

Synergy of Schweinfurthins with Immunotherapy for Melanoma

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Intellectual Property:

Issued Patent:

- U.S. 9,428,493 (U. of Iowa)

Pending Applications:

Penn State

- PCT/US2019/017656

U. of Iowa

- Canada: 2,868,508

- Europe: 13769473.3

- Hong Kong: 15107463.6

Licensing Contact:

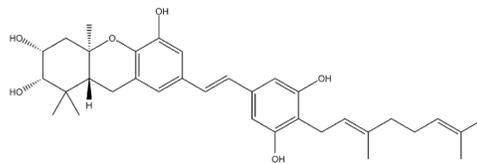
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Clinical Need:

Melanoma of the skin has the fastest growing incident rate of all cancers. The annual number of new melanoma cases is slightly over 100,000 in the US and 300,000 worldwide. Immune checkpoint inhibitors (ICIs) are the standard of care for metastatic melanoma; however, new synergistic products are in demand to increase immune response and reduce toxicity.

Value Proposition:

To improve outcomes for patients with metastatic melanoma through administration of a unique small molecule lipid signaling modulator in combination with an immune checkpoint inhibitor resulting in enhanced immunotherapy efficacy.

Technology Solution:

ICIs are undergoing rapid expansion due to growing clinical evidence demonstrating the effectiveness of these agents to improve outcomes for a subset of patients with several difficult to treat and advanced cancers. An adjuvant treatment that would expand the utility of these drugs to treat additional patients would find widespread clinical use. Researchers in the Penn State College of Medicine have demonstrated improved tumor immunity using a novel, small molecule in combination with an anti-PD-1 ICI in a melanoma mouse model where immunotherapy alone fails. The lead compound has potent ICI synergistic effects using a fraction of the maximum tolerable dose administered in short durations without any apparent toxicity.

Market Opportunity:

By 2026, melanoma therapeutic & treatment sales are forecasted to exceed \$5B worldwide with the U.S. representing about 70% of the market. Checkpoint immunotherapy & BRAF/MEK drug classes will comprise >96% of global melanoma drug sales. Despite the tremendous success of ICIs in improving outcomes in advance-stage cancers, response rates are ~40% and significant immuno-related side effects occur. To improve response rates and decrease adverse events, combinatorial therapies are showing promise and driving growth in this space.

Path Forward:

A startup company, IOThera, is in discussions with the Penn State Research Foundation for an option to license the PSU IP. Key next steps: confirm efficacy, tolerability & PK *in vivo*; validate *in vitro* tox screen; complete synthesis of 5-10 gram batch (non-GMP); rat and dog dose-ranging & PK studies.



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