Tyme Technologies and Eagle Pharmaceuticals Announce Strategic Collaboration to Advance Innovative Oral SM-88 for the Treatment of Patients with Cancer

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- Collaboration leverages combined capabilities of Tyme Technologies and Eagle Pharmaceuticals to maximize potential of oral SM-88 by advancing pivotal trials and commercialization.
- TYME recently launched the TYME-88-PANC pivotal trial to evaluate oral SM-88 for third-line treatment of patients with metastatic pancreatic cancer.
- TYME is entitled to receive up to a total $40 million as follows:
    - an initial $20 million upfront. In return, Eagle will receive 10 million restricted shares of TYME's common stock at $2.00 per share.
    - a second $20 million milestone payment upon achieving primary endpoints in pivotal trial results or approval of a cancer indication in the U.S. for SM-88. This payment will be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price.
- Eagle will be responsible for 25% of the promotional sales effort of SM-88 and will receive 15% of net revenues of SM-88 in the U.S.
- TYME retains all commercial rights to SM-88 outside the U.S. and reserves the right to repurchase Eagle's U.S. co-promotion right for $200 million.
- Oral SM-88 represents a novel therapeutic approach designed to selectively disrupt protein synthesis in cancer cells with demonstrated tumor responses in 15 different cancer types across multiple studies.
- In a Phase II study of patients with actively progressing metastatic pancreatic cancer who had failed previous therapy, evaluable patients on SM-88 demonstrated median overall survival of 6.4 months as of April 25, 2019; patients who achieved stable disease or better had a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death.

NEW YORK & WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--**Tyme Technologies, Inc. (Nasdaq: TYME) ("TYME"),** an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™), and **Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle"),** today announced the formation of a U.S. strategic collaboration focused on the co-promotion of TYME's lead CMBT candidate oral SM-88 in advanced cancers. CMBTs are proprietary investigational compounds that are believed to disrupt cancer cells' protein synthesis, leading to a breakdown of the cancer's key defenses and cell death. In clinical trials, oral SM-88 has demonstrated complete or partial responses across 15 different cancers, including pancreatic, prostate, sarcoma, breast, lung, and blood cancers with minimal serious grade 3 or higher adverse events.

"TYME's approach is unique and transformational. Targeting cancer's metabolism by disrupting protein synthesis has advantages over existing treatment approaches in terms of both efficacy and safety," said Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals. "This collaboration provides an excellent opportunity to continue expanding our presence in the oncology space, as well as to evaluate potential combination opportunities with SM-88 in our existing pipeline. We look forward to leveraging our oncology sales infrastructure to maximize the commercialization of SM-88 in the U.S., if approved. As always, our goal remains to deliver innovative, next-generation therapeutics to address patient needs and to create value for our shareholders," concluded Tarriff.

Terms of the Agreements

Under the terms of the securities purchase agreement, TYME will receive a $20 million upfront cash payment for 10 million restricted shares of TYME common stock at $2.00 per share. In addition, TYME will receive a $20 million milestone payment upon the successful completion of the first to occur of the following three events: (1) achievement of the primary endpoint of overall survival in its TYME-88-Panc pivotal trial; or (2) achievement of the primary endpoint of overall survival in the PanCAN Precision Promise℠ SM-88 registration arm; or (3) U.S. Food and Drug Administration (FDA) approval of SM-88 in any cancer. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle's shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.

Under the terms of the co-promotion agreement, Eagle Pharmaceuticals will undertake 25% of the promotional sales effort for SM-88 in the U.S. oncology market and receive 15% of the net U.S. revenues of SM-88, and TYME will be responsible for the remaining promotional effort. TYME will also be responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. TYME retains the remaining 85% of net U.S. revenues and reserves the right to repurchase Eagle's co-promotion right for $200 million.

As part of this partnership between TYME and Eagle, there is also the potential to evaluate oral SM-88 in combination therapy or as monotherapy through leveraging Eagle's oncology pipeline and expertise in oncology settings, which may include trials in breast or lung cancers and other tumor types.

"We are extremely pleased to establish this collaboration with Eagle Pharmaceuticals who shares our passion and commitment to improving the lives of patients with advanced cancers. After a thorough due diligence process by both parties, each came away with great respect for each organization's capabilities and potential," said Steve Hoffman, Chairman and Chief Executive Officer of TYME. "This alliance provides TYME with the commercial and capital resources to advance our leadership position in the field of cancer metabolism and the potential to expand our capabilities and accelerate clinical programs that will create value for all of our stakeholders, most importantly for the patients we serve."

About SM-88

SM-88 is an oral investigational modified proprietary tyrosine derivative that is believed to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. Clinical trial data have shown that SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, lung, breast, prostate and sarcoma cancers with minimal serious grade 3 or higher adverse events.

Clinical results of SM-88, based on data as of April 25, 2019, from the Phase II portion of the TYME-88-Panc study, were presented at the European Society of Medical Oncology **21st World Congress on Gastrointestinal Cancer in** Barcelona, Spain on Wednesday, July 4, 2019 (TYME-88-Panc poster). The study demonstrated a median overall survival in evaluable patients (38 of 49) of 6.4 months. These survival results compare very favorably to the analysis of 19 prospective pancreatic cancer trials where the median reported survival after progressing on second-line therapy was 2.0 – 2.5 months[1] based on reported historical trials. In the Phase II portion of the TYME-88-Panc study, a RECIST CBR of stable disease or better was achieved by 44% of patients (11 of 25) with available imaging. Patients achieving stable disease or better demonstrated a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death (hazard ratio=0.08). The CBR was durable with a majority of patients remaining in stable disease or better for more than 7 months after receiving treatment with SM-88. The study showed a median reduction of 63% in CTC burden in evaluable patients. Patients (10 of 24) with available results reaching an 80% reduction or greater in CTCs demonstrated a 60% decrease in risk of death (hazard ratio=0.40).

The Phase II portion of the TYME-88 Panc study reported that SM-88 was well tolerated with only 4.0% of patients (2 of 49) who experienced serious adverse events (SAEs) deemed at least possibly related to SM-88 (abdominal pain, arthralgia, and hypotension). One patient with reported SAEs continued on treatment.

About Advanced Pancreatic Cancer

Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is 8% and is less than 3% for those with advanced disease.[2] The median survival for patients in end-stage of the disease is approximately 3 months. There are two main types of pancreatic cancer - adenocarcinomas, which accounts for approximately 90% of all pancreatic cancer, and neuroendocrine tumors. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers. However, pancreatic cancer is the fourth most common cause of cancer death for men and women in the United States.

About Precision Promise℠

Precision Promise℠ is an adaptive randomized Phase III registration-ready clinical trial. The objective of Precision Promise℠ is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. The primary goal of SM-88's inclusion is to study SM-88 as a monotherapy treatment arm for patients who have failed one prior line of chemotherapy. Additionally, it is planned that SM-88 will be evaluated in combination with gemcitabine (Gemzar ®) and nab-paclitaxel (Abraxane ®) for first-line patients. The primary end point of these randomized trials is overall survival.

About Tyme Technologies

Tyme Technologies, Inc., is an emerging biotechnology company developing cancer therapeutics that are intended to be broadly effective across tumor types and have low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, the Company's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic weaknesses to compromise its defenses, leading to cancer cell death through oxidative stress and exposure to the body's natural immune system. For more information, visit www.tymeinc.com. Follow us on social media: @tyme_Inc, LinkedIn, Instagram, Facebook and YouTube.

About Eagle Pharmaceuticals

Eagle is a pharmaceutical company focused on developing and commercializing innovative and differentiated injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Additional information is available on the Company's website at www.eagleus.com.

Forward-Looking Statements/Disclosure Notice

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between Eagle Pharmaceuticals and Tyme Technologies; the ability of Tyme and Eagle to develop synergies as collaborators; the potential of SM-88 as a therapeutic drug; the ability of Tyme to achieve the milestone events described herein; Eagle's and Tyme's ability and willingness to perform their respective obligations under the transaction agreements; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

[1]Manax et al 2019 J Clin Oncol 37, 2019 (suppl 4; abstr 226)
[2]Statistics adapted from the American Cancer Society's (ACS) publication, Cancer Facts & Figures 2018.

Contact:

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Public Relations for Eagle Pharmaceuticals, Inc.:
Rose Ramseth
WE Communications
T: 212-551-4841
M: 206-898-7551
E: rramseth@we-worldwide.com

Investor Relations & Media Inquiries for TYME:
T: 212-461-2315
E: investorrelations@tymeinc.com
E: media@tymeinc.com

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