SPG Therapeutics, Inc.
Androgen Receptor Degradation for Dermatological Indications

Opportunity

Acne, androgenetic alopecia (male-pattern baldness), hirsutism and hidradenitis suppurativa (HS) are cumulatively the predominant reason for visits to a dermatologist. Each of these indications represents over a $500 million dollar a year opportunity in the US alone. Current treatment options are limited to just a handful of drugs that are largely generic, used off-label and have side effects that significantly limit their use.

Company Focus

We are focused on developing drugs that disrupt the androgen receptor to address unmet medical needs in dermatology. The activity of the androgen receptor has been established to be the driver of acne, androgenetic alopecia, hirsutism and the severe inflammatory disease hidradenitis suppurativa. Current therapeutic options for these indications are typically oral, decades old or consist of new formulations of generic drugs. We have developed topical analogs of the oral anti-androgen spironolactone and filed IP that has the promise to address these conditions in a way that would disrupt all current therapeutic treatment options. We term these compounds androgen receptor eliminators (**ARE**). Our lead ARE is an NCE called SPG-3. We are in the process of executing a development plan consistent with filing an IND within 16 months.

Innovation

The classes of compounds we are focused on utilize novel biological mechanisms of action that promote the selective degradation of our target protein in cells while not altering normal hormonal levels in patients. This selective degradation is believed to occur by the ability of our compounds to disrupt the interaction of the androgen receptor with particular binding partners that shield it from the natural cellular clearance process regulated by the activity of the ubiquitin/proteasome pathway. We believe our ARE-based approach to androgen receptor degradation is the preferred method to treating disorders of the androgen receptor.

Summary of Androgen Receptor Antagonist/Degrader (ARE) Data

- SPG-3 is a novel analog of a generic drug used off-label for the treatment of hormonal skin issue in women with no approved topical formulation.
- SPG-3 shows superior AR antagonist activity by targeted reduction in AR protein levels in primary human keratinocytes.
- SPG-3 can be formulated into a topical formulation with good skin permeation properties.
- SPG-3 has been shown to be well tolerated and active in vivo in a 21 day hamster ear sebum model.

SPG Therapeutics Business Model

We are following a "virtual" development model where we maintain oversight centrally but outsource the research, manufacturing and clinical trials management work. Our goal is to de-risk our compounds in a way that makes our company attractive to an acquirer in the biotechnology or pharmaceutical space. We would be looking for such a deal following completion of an IND filing, a Phase 1 hirsutism study with evidence of proof-of-concept (POC) human data or a larger Phase 2 POC study and expansion into additional indications of hidradenitis suppurativa, acne and androgenetic alopecia.

Financing Strategy

We have initially utilized seed funding from our founder to help us develop SPG-3. Having verified that it has the properties of a clinical candidate, we are actively pursuing partnerships and investments from strategic partners, VCs and other investors to help support our development plans by funding our IND enabling studies through 2021 and initiate Phase 1 studies in 2022 for hirsutism to obtain POC. We plan to raise funds to support a Phase 1 study and then seek additional funds in a “B” round in to fund Phase 2 studies to establish definitive proof-of-concept that would

support a higher valuation exit via a licensing deal, IPO or M&A. We have received interest in our proposal from established dermatology companies.

2019-2020 Achievements and Milestones

- Developed and filed key SPG-3/AR degrader IP internationally.
- Obtained commitment for contingent financing.
- Completed a 21-day hamster topical toxicology and hormonal skin model study with SPG-3.

Our primary goal over the next 18 months is to complete IND enabling studies for our compound in order to initiate a clinical trial in hirsutism. The bulk of our financing over this period of time will be dedicated to those efforts. Below is a summary of those studies and costs.

Three Year/ Five Year Budget Estimate to Exit

We see three major value inflection points for SPG-3 based on discussions with strategic investors. Point 1 occurs following completion of the IND enabling tox. studies at a cost of $3.6 million. Point 2 occurs following the completion of a Phase 1 hirsutism study or hidradenitis suppurativa patients with an additional cost of $1.5 million for a total cost of $4.6 million. Point 3 is following completion of Phase 2 study for definitive clinical POC within 5 years for a total cost of $20 million.

Key Team Members

- CEO/CSO: Zory Shaposhnik, PhD

Former Research Program Leader at Kythera Biopharmaceuticals. Contributed to approval for Kybella®, a first-in-class drug for submental fat reduction and developed a first-in-class clinical-stage treatment for androgenic alopecia (ATX-105). Published in the areas of tumor biology, nanotechnology, lipids and inflammation. Collaborated with Merck, Anthera and Celgene.

- IP/Patent Consultant: Richard Hake, PhD/JD

Former Chief Patent Counsel, Kythera Biopharmaceuticals. Over 15 years of experience in biotechnology IP management and business development for Elan, Chugai, and P&G.

- Clinical/Regulatory Consultant: Ken Washenik, MD/PhD

Bosley Medical Group Medical Director. Former CEO of Aderans Research, a regenerative medicine biotechnology company. Former director of the Dermatopharmacology Unit at the New York University School of Medicine.

- Product Development Consultant: Vern Leibman, MS/MBA

Former COO of Aderans Research, a regenerative medicine biotechnology company focused on androgenetic alopecia. Previously VP of R&D at C.R. Bard.

- Medicinal Chemistry/Operations Consultant: Pascal Druzgala, PhD

Co-founder and former CSO of ARYx. Senior VP of R&D of Armethon.

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