at a glance™

CHECKPOINT THERAPEUTICS

Upcoming: ***Checkpoint's most advanced candidate is designed to compete initially with Merck's Keytruda® and Regeneron/Sanofi's Libtayo® in the $32 billion checkpoint inhibitor market. Following positive top-line results in January, Checkpoint will be presenting further detailed results from its registration-enabling trial in metastatic cSCC (skin cancer) next month at ASCO, the world's premier cancer conference. An FDA filing for US marketing approval is expected before year-end, followed by a filing in 1Q23 for Europe/UK approval.***

Key Considerations

- **Checkpoint is one of eleven biopharma/medical companies founded by Fortress Biotech (Nasdaq: FBIO).**
- **The company announced positive top-line results in January 2022 from a registration-enabling clinical trial of its lead molecule cosibelimab (ko-see-bell-a-mab) in metastatic cutaneous squamous cell carcinoma (cSCC), the second most prevalent skin cancer ($1 billion+ market).**
- **Topline results put cosibelimab ('cosi' for short) on par with, or ahead of, currently approved immunotherapies for cSCC in terms of efficacy and may ultimately show it to have fewer side effects.**
- **The company is on schedule to file a Biologics License Application, or BLA, with the FDA in 4Q22 for US marketing approval in cSCC. A similar submission for European approval is expected to be filed in 1Q23.**
- **The cSCC trial also includes a cohort of locally advanced cSCC patients. An interim analysis is planned for 2Q22.**
- **A Phase 3 trial of cosibelimab is underway in metastatic non-small cell lung cancer (NSCLC), the most common form of lung cancer ($12 billion+ immunotherapy market).**
- **Checkpoint expects to grab market share quickly through disruptive pricing in a market where currently approved drugs in the same class as cosibelimab cost $160K a year.**
- **Cosi's safety profile may make it the PD-(L)1 checkpoint inhibitor of choice for combination therapies, a significant growth category for immunotherapeutics.**
- **A second compound, olafertinib, is being developed specifically to address key deficiencies of AstraZeneca's blockbuster lung cancer drug, Tagrisso® – currently selling at an annualized rate of roughly $6 billion.**
- **At March 31, 2021, Checkpoint reported $41.5 million in cash and cash equivalents.**

Checkpoint Therapeutics, Inc.

(Nasdaq: CKPT)

Recent Price:	**$1.28**
Shares O/S:	**90 Million**
Approx MktCap:	**$115 Million**
Average Volume:	**950,000**
Fiscal Year Ends:	**Dec. 31**

Published: May 2022

Overview

Multi-billion-dollar-a-year drugs usually remain blockbusters until their patents expire – unless someone comes up with a better mousetrap. And if they do, they don't need a big share of a billion-dollar plus market to have a good business.

One way of doing this is to develop a lower cost alternative to the blockbuster – an especially viable strategy these days when big pharma companies often charge $150K or more a year for their big selling drugs.

Another way is to capitalize on a blockbuster's weak points – unacceptable side effects among certain users, for example.

These 'warm spots in a hot kitchen' strategies underpin Checkpoint's business and technical programs and define its strategy in immuntherapeutics and targeted drugs.

Checkpoint's anti-PD-(L)1 monoclonal antibody cosibelimab is being developed as a potentially better and lower-cost alternative in the fast growing $32 billion checkpoint inhibitor market, now dominated by Merck's Keytruda and a small handful of others.

Cosibelimab has shown efficacy on par or better than the current first line checkpoint therapies in cSCC and NSCLC and, if current data trends continue, it may prove to be safer with a more durable therapeutic effect. Filing of the first marketing approval application for cosibelimab is expected before year-end.

Lead Candidate Cosibelimab

Cosibelimab, a potentially best-in-class anti-PD-(L)1 antibody, was in-licensed by Checkpoint from the Dana Farber Cancer Institute. It belongs to a proven class of molecules known as checkpoint inhibitors, for which Checkpoint Therapeutics is named.

Just like the first seven PD-1 and PD-(L)1 checkpoint inhibitors (Opdivo®, Keytruda, Libtayo, Tecentriq®, Bavencio®, Imfinzi®, and Jemperli®), Checkpoint's candidate enables native killer T-cells to attack cancer cells by unblocking one of the tumor's main defense mechanisms.

In the case of cosibelimab, the unblocking is accomplished by binding to the ligand PD-(L)1, the tumor's protective shield, allowing killer T-cells to 'see' and attack the previously hidden tumor cells.

Cosibelimab's strong activity may provide greater cancer killing power than currently approved PD-1 and PD-(L)1 inhibitors.

Notable & Upcoming

1Q20-FDA confirmed plan to submit cosibelimab for full approval in cSCC upon successful completion of ongoing registration-enabling trial

4Q21-Start of Ph. 3 trial of cosibelimab in NSCLC

1Q22-Positive topline results reported from trial of cosibelimab in metastatic cSCC skin cancer

2Q22-Cosibelimab cSCC full dataset presentation at ASCO

2Q22-Interim analysis of cosiblimab in locally advanced cSCC skin cancer (potential 2nd indication)

4Q22-Planned filing for FDA approval of cosibelimab in cSCC

1Q23-Planned filing for EMA (European) approval of cosibelimab in cSCC

On January 25, 2022, the company reported positive topline results from its registration-enabling clinical trial evaluating the safety and efficacy of cosibelimab administered as a fixed dose of 800mg every two weeks in patients with metastatic cSCC.

The trial met its primary endpoint with cosibelimab demonstrating a confirmed objective response rate (ORR) of 47.4 percent based on independent central review of 78 patients using Response Evaluation Criteria in Solid Tumors version 1.1 (RESIST 1.1) criteria.

Cosibelimab's 47.4 percent ORR in metastatic cSCC compares favorably to Libtayo's 46.7 percent ORR (approval label) and is substantially higher that Keytruda's 34.3 percent ORR (approval label).

The median duration of response of cosibelimab therapy had not been reached at the data cut-off point with 76 percent of patient responses on-going. Safety data across 201 patients with advanced cancers enrolled and treated in all cohorts of the on-going study remain consistent with those previously disclosed. The majority of treatment-emergent adverse events reported were mild or moderate in severity.

The safety performance of cosibelimab in metastatic cSCC to date may give it a second edge beyond efficacy: The compound appears to be better tolerated than Libtayo and Keytruda.

Recently released topline results showed that less than ten percent of the cSCC patients treated with cosibelimab experienced severe treatment-related adverse events, whereas severe or worse treatment-related adverse events reported for the leading drugs in this class, Opdivo and Keytruda, were 21 percent (CheckMate 142), and 27 percent (*New England Journal of Medicine*), respectively.

With the potentially better toxicity profile, cosibelimab could become a checkpoint inhibitor of choice for combo therapies, one of the fastest growing areas in immunotherapy and the key reason analysts predict the category is on its way to $50 billion in annual sales.

I/O Leader Board - cSCC

ORR (percent)

Libtayo	46.7	(approved label)
Keytruda	34.3	(approved label)
Cosibelimab	47.4	(ICR 1/25/22)

Eyeing Keytruda's Dominance

Checkpoint is moving beyond skin cancer, eyeing Keytruda's $12 billion-a-year category-dominating franchise in metastatic non-small cell lung cancer, or NSCLC, the most common form of lung cancer.

In December 2021 Checkpoint initiated enrollment in the CONTERNO trial, a global, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for first-line treatment of patients with non-squamous NSCLC.

Approximately 560 patients will be enrolled in CONTERNO, randomized 2:1 to receive cosebelimab in combination with chemotherapy or chemotherapy alone. The primary endpoint is overall survival (OS). Key secondary endpoints include progression free survival (PFS), objective response rate (ORR), and safety.

I/O Leader Board in NSCLC

Median PFS (months)

Tecentriq	8.1	(Impower 110)
Keytruda	10.3	(Keynote-024)
Cosibelimab	10.3	(STIC 2020 Interim)

Lung cancer is the leading cause of cancer deaths, accounting for almost 25 percent of all cancer deaths. NSCLC accounts for approximately 85 percent of lung cancer cases with an annual prevalence of 1.7 million new cases. The current 5-year survival rate for lung cancer is less than 20 percent, decreasing further when the disease is diagnosed at later stages.

The Growing Case for Combos

Analysts forecast sales for PD-1/PD-(L)1 checkpoint inhibitors will reach more than $50 billion in three years, underscoring the key role anticipated for this technology in the fast-emerging field of immunotherapy. It's created a rich deal market with eye-popping buyouts and licensing deals -- even for development-stage candidates.

One of the biggest drivers of growth will be therapies that combine targeted agents to kill cancer cells with immunotherapeutic agents that enlist the body's immune system to extend the duration of the response.

A quick visit to www.clinicaltrials.gov will display hundreds of trials underway at scores of company, university and government labs that are teaming checkpoint inhibitors with tumor-targeted agents to find the right combinations to produce more durable remission rates.

When two or more drugs are combined, it puts a special spotlight on each agent's safety profile. Based on data presented to date, cosibelimab's safety profile may give it an important leg up as the immunotherapeutic component of choice in a combination therapy. The lower the toxicity of each component of a combo drug, the lower the combination's overall toxicity will likely be unless they are contraindicated.

Summary

- **Checkpoint's cosibelimab is an anti-PD-(L)1 checkpoint inhibitor being developed as a potentially better and lower cost alternative to current therapies in the $32 billion and growing checkpoint inhibitor market.**
- **Recently released topline data indicates cosebelimab is at least as effective and potentially safer than current immunotherapies.**
- **Checkpoint expects to file for US FDA approval for cosibelimab in cSCC in 4Q22 and, if approved, it would anticipate product launch in 1Q24. Filings for approvals in other jurisdictions are expected to start 1Q23.**
- **A survey of major commercial payers indicates cosibelimab's market penetration could be accelerated by offering launch discounts to peer pricing of 30 percent in the US, and 20 percent in Europe, a strategy Checkpoint intends to pursue while still maintaining pharmaceutical margins.**
- **Multiple disease indications are potentially addressable by single agent cosibelimab, as has been the case with other drugs in the class. Its trending efficacy and safety attributes may also make it a drug partner of choice in combination immunotherapies.**
- **The company's second candidate, olafertinib, is aimed at the current $6 billion (and growing) annual market AstraZeneca created with Tagrisso for EGFR mutant lung cancer patients. Olafertinib is designed to sidestep some of the treatment limiting side effects of Tagrisso, which are experienced by roughly 13 percent of users.**
- **Cash and cash equivalents stood at $41.5 million at March 31, 2021.**

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