Media Release
Thursday, 13 August 2020

Stamford Pharmaceuticals Inc and Ascend Biopharmaceuticals Ltd (its Australian affiliate) announces the first patient on-study to be treated with ASN-002 in combination with Erivedge® in a Phase 2a Study in BCNS and sporadic BCC subjects

Thursday, August 13, 2020

Ascend Biopharmaceuticals Ltd, the Australian affiliate of Stamford Pharmaceuticals, today announced the recruitment of its first patient onto its Phase 2a study (NCT 04416516). The study conducted in collaboration with Roche (SIX:RO, ROG) will evaluate ASN-002 (also known as SP-002), an adenoviral vector immunotherapy, in combination with Roche's vismodegib (Erivedge®), a Hedgehog Pathway inhibitor, approved for the treatment of adult patients presenting with locally advanced and metastatic basal cell carcinoma. The combination study will be conducted in both Gorlins-Goltz Syndrome and sporadic Basal Cell Carcinoma (BCC) subjects with multiple BCCs.

"This collaboration is an opportunity to create a new treatment paradigm for patients with multiple BCCs." said Clement Leong, PhD., Stamford Pharmaceutical's Chief Executive Officer. "We believe that ASN-002/SP-002 when combined with vismodegib has the potential to achieve clinical responses in BCC lesions directly injected with SP-002 but can also confer responses in distant non-injected BCCs. This would represent a major advancement for the management of patients with multiple BCCs who currently have to endure the morbidity that arises from many surgical procedures."

ASN-002/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. Ascend has an exclusive worldwide license to develop ASN-002 (formerly TG1042) from the French

Stamford Pharmaceuticals
Level 2, 330 Railroad Ave,
Greenwich, CT 0683
USA

Ascend Biopharmaceuticals
1/159 Dorcas Street
South Melbourne, VIC 3205
Australia

biopharmaceutical company Transgene SA (Euronext: TNG). Clinical studies with ASN-002/SP-002 alone have already been completed in Cutaneous Lymphomas, Advanced Melanomas and BCCs. These studies demonstrated that ASN-002 is safe, well tolerated and conferred clinical benefit. In the current study, ASN-002/SP-002 will be evaluated in combination with a shorter treatment schedule of vismodegib (4 weeks). It is expected that the combination strategy will create a tumour microenvironment supporting more potent and durable anti-tumour responses. It is also anticipated that the shorter treatment schedule of vismodegib will result in an improved tolerability profile when compared to its current treatment schedule. The multi-centre Phase 2a study (NCT04416516) is an open-label trial of ASN-002/SP-002 administered as an intra-lesional injection in combination with subjects receiving oral Erivedge®. The primary objective of the study is to evaluate the efficacy, safety and tolerability of ASN-002/SP-002 in combination with vismodegib in both target (lesions injected with ASN-002/SP-002) and non-target (non-injected) lesions.

The study will be conducted in up to 84 subjects and interim results from the trial are expected by the H1, 2021[1] and study completion to occur in H2, 2022.

-ENDS-

Details on the trial:
(https://clinicaltrials.gov/ct2/show/NCT04416516?term=NCT04416516&draw=2&rank=1)

For more information, please contact:
Clement Leong
Ascend Biopharmaceuticals Ltd, CEO
T: + 61 421 837 218
E: clementleong@ascendbiopharma.com

About Ascend Biopharmaceuticals

Ascend is 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.

We believe that taking a network multi-target approach offers a better opportunity to improving response rates and durability by maximizing synergistic efficacy while reducing off-target toxicities.

For more information, please visit www.stamfordpharmaceuticals.com .

[1] Completion for the first two-arms of an adaptive trial design. If additional arms are opened the completion date will change.