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Media Release

10 April 2024

Stamford Pharmaceuticals Inc announces the first patient to be treated with SP-002 in combination with Erivedge® in a Phase 2 Study in locally advanced BCC subjects.

Austin, Texas, April 10, 2024

Stamford Pharmaceuticals Inc, a clinical-stage biotechnology company developing science-driven immune therapies, today announced initiation of its locally advanced basal cell carcinoma (laBCC) trial (NCT06344052). The study will evaluate SP-002, an adenoviral-based immunotherapy, in combination with Roche's vismodegib (Erivedge®), a Hedgehog Pathway inhibitor (HHPI), approved for the treatment of adult patients presenting with locally advanced and metastatic basal cell carcinoma. The phase 2 clinical study is funded with proceeds from a Series A led by Tenmile Ventures, Prevail Partners and other syndicate parties completed in October 2023.

SP-002 is a biologic therapeutic based on an adenovirus (a type of cold-virus) that has been engineered to produce the immunostimulatory anti-cancer protein, Interferon-γ. Stamford has an exclusive worldwide license to develop SP-002 (formerly TG1042) from the French biopharmaceutical company Transgene SA (Euronext: TNG). Clinical studies with SP-002 alone have already been completed in cutaneous lymphomas, melanomas and BCC. These studies demonstrated that SP-002 was safe, well tolerated and showed favorable clinical activity.

"We are excited to progress SP-002 in combination with HHPI into this subset of locally advanced BCC patients. This study was motivated by encouraging results observed in clinical studies evaluating SP-002 as a monotherapy or in combination with HHPI in other BCC settings. We believe there is an opportunity to further improve patient benefit in locally advanced BCC patients based on the current standard of care." said Clement Leong, PhD., CEO of Stamford Pharmaceuticals.

SP-002-004 is a multi-center randomized, phase 2 study that will enroll patients with locally advanced BCC patients. Patients will be randomized to receive oral vismodegib in combination with intratumoral injection of SP-002 or vismodegib alone. The primary objective is to determine overall response rate (ORR) for a target tumor following 1 or 3 cycles of SP-002 given as an add-

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on to HHPI in patients with laBCC. While the secondary objective is to determine the clinical benefit for a target tumor following 1 or 3 cycles of SP-002 given as an add-on to HHPI in patients with laBCC.

About locally advanced basal cell carcinoma

Basal cell carcinomas (BCCs) account for 80% of non-melanoma skin cancers. Their incidence is increasing worldwide with a lifetime risk of 20–30%. Basal cell carcinomas are usually located in sun-damaged areas of skin. Risk factors therefore include chronic ultraviolet light exposure, blistering sunburns, tanning bed use, ionizing radiations, fair skin, age >70 years, immunosuppression and chronic inflammation3. Approximately 3 million patients in the United States (US) are affected by BCC annually and the incidence is estimated to be increasing worldwide between 7-10% annually. About 2% of these patients progress to advanced disease and it is estimated that there are ~60,000 advanced cases annually in the US.

Locally advanced basal cell carcinomas (laBCCs) can be large, aggressive, or recurrent tumors that have the potential to become invasive and require extensive surgery4 and reconstruction. laBCCs continue to pose a challenge as existing options have modest complete response (CR) rates and durability and significant morbidity and complications. Surgical resection is generally considered first-line treatment. However, this is not always feasible if the laBCC has invaded into surrounding tissues, requiring extensive surgery. Radiation therapy may be offered as a definitive treatment for patients who are not surgical candidates, however it has modest efficacy and durability. Systemic therapy with hedgehog pathway inhibitors (HHPIs) is generally considered when surgery and radiation are no longer an option, followed by Programmed death 1 (PD-1) inhibitors for patients that have progressed on HHPI. The use of HHPI and PD-1 are associated with many adverse events (AEs). It is estimated that only ~10-15% of patients with laBCC use HHPIs. This is primarily due to modest complete and durable response rates and the persistence of residual cancer cells even with continued HHPI treatment. These residual cancer initiating cells can cause recurrences when patients discontinue treatment which occurs often due to intolerability. Additionally, it has been widely reported that 20-30% of advanced BCCs harbor primary or develop secondary resistance to HHPIs further reducing the efficacy of this treatment option.
Details on the trial: https://clinicaltrials.gov/study/NCT06344052

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About Stamford Pharmaceuticals

Stamford's a clinical-stage company developing innovative cancer treatments. The company focuses on identifying disease settings where targeting the disease microenvironment or important cell types can bring about meaningful improvements in clinical outcomes.
For more information, please visit www.stamfordpharmaceuticals.com

About Tenmile

Tenmile is a dedicated health technology investment business owned by Tattarang, one of Australia's largest private investment groups. With an initial capital allocation of $250 million, we act fast and with confidence, investing without some of the constraints of other venture capital funds. Focused on supporting and building early-stage companies, we have the know-how, networks, and evergreen capital to partner through all stages of growth. With team members in Perth, Sydney, and San Franscisco, we seek to address unmet needs in human health and support the development of a globally significant health science and technology sector in Australia.
For more information, please visit www.tenmile.com

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing cancer cells.
The Company's clinical-stage programs consist of a portfolio of therapeutic vaccines and oncolytic viruses: TG4050, the first individualized therapeutic vaccine based on the myvac® platform, TG4001 for the treatment of HPV-positive cancers, as well as BT-001 and TG6050, two oncolytic viruses based on the Invir.IO® viral backbone.
With Transgene's myvac® platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The myvac® approach allows the generation of a virus-based immunotherapy that encodes patient-specific mutations identified and selected by Artificial Intelligence capabilities provided by its partner NEC.
With its proprietary platform Invir.IO®, Transgene is building on its viral vector engineering expertise to design a new generation of multifunctional oncolytic viruses.
Additional information about Transgene is available at: www.transgene.fr
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