 2018:** Circassia Pharmaceuticals plc (“Circassia” or “the Company”; LSE: CIR), a specialty pharmaceutical company focused on respiratory disease, today announces it has issued a notice of option exercise to AstraZeneca to acquire the full US commercial rights to Tudorza® (aclidinium). Circassia currently promotes the COPD treatment in the United States under a profit share arrangement established by the two companies in April 2017. Circassia anticipates completing the option exercise on 31 December 2018.

**Steve Harris, Circassia’s CEO, said:** *“Exercising our option for the full US commercial rights to Tudorza® represents a strategic opportunity for Circassia. We will have significantly more control of the product’s commercialisation strategy, and with prescription levels continuing to stabilise, we now have a robust foundation from which to grow the product. We plan to build on our learnings of the past 18 months and are launching a dedicated COPD sales force alongside a focused NIOX® team, which we believe will improve promotion of our existing products and provide a platform for the launch of Duaklir®, once approved. With both the Tudorza® option exercise and Duaklir® regulatory review process anticipated to complete in the coming months, we look forward to 2019 with significant optimism.”*

### **Option exercise**

Under the terms of Circassia’s agreement with AstraZeneca, completion of the option exercise will trigger a payment of \$5 million. A deferred Tudorza® option payment of \$20 million will be payable upon approval of Duaklir® (aclidinium / formoterol), in addition to deferred consideration of \$100 million due under the companies’ agreement. Circassia holds the US commercial rights to Duaklir®, and a New Drug Application (NDA) for the product is currently under review by the FDA with a target completion date of 31 March 2019. The Company anticipates satisfying the option payments and deferred consideration via third-party funding, or through a loan facility provided by AstraZeneca under the companies’ agreement if this is unavailable.

### **Tudorza® commercialisation**

In the coming weeks, the companies will finalise a transition plan for the support services, including pharmacovigilance, regulatory and sales order processing, that AstraZeneca will continue to provide for a period following completion of the option exercise before Circassia assumes responsibility for these activities. Circassia will also retain responsibility for Tudorza®’s promotion and AstraZeneca will continue its manufacture. Following completion of the option exercise, Circassia will record Tudorza®’s in-market sales and cost of commercialisation and will retain the full profits.

### **Tudorza® product licence**

AstraZeneca is the Tudorza® licence holder in the United States and recently submitted a supplemental NDA requesting inclusion of positive clinical data from the ASCENT study in the product’s label. The FDA is currently reviewing the filing with a target action date of 31 March 2019. Following completion of this review, the Tudorza® product licence will be transferred to Circassia.

### **Transaction benefits**

The option exercise and licence transfer represent an important opportunity for Circassia. In addition to receiving the economic benefits of Tudorza®’s commercialisation, the Company will have further flexibility in managing the composition of its sales force, customer targeting, product detail prioritisation, territory definition, distribution strategy, pricing and market access priorities. In preparation, Circassia is launching a dedicated COPD sales force focused initially on Tudorza® and, once approved, Duaklir®. In parallel, the Company is establishing a dedicated NIOX® promotional team, which will include a smaller dedicated sales force supported by telesales and customer service professionals. The Company believes this structure will improve targeting and promotional efficiency for its current products and enhance launch preparations for Duaklir®.

### **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](http://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.*

Aclidinium is marketed under a number of brand names around the world, including Tudorza®, Eklira® and Bretaris®  
Duaklir® is a registered trademark in Europe and other markets; use of the US trademark is subject to review and approval by the FDA  
Duaklir® and Tudorza® are registered trademarks of Almirall S.A.