



STAMFORD
PHARMACEUTICALS INC

Media Release
Friday, 14 April 2023

Stamford Pharmaceuticals Inc announces amendment and expansion of the ASN-002-003 Phase 2a Study in BCNS and sporadic BCC subjects with up to an addition 5 arms.

Friday, April 14, 2023. Austin Texas.

Stamford Pharmaceuticals Inc, today announced the expansion of its ASN-002-003 Phase 2A study (NCT 04416516). The study performed in collaboration with Roche (SIX:RO, ROG) evaluating 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 is currently being conducted in both Gorlins-Goltz Syndrome and sporadic Basal Cell Carcinoma (BCC) subjects with multiple BCCs. 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 . In the current study, SP-002 will be evaluated in combination with a shorter treatment schedule of vismodegib. It is expected that the combination of the SP-002 will provide a more robust anti-tumour response due to the complementary mechanisms of action.

The objective of the protocol amendment and additional arms is to assist with the powering and design of a pivotal study. The multi-centre Phase 2A study (NCT04416516) is an open-label trial of 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 SP-002 in combination with vismodegib in both target (lesions injected with SP-002) and non-target (non-injected) lesions. The study will recruit up to a further 30 subjects and final results from the trial are expected in 2024.

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About Stamford Pharmaceuticals and Ascend Biopharmaceuticals

Stamford Pharmaceuticals Inc is a clinical-stage oncology focused company development treatments for cutaneous and visceral cancers.

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