gem global emerging markets

Over the last 12 months GEM has made a series of early stage investments totaling, $9.1 million into Tyme (http://www.tymetechnologiesinc.com), which owns an effective, well-tolerated cancer therapeutic technology named SMK.

Tyme Technologies, Inc. Receives FDA Acceptance of Investigational New Drug Application for Oncology Drug Candidate, SM-88

October 26, 2015 04:30 PM Eastern Daylight Time

NEW YORK--(BUSINESS WIRE)--Tyme Technologies, Inc. (OTC QB: TYMI), a research and development company operating through its wholly-owned subsidiary, Tyme Inc., focused on development and eventual commercialization of oncology products, announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) Application for SM-88, its breast cancer drug candidate.

"FDA acceptance of this IND is a major milestone for Tyme in our efforts to provide a new class of tools in the fight against cancer. We were delighted to receive the FDA response to our extensive preclinical data package, as well as the approval of our trial design" Tweet this

SM-88 is believed to be a first-in-class metabolic inhibitor targeting cancer cells intended to result in decreased mucin defense to reactive oxygen. Enrollment of patients into the study is expected to begin shortly.

"FDA acceptance of this IND is a major milestone for Tyme in our efforts to provide a new class of tools in the fight against cancer. We were delighted to receive the FDA response to our extensive preclinical data package, as well as the approval of our trial design," said Steve Hoffman, President and Chief Executive Officer of Tyme Inc. "Our focus now is on preparing to enroll the first patients in the study. In addition to studying SM-88 in breast cancer patients, we are also contemplating, with guidance from our Scientific and Medical Advisory Board, expanding our program to include multiple arms focused on differentiated types of cancer."

SM-88 is a proprietary compound which Tyme believes to be a first-in-class drug that harnesses the body's own immune defenses to fight tumor cells. Tyme previously completed a proof-of-concept clinical study for SM-88 in late-stage cancer patients with relapsed or highly refractory disease.

About Tyme

Tyme is a pharmaceutical company focused on discovering and developing highly targeted cancer therapeutics for a broad range of oncology indications. Tyme is the originator of what it believes to be a novel, proprietary treatment regimen consisting of a rationally-designed combination of therapeutic agents aimed at exploiting the aberrant metabolic characteristics of cancer cells as well as activating the endogenous immune response against tumors. Tyme's approach is hypothesized to permit selective elimination of cancer cells, while simultaneously improving patients' well-being, particularly with respect to pain severity and functional independence.

Tyme is currently developing for use in humans SM-88, a proprietary compound, which the Company believes to be a first-in-class drug that harnesses the body's own immune defenses to fight tumor cells. SM-88 is a novel combination drug that synergistically targets the unique metabolic features of cancer cells, thus providing a selective method of altering the susceptibility of cancer cells to oxidative stress. Tyme has completed a proof-of-concept clinical study for SM-88 in late-stage cancer patients with relapsed or highly refractory disease.

For more information, visit our website: www.tymetechnologiesinc.com.

Safe Harbor Statement

This press release contains forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any historical results and future results, performances or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the factors described in the section captioned "Risk Factors" of Tyme's Current Report on

Form 8-K/A filed with the U.S. Securities and Exchange Commission on April 16, 2015 (available at www.sec.gov).

Readers can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements, and forward-looking statements within this press release include statements regarding our drug development strategies and clinical trials. Forward-looking statements reflect Tyme's current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, readers should not place undue reliance on these forward-looking statements.

Contacts

Tyme Technologies, Inc.
Investor Relations
Raghuram Selvaraju, 646-205-1603
investorrelations@tymeinc.com
or
Media Contact:
Sam Brown Inc.
Mike Beyer, 312-961-2502
mikebeyer@sambrown.com