Company Overview

Stamford Pharmaceuticals is a clinical stage immunology and inflammation focused company developing novel gene therapies and biologics, and applying a systems approach to creating rational combination therapies. The Company believes that taking a network-based multi-target approach offers an opportunity to improving response rates and durability by maximizing synergistic efficacy while reducing off-target toxicities.

As its first indication, the company is developing a non-surgical treatment for Basal Cell Carcinomas ("BCC"), a common type of skin cancer. Stamford will initially target patients with Basal Cell Nevus Syndrome ("BCNS"), aka Gorlin Syndrome, who develop many BCCs annually.

Highlights

- The focus on BCNS enables the Company to move rapidly to product approval via the orphan regulatory pathway (FDA Orphan designation for SP-002 granted) - this will be followed up with sporadic BCC, cutaneous SCC (Squamous Cell Carcinoma), cutaneous breast cancer (cBCa) and advanced melanomas.
- Recent Phase I/II Study data show excellent cure rates (mid-80%), good tolerability with systemic responses even in non-injected distant BCC lesions – superior cure rates and tolerability compared to other approved or in development non-surgical treatments for BCNS.
- FDA IND in place and preliminary FDA guidance provided on Phase 3 clinical trial (general design and endpoints).

The Technology

SP-002 is a gene therapy based on a type of cold virus that has been engineered to encode the gene for human interferon gamma (IFNγ). IFNγ is a protein normally produced by immune cells & has potent anti-cancer effects – it can prevent tumor and new blood vessel growth and can also induce programmed cell death. SP-002 has been designed with safety and tolerability in mind and is administered by direct injection into tumors.

First indication: Basal Cell Nevus Syndrome

Stamford's initial focus is to develop an injectable product for curing BCCs in BCNS patients. These patients have a rare genetic mutation which can lead to the growth of hundreds of primary BCCs on the skin.

The standard of care for BCNS is surgery when the tumors reach a certain threat level. Severely affected patients undergo multiple procedures on a weekly or monthly basis. The removal of around 3-4 BCCs per visit is common while lower threat lesions are often left for subsequent visits or managed with other approaches that can slow progression but are not particularly curative.

Surgical Excision or Mohs surgery are highly curative treatments for BCCs but patients that undergo hundreds of procedures experience significant morbidity and disfigurement. There is currently a major opportunity and an important need for a non-surgical (minimally invasive), well tolerated treatment that provides a high cure rate for treated (injected) lesions but can also control non-treated lesions (non-target) in BCNS patients. Due to SP-002's ability to induce a strong immune response like a therapeutic vaccine, it can be highly curative for injected BCCs but can also be efficacious in non-injected lesions.

Market Opportunity

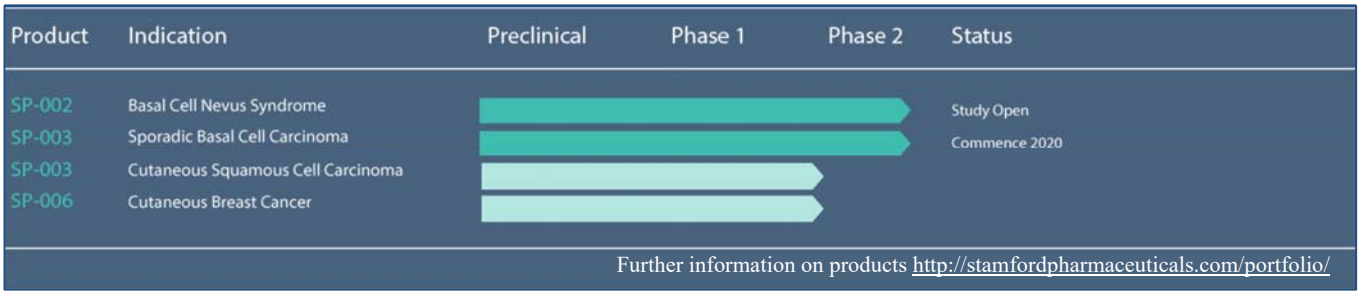
BCNS is a rare disease with ~30,000 patients worldwide and ~10,300 patients in USA. In 2017, the FDA granted SP-002 Orphan Drug designation for the treatment of BCNS.

SP-002 developed for BCNS has a fast-regulatory pathway and has good prospects for success in its planned pivotal Phase III study. Once approved, it is also expected to be able to generate significant revenues. Based on market research performed by Stamford, SP-002 pricing of between US$600 and $1,500 for each lesion treated would be acceptable to US payors.

A recent study estimated the median number of new lesions in BCNS patients to be around 30 BCCs per year. Based on these assumptions, the SP-002's addressable market in the US could be ~US$180 to 450M annually for BCNS. However, the market opportunity for SP-002 in sporadic BCC (see footnote 2) would be substantially larger as the product would be priced comparably (on a per lesion basis) but the incidence of sporadic BCC in the US is ~4 million new cases annually, therefore representing a very significant opportunity.

Pipeline and follow-on indications

There is also a strong scientific rationale for the use of SP-002 in other cancers such cutaneous squamous cell carcinoma; cutaneous breast cancers, melanomas and ovarian cancers. Stamford has licensed global rights to SP-002 for all types of skin cancers, peritoneal (which includes ovarian cancer) and breast cancers. SP-002 has also previously been shown to be effective in treating cutaneous lymphomas and advanced melanomas. Stamford has now demonstrated that SP-002 is also effective in curing BCCs.



SP-002 — Basal Cell Nevus Syndrome

SP-002 is an adenovirus 5 vector encoding Interferon-γ and for the BCNS indication it will be used in conjunction with a oral administered small molecule pathway inhibitor that inhibit basal cell carcinoma growth. The combination therapy allows lower doses of active ingredients to be used and is designed to be able to treat multiple BCCs concurrently in BCNS patients.

SP-003 – Sporadic Basal Cell Carcinoma and Cutaneous Squamous Cell Carcinomas

SP-003 is a combination therapy based on an adenovirus 5 vector encoding Interferon-γ used in combination with a small molecule inhibitor which reverses an immune-suppressive pathway induced by Interferon-γ. This pathway is common in both sporadic Basal Cell Carcinomas and Squamous Cell Carcinomas. The combination therapy has been designed to treat a single nodular and superficial sporadic basal cell carcinoma with curative intent and good cosmesis.

SP-006 – Advanced cancers

SP-006 is a combination therapy based on an adenovirus 5 vector encoding Interferon-γ used in conjunction with a second adenovirus encoding a biological targeting an important cell surface receptor expressed on stromal cells including Cancer Associated Fibroblasts (CAFs). This combination therapy is designed to treat advance cancers that have highly fibrotic and rigid tumor stromas (i.e., desmoplastic stroma).

Key Personnel

Dr Clement Leong, CEO

- Over 20 years' experience in biotechnology and venture capital. Former SciVentures Investments Director.
- Ph.D. from University of Western Australia; MBA from the Australian Graduate School of Management

Dr Paul Weiden, Chief Medical Officer

- More than 10 years' biotech experience. Former Medical Director, Dendreon Corporation.
- MD from Harvard Medical School

Dr Geoffrey Pietersz, Chief Technology Officer

- More than 30 years' experience in immunology and bioorganic chemistry. Co-inventor of key technologies.
- Ph.D. from University of Melbourne

Dr Jacqui Waterkeyn, Head Clin. Operations & Regulatory Affairs

- Regulatory Affairs and Clinical Operations background (20+ years) in the Biotechnology and Pharmaceutical Industries, including Clinical Research Organisations.
- Ph. D. from the University of Melbourne

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STAMFORD
PHARMACEUTICALS INC

Further Information

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