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NEWS RELEASE

Agenus Reports Fourth Quarter and Full Year 2023 Results

3/14/2024

FDA Grants Fast Track designation for BOT/BAL in metastatic, refractory colorectal cancer (CRC) patients who have failed 1st and 2nd line standard of care treatments

Data from Phase 1 of BOT/BAL in refractory CRC showed durable ORR of 24% in patients with non-active liver metastases (NLM); Completed enrollment of randomized Phase 2 trial (n=230)

Clinical data sets path for expansion opportunities in pancreas, lung, neoadjuvant CRC, and melanoma

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (“Agenus”) (Nasdaq: AGEN), a leader in discovering and developing novel immunological agents to treat various cancers, today provided a corporate update and reported financial results for the fourth quarter and full year 2023.

“In 2023, Agenus made significant advances across our BOT/BAL development program. Our first target indication is metastatic, refractory colorectal cancer that is not MSI-H/dMMR, for which we are focused on pursuing accelerated approval,” said Garo Armen, Ph.D., Chief Executive Officer. “We are also pursuing multiple strategies to capitalize the company through this important path in our efforts to bring BOT and BOT/BAL to the forefront of solid tumor cancer treatment. Our vision is to maximize BOT's utility to benefit patients in combination with other immune therapies as well as current standards of care for patients with both early and late-stage tumors.”

2023 Highlights on Botensilimab

Colorectal Cancer:

- Received Fast Track designation for patients with metastatic colorectal cancer that is not MSI-H/dMMR and who do not have liver metastases, and who were previously treated with standard combination chemotherapy, anti-VEGF and anti-EGFR if RAS wild type (“refractory MSS mCRC NLM”)
- Completed enrollment of patients with refractory MSS mCRC NLM in a Phase 1 (n=150) and randomized Phase 2 (n=230) in October 2023.
- Clinical data reported by Agenus in October 2023 revealed:
    - Among the 70 efficacy evaluable ("EE") patients in the refractory MSS mCRC NLM treatment setting, a 24% RECIST v1.1 response rate was observed in those treated with the BOT/BAL combination. Based on literature review, the response rate in a similar population treated with standard of care therapies ranges from 1% to 6.1%[1, 2].
    - The 12-month overall survival (OS) rate is 74% with median OS not yet reached.
    - Topline data from the ongoing Phase 2 study are expected in 2H 2024.
    - The most common safety observations are immune-related diarrhea and colitis, which are managed in accordance with standard therapies. Grade 3 treatment related diarrhea/colitis occurred in approximately 14% of patients.

Neoadjuvant CRC:

- Clinical data presented at ASCO-GI January 2024:
    - In an investigator sponsored trial (IST) led by Dr. Pashtoon Kasi at Weill-Cornell Medicine, patients diagnosed with resectable localized colon or rectal cancer were treated with one dose of BOT and two doses of BAL approximately 4 weeks prior to planned surgery. After surgery, pathologic analysis reported significant tumor shrinkage.
    - 3/3 patients (100%) with MSI-H CRC experienced major pathological responses (>90% tumor shrinkage) in less than 4 weeks, while 6/9 (67%) MSS CRC patients had tumor shrinkage of 50% or more.
    - IST is expanding to 24 patients with an extended follow-up time (6-8 weeks); Agenus plans to prioritize neoadjuvant development and is evaluating study designs for subsequent pivotal trials.

2L Metastatic Pancreatic:

- In patients with metastatic pancreatic cancer who have failed or don’t respond to FOLFIRINOX (2L Pancreatic) and received treatment with BOT in combination with gemcitabine+nab-paclitaxel, significant tumor marker reductions were observed in 4 of 5 patients, all with liver metastases.
- Two (2) of the 4 patients achieved PRs at 16 weeks (target lesion reductions of 47% (confirmed) and -37% (pending confirmation). Two other patients showed stable disease at their first 8-week scan with tumor reductions of -20% and -13%.
- A Phase 2 randomized study is in progress, with preliminary data expected to be available mid-year.

CTLA-4/PD-1 Relapsed Refractory Advanced Melanoma (“2L+ Melanoma”):

- Phase 1b expansion cohort in 2L+ Melanoma reported a 30% ORR and 60% disease control rate (n=10; 2/8 BOT responses and 1/2 BOT/BAL responses); all patients had failed anti-PD-1 therapy and 8/10 had failed both anti-PD-1/CTLA-4 therapy.
- In the Phase 2 study in 2L+ Melanoma, data from the fully enrolled BOT monotherapy arm and a cohort of patients on BOT/BAL (n=30) are anticipated in 2H2024.

Refractory Non-Small Cell Lung Cancer (NSCLC):

- In the PD(L)-1 refractory cohort, a 56% ORR and an 89% disease control rate were observed in patients treated with the BOT/BAL combination (n=9).
- In a TKI-refractory cohort, 2 out of 7 patients experienced complete confirmed objective responses after treatment with BOT/BAL*.

Advanced Sarcomas:

- Updated findings from a Phase 1b study of 41 efficacy evaluable patients treated with BOT/BAL showed durable responses with an ORR of 20%, a median response duration of 19.4 months (iRECIST), and a 6-month progression-free survival rate of 40%.
- A higher ORR was observed by dose level, with 29% at 2 mg/kg BOT compared to 15% at 1 mg/kg BOT.

Refractory Ovarian:

- In a total of 24 evaluable patients treated with BOT/BAL, with a median of four prior lines of therapy, an overall response rate of 33% was observed. The disease control rate was 67% and the median Duration of Response (DOR) was not yet reached.

Finance

- $25 million milestone payment from BMS triggered by the commencement of a Phase 2 study with BMS-986442 in December 2023.
- Advancing in our discussions on monetizing non-strategic assets, royalty monetization, and project financing, with the potential to yield $100-200 million in cash proceeds.
- Currently we are in active discussions with several potential biopharma partners for potential co-development and co-commercialization of BOT/BAL.

Fourth Quarter and Full Year 2023 Financial Results

For the year ended December 31, 2023, we recognized revenue of $156 million and incurred a net loss of $257

million, or $0.69 per share. For the fourth quarter ended December 31, 2023, we recognized revenue of $84 million and incurred a net loss of $49 million or $0.13 per share. Revenue primarily includes revenue under our collaboration agreements, including milestones achieved, and revenue related to non-cash royalties earned.

We ended the year with a $76.1 million cash balance; subsequent to which in January 2024 we received the $25 million milestone payment from BMS triggered by the commencement of a Phase 2 study with BMS-986442, the AGENUS discovered TIGIT bispecific antibody. Additionally, we've progressed in monetizing non-strategic assets and future milestones and royalties from ongoing partnerships. These efforts are expected to yield significant cash proceeds by mid 2024. Accordingly, we anticipate being funded through 2024. In parallel, we're pursuing potential partnership discussions with several biopharmaceuiticsl parties to further expand our cash resources.

	December 31, 2023	2022
Cash, cash equivalents and short-term investments	$ 76,110	$ 193,358

	Three months ended December 31, 2023	2022	Year ended December 31, 2023	2022
Revenues, research and development	$ 30,249	$ 3,755	$ 38,764	$ 16,975
Revenues, non-cash royalty	53,038	18,284	114,572	45,285
Revenues, royalty sales milestone	-	-	-	25,250
Revenues, other	514	6,347	2,978	10,514
Total Revenue	83,801	28,386	156,314	98,024
Research and development expenses	66,723	53,279	234,569	186,691
General and administrative expenses	21,177	25,036	78,739	81,007
Cost of service revenue	260	7,693	3,111	10,568
Other income	(193)	(3,918)	(2,663)	(10,944)
Non-cash interest expense	44,574	18,326	100,551	62,955
(Gain) loss related to debt	-	1,937	-	(782)
Non-cash contingent consideration fair value adjustment	(158)	135	(556)	(815)
Net loss	$ (48,582)	$ (74,102)	$ (257,437)	$ (230,656)
Net loss per share attributable to Agenus Inc. common stockholders	$ (0.13)	$ (0.24)	$ (0.69)	$ (0.78)
Cash used in operations	$ 40,590	$ 47,338	$ 224,202	$ 175,373
Non-cash operating expenses	$ 56,455	$ 32,777	$ 139,015	$ 96,286

Conference Call

Date: March 14th, 2024, 8:30 a.m. ET

To access dial-in numbers, please register **here**.

Conference ID: 73242

Webcast

A live webcast and replay of the conference call will be accessible on the company's website at **https://investor.agenusbio.com/events-and-presentations** and via **https://events.q4inc.com/attendee/678927380**.

References

[1] Prager et. al NEJM 2023

[2] Grothey et al. Lancet 2013

* Investigator reported, subject to change

About Botensilimab

Botensilimab is an investigational multifunctional anti-CTLA-4 immune activator (antibody) designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to "cold" tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 900 patients have been treated with botensilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus' investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. For more information about botensilimab trials, visit **www.clinicaltrials.gov** with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer and infectious diseases with a comprehensive pipeline of immunological agents. The company's mission is to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants (through SaponiQx). Agenus is headquartered in Lexington, MA. For more information, visit **www.agenusbio.com** or **@agenus_bio**. Information that may be important to investors will be routinely posted on our website and social media channels.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the

federal securities laws, including statements regarding a its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," “establish,” “potential,” “superiority,” “best in class,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K filed with the Securities and Exchange Commission and available on our website at **www.agenusbio.com**. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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