

# Circassia Pharmaceuticals

10:00 25 Mar 2019

## Circassia enters pivotal week with two big FDA decisions due

Circassia Pharmaceuticals PLC (LON:CIR) shares edged higher on Monday ahead of what looks set to be a pivotal week for the junior drug developer.

After ten months of analysis and reviews, the company will know whether US regulators have approved its Duaklir chronic obstructive pulmonary diseases (COPD) drug by 31 March.

It will also have found out about a supplemental new drug application (NDA) for Tudorza, another COPD drug it acquired from Astra two years ago.

**READ:** Circassia coughs up US\$32m for PPHN drug

The US is arguably the world's most important and lucrative pharma industry, so the Food and Drug Administration's (FDA) decisions are undoubtedly important.

There is plenty of competition in the US COPD market, but if Duaklir can secure even a slither of it, it would likely add tens of millions every year to Circassia's top-line.

The inhaler already generates almost US\$100m in a year for AstraZeneca PLC (LON:AZN), and that's obviously without any sales in the US, where COPD is the third biggest killer that affects more than 10m people.

AstraZeneca investors will also be keeping an eye out on the decisions as the pharma giant will receive a US\$100m pay-out should Duaklir gets the thumbs-up.

Positive data from two Phase III studies, as well as exacerbation data from another late-stage trial support the new drug application (NDA), so bosses are, as ever, upbeat about the drug's prospects.

Initial decision not everything - ask Motif Bio

But even if the worst does happen, and there is no evidence to suggest it will, can Circassia take heart from Motif Bio PLC's (LON:MTFB) recent disappointment?

Last month, the FDA rejected Motif's NDA for its iclaprim antibiotic, saying that it **required more data**.

But AIM-quoted Motif asked for talks to iron out the issues and the pair are now meeting in a few weeks.

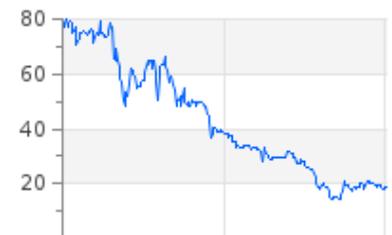
The company remains upbeat about its drug prospects. It is not going there merely for an explanation, it hopes the talks will help determine "the best way to move iclaprim towards marketing approval".

Circassia shares were up just over 1% to 33.5p on Monday.

**Price:** 19p

**Market Cap:** £710186000M

### 1 Year Share Price Graph



August 2018 February 2019 August 2019

### Share Information

**Code:** CIR

**Listing:** LSE

<b>52 week</b>	<b>High</b>	<b>Low</b>
	<b>82.70p</b>	<b>13.25p</b>

**Sector:** Pharma & Biotech

**Website:** [www.circassia.com](http://www.circassia.com)

### Company Synopsis:

*Circassia is a specialty pharmaceutical company focused on respiratory disease. Our growing commercial organization promotes our innovative asthma management products directly to specialist physicians in a number of key markets, and we market the chronic obstructive pulmonary disease (COPD) product Tudorza® in the United States.*

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