

Synthis
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New York, NY 10038

Dori T. Karyat, Ph.D., Founder & CEO
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Company website
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Industry:

Pharma
 Biotech

Management:

- Executive Leadership
Dori T. Karyat, Ph.D., Founder
- Scientific Advisory Board
Satwant Narula, Ph.D.,
Robert Lutz, Ph.D.
Amy Ripka, Ph.D.
William Ripka, Ph.D.
Kenny Wong, Ph.D.
- Business Advisors
Tom Cirrito, Ph.D.
Lisa Wisniewski, Ph.D.

Number of Employees: 1

Finance:

- Pre-clinical early discovery stage
- Self-funded/boot strapped
- Amount of Financing Sought: \$1M

Legal:

- IP: Muna Abu-Shar, JD, Ph.D., BioSpark IP, Cambridge MA

Executive Summary:

Company History:

Synthis is a NY based, pre-clinical stage, biotech company developing novel immune-oncology (IO) therapeutics that reverse immune suppression and increase survival rates in advanced cancer patients.

Market Opportunity / Unmet Need:

Nearly 90,000 new cases of invasive melanoma are diagnosed each year in the US. Metastatic melanoma has a 5 year survival rate of less than 20%, accounting for nearly 10,000 deaths annually. The US melanoma market is predicted to grow to >\$2B by 2020, with immune checkpoint inhibitors (ICI) driving the majority of sales (~\$1.3B). Although ICI are first line therapy for metastatic melanoma, less than half of the patients actually respond to treatment, due to additional immune blocking mechanisms that make tumor clearance impossible. If these pathway(s) are also eliminated, patient responses and survival will increase. In addition, ICI resistant patients have limited follow on treatment options. While ICI have fundamentally changed how cancer is treated, there is still significant need for novel combination therapies to increase survival rates in all melanoma patients.

Products/Services – Launched & Pipeline:

TGF- β is an immunosuppressive cytokine that drives tumor growth in most cancers, including melanoma. Inhibiting the TGF- β pathway as a cancer therapy has long been of interest for the pharmaceutical industry. However, current TGF- β antagonists cause severe host toxicity, limiting their efficacy and usefulness. Interest waned over the years, but has seen a resurgence due to the recent discovery that TGF- β drives ICI resistance in melanoma and urothelial cancer patients. But the original concerns about toxicity remain. To bypass the host toxicity seen with current TGF- β inhibitors, Synthis developed a T-cell targeted TGF- β antagonist (T3A), to eliminate the effects of TGF- β only on immune cells and not affect host tissues. T3A is superior to current TGF- β strategies due to: 1) a clearly differentiated MOA and 2) ability to safely and selectively reverse immune suppression to boost patient responses. Combination of T3A with ICI will increase patient survival and provide new treatment options for refractory patients.

Commercial / Technical Milestones:

Synthis designed and tested multiple T3A candidates and identified the key T3A characteristics required to reverse immune suppression *in vitro*. By Q4 2018, the T3A milestones will be: 1) immune cells specificity, 2) limited cardiac toxicity, 3) *in vivo* efficacy in melanoma tumor models & 4) generation and *in vitro* testing of T3A clinical candidates.

Intellectual Property:

Wholly owned, financed and developed by Synthis, a US patent was filed in 2017 and an international PCT will be filed Q2 2018.

Competition:

General TGF- β inhibitors are currently in Phase I/II clinical trials. Eli Lilly's galunisertib, a small molecule TGF- β receptor inhibitor and Novartis' anti-TGF- β antibody are in combination trials with ICI. EMD Serono has a bi-specific ICI-TGF- β receptor trap. All are predicted to have similar host toxicity issues that have previously limited therapeutic dosing and efficacy.

Please indicate primary purpose of Presentation: Investment