

Aytu BioScience Announces Exclusive Distribution Agreement with Beijing Dahua Sanxin Technology Development Co., Ltd. to Commercialize MiOXSYS(R) Male Infertility Test in China

Initial Purchase by Beijing Dahua Sanxin Technology Development Co., Ltd. Represents First MiOXSYS Commercial Sale in China.

ENGLEWOOD, CO / June 4, 2019 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, today announced an exclusive distribution agreement in the People's Republic of China with Beijing Dahua Sanxin Technology Development Co., Ltd. to commercialize MiOXSYS®, the company's first-in-class seminal oxidative stress test for the assessment of male infertility. As part of this agreement, Beijing Dahua Sanxin Technology Development Co., Ltd. has made an initial MiOXSYS purchase for the purpose of conducting the China-based clinical studies required for market clearance.

In the coming months, Beijing Dahua Sanxin Technology Development Co., Ltd. plans to begin clinical studies and initiate communications with the China Food and Drug Administration (CFDA) in order to work toward approval and Chinese market availability, with the completion of these studies expected in 2021.

According to the National Health Commission of the People's Republic of China statistics, the infertility rate in China rose from 2.5-3% in 1992 to 12-15% in 2018, with about 50 million infertile couples. By the end of 2018, China had approved 497 IVF centers and 26 sperm banks. In recent years, the total number of cycles of IVF in China has exceeded 1 million per year, and the number of babies born has exceeded 0.3 million per year.

The IVF market in China reached 12.2 billion Chinese Yuan (USD \$1.7 billion) in 2016. The cost of IVF treatment mainly includes IVF (51%), pharmaceutical treatment (34%), and examination (15%) based on the per-IVF treatment cost of 25,000 – 30,000 Chinese Yuan (USD \$3,620-\$4,345). It is estimated that the potential of the China IVF market is now as large as 15.0 billion Chinese Yuan (USD \$2.2 billion).

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We are pleased to be partnering with Beijing Dahua Sanxin Technology Development in China to begin the clinical and regulatory process that, if successful, will bring MiOXSYS to the 50 million Chinese couples struggling with infertility. Clinicians around the world understand very well that male factor infertility is a major factor in up to half of all infertility cases, so we're hopeful that, upon approval, the MiOXSYS male infertility system will help address this significant, growing national issue in China."

MiOXSYS, the Male Infertility Oxidative System, is CE marked and cleared by Health Canada,

Australia's TGA, and Mexico's COFEPRIS. MiOXSYS is the first cleared advanced *in vitro* diagnostic test that assesses seminal oxidative stress, a major cause of male infertility.

Currently, MiOXSYS is sold in over thirty countries through a global distribution network.

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The company currently markets Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"). Aytu also has exclusive U.S. and Canadian rights to ZolpiMist™, an FDA-approved, commercial-stage prescription sleep aid indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Aytu recently acquired exclusive U.S. commercial rights to Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension. Additionally, Aytu is developing MiOXSYS®, a novel, rapid semen analysis system with the potential to become a standard of care for the diagnosis and management of male infertility caused by oxidative stress. MiOXSYS is commercialized outside of the U.S. where it is a CE Marked, Health Canada cleared, Australian TGA approved, Mexican COFEPRAS approved product, and Aytu is planning U.S.-based clinical trials in pursuit of 510k de novo medical device clearance by the FDA. Aytu's strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com.

About Beijing Dahua Sanxin Technology Development Co., Ltd.

Beijing Dahua Sanxin Technology Development Co., Ltd. is a sales company specializing in IVF products for the Chinese market, and since 2008 the sales network has covered hundreds of hospitals. The company manages IVF equipment, andrology equipment and reagents products, such as CASA, DNA fragment testing, sperm function testing, autoimmune testing, and sex hormone testing. Its affiliated enterprises, Sperm Capturer (Beijing) Biotechnology Co., Ltd and Guangzhou Darui Reproductive Technology Co., Ltd are committed to building the most comprehensive product and service providers in the Chinese IVF field.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,'

'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: risks relating to gaining market acceptance of our products, obtaining reimbursement by third-party payors, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future revenue growth, our anticipated future cash position and future events under our current and potential future collaboration. We also refer you to the risks described in 'Risk Factors' in Part I, Item 1A of Aytu BioScience, Inc.'s Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

Contact for Investors:

James Carbonara

Hayden IR

(646)-755-7412

james@haydenir.com

SOURCE: Aytu BioScience, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/547547/Aytu-BioScience-Announces-Exclusive-Distribution-Agreement-with-Beijing-Dahua-Sanxin-Technology-Development-Co-Ltd-to-Commercialize-MiOXSYSR-Male-Infertility-Test-in-China>