PUBLIC STATEMENT

Chao Center Reacquires Rights to Cycloserine

WEST LAFAYETTE, Ind. – (September 21, 2015) Tuberculosis (TB) and multidrug-resistant tuberculosis (MDR-TB) in the U.S. and North America while thankfully in decline has proven stubbornly hard to eliminate.

Every year approximately 90 people in the U.S. are diagnosed with multidrug-resistant tuberculosis. One of the many available drug options used to combat this disease is Seromycin, (Cycloserine capsules, USP). According to the CDC, compliance, drug choice, length of therapy continue to be some of the biggest challenges in fighting TB and MDR-TB.

The Chao Center for Industrial Pharmacy & Contract Manufacturing has been manufacturing and selling Cycloserine since 2007. As production volumes declined and FDA fees have increased dramatically, the Chao Center lost more than $10 million due to the fixed regulatory costs, manufacturing expenses, and low prescription volumes to a vulnerable patient population in North America.

As part of a no-profit agreement for the Chao Center, on August 19, 2015, the Chao Center transferred ownership of Cycloserine to Rodelis Therapeutics, a Dublin-based company whose purpose is to efficiently provide orphan and specialty drugs to the market. Chao Center officials had hoped this transfer would be a best option for maintaining a long-term supply in the U.S. and North America at a fair price and return.

Following a substantial increase in the cost of Cycloserine by Rodelis, it became clear that the Rodelis strategy was not consistent with the Chao Center's expectations or vision.

Therefore, this notice is to advise health organizations and the public that the Chao Center has reacquired the rights of Cycloserine from Rodelis.

Chao Center officials will work with its partners, suppliers and the FDA to attempt to make this a sustainable economic model at the lowest burden possible to the health care system and patients.

Chao Center officials encourage an ongoing discussion with FDA, CDC, WHO and other health and safety organizations to more deeply pursue the need for support and allowances for small, legacy and orphan drug manufacturers with new ways to maintain drugs like Cycloserine. If manufacturers are to keep these drugs in production for the low-volume, high-need patient, then the drugs should be handled much differently than the blockbuster drugs of high volume to assure patient access.

Effective immediately the price per blister pack of Cycloserine is $1,050 ($35 a capsule*30 capsules) and the previously announced price of $10,800 for a package of 30 capsules (250 mg, $360 a capsule) as reported by Rodelis on August 19, 2015 is no longer in effect.

We believe that by acting quickly to reacquire these rights and reprice the product in the system, we have minimized any short-term effect caused by the Rodelis price increase.

Contact: Dan Hasler, 765-588-3826, djhasler@prf.org