Biotech Daily

Monday October 2, 2023

Daily news on ASX-listed biotechnology companies

US FDA Approves Cyclopharm Technegas - $280m A Year Market

Cyclopharm says the US Food and Drug Administration has approved Technegas for pulmonary embolism imaging - opening a $US180 million ($A279.5 million) a year market.

Cyclopharm managing-director James McBrayer told Biotech Daily that Technegas had been approved as a point-of-care combination product meaning that the FDA considers the Technegas generators as both a device and a drug.

Mr McBrayer said the company's founders contacted the FDA to discuss approval 32 years ago, in 1991, he joined the company in 2008 and his first contact with the US regulator was the following year in 2009.

Mr McBrayer said the US was the 65th jurisdiction to approve Technegas.

In its announcement to the ASX, Cyclopharm said the US was the largest market for Technegas and "strong pre-existing demand [was] expected to drive sales momentum for an immediate US wide rollout".

The company said that the FDA approval allowed broad use of Technegas, supporting wider future indications across other respiratory disease states including chronic obstructive pulmonary disease (COPD), asthma, long Covid and lung cancer

Cyclopharm said it would complete final assembly of its first wave of 200 generators, with plans for the first air shipments to arrive in the US by early November.

The company said it would provide and install Technegas generators to nuclear medicine departments to increase adoption and use of the single patient consumables which generated recurring annuity style revenue.

Cyclopharm said that agreements were in place for third-party distribution, generator service, installation and administrative support for Technegas in the US, with 420 formal expressions of interest in the product.

The company said that over the past three decades Technegas had been successfully used in 64 countries worldwide, amassing 4.7 million patient studies, with Technegas the preferred nuclear medicine lung ventilation imaging agent, referenced, in the Canadian and European nuclear medicine guidelines.

Cyclopharm said that the FDA approval covered the complete Technegas product, including its manufacture in and distribution from Australia.

The company said the US had about four million procedures a year to rule out pulmonary embolism, with 15 percent, or 600,000 procedures, using nuclear medicine for patients contra-indicated for computed tomography contrast media, including pregnant patients, those with renal impairment or allergies to the contrast or had radiation concerns.

Cyclopharm said the initial target of 600,000 nuclear medicine imaging procedures was estimated to be about $US90 million a year, and it expected a 50 percent share over the next two to three years, rising to more than 80 percent over three to five years; and it hoped to double the US nuclear medicine pulmonary embolism imaging market.

Cyclopharm said that US reimbursement codes were based on established procedures and Technegas could be used immediately under existing bundled procedural codes. “While FDA approval for Technegas is a major milestone for Cyclopharm, our ability to now make this technology available to US clinicians and to the patients they serve, is where the key significance lies,” Mr McBrayer said.

In 2020, Cyclopharm said its 240-patient, phase III Technegas lung imaging trial was halted after data from 200 patients met the primary efficacy endpoint and in January the Society of Nuclear Medicine and Molecular Imaging called on the FDA to expedite the approval of Technegas (BD: Sep 15, 2020; Jan 22, 2021).

In 2021, Cyclopharm received an FDA complete response letter and in March 2023 filed its response (BD: Jun 28, 2021; Mar 30, 2023).

Cyclopharm was up four cents or 1.4 percent to $2.87 with 482,472 shares traded.